Award Number: W81XWH-17-1-0041

TITLE: Adaptive Disclosure: A Combat-Specific PTSD Treatment

PRINCIPAL INVESTIGATOR: Brett Litz, Ph.D.

CONTRACTING ORGANIZATION: Boston VA Research Institute, Inc. Boston, MA 02130

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Fort Detrick, Maryland 21702-5012

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Many service members exposed to combat and operational stressors develop posttraumatic stress disorder (PTSD). Evidence-based interventions for treating PTSD, however, were not developed for military trauma and thus may be suboptimal for this population. This study compares Adaptive Disclosure, an intervention for Marines and Sailors with PTSD stemming from deployment experiences, to an empirically supported PTSD treatment. The report details the fifth year of work on this trial, in which we continued recruitment. The Boston team has principally been involved in conducting pre- and post-treatment psychosocial assessments that will be used to determine treatment efficacy.
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INTRODUCTION:
More than 2 million U.S. troops have served in the wars in Afghanistan and Iraq. Findings from epidemiologic studies of infantry troops in the early stages of the wars suggest that 10-18% of combat troops experience deployment-related psychological health problems, such as posttraumatic stress disorder (PTSD; e.g., Hoge et al., 2004; see Litz & Schlenger, 2009). Once service members and new Veterans develop sustained mental health problems related to combat and operational stress, many are at risk to remain chronic across the lifespan (e.g., Kessler et al., 1995; Kulka et al., 1990; Prigerson et al., 2001). Thus, primary and secondary prevention of PTSD is a critical challenge for the military and the VA (e.g., Litz & Bryant, 2009). We have developed a novel intervention, Adaptive Disclosure (AD), to address these needs. AD is a hybrid and extension of evidence-informed cognitive-behavioral therapy strategies packaged and sequenced to target the three high base-rate combat and operational traumas, namely, life-threat trauma, loss (principally traumatic loss), and experiences that produce inner moral conflict (Steenkamp et al., 2011). AD employs a Prolonged Exposure (PE) strategy (imaginal emotional processing of an event) and cognitive-therapy-based techniques used in Cognitive Processing Therapy (CPT), but also includes gestalt-therapy techniques designed to target loss and moral injury. In our open pilot trial, we demonstrated treatment acceptability among Marines and large reductions in PTSD and comorbid symptoms. The primary objective of the current randomized control non-inferiority trial is to determine whether AD is as least as effective as CPT, cognitive only version (CPT-C), in terms of its impact on deployment-related psychological health problems (specifically PTSD and depression) and functioning.

KEYWORDS:
Active-duty, Marine Corps, Navy, Posttraumatic stress disorder, Cognitive Therapy

ACCOMPLISHMENTS:
- Goal: Hire and credential new study staff (Months 1-29)
  - % Completion: 100%
  - The Postdoc at the Boston site was hired and credentialed
  - The Postdoc was trained as an independent evaluator
- Goal: Establish weekly meetings with PIs (Months 1-29)
  - % Completion: 100%
  - Principal Investigators hold monthly conference call meetings to discuss study progress and adjudicate cases
- Goal: Train and certify study personnel on all study procedures (Months 1-29)
  - % Completion: 100%
  - All staff at the Boston site are trained on all study procedures
  - All regulatory requirements for the Boston site are completed
- Goal: Train independent evaluator in CAPS administration (Months 1-29)
  - % Completion: 100%
  - Postdoc was trained in CAPS administration
- Goal: Continue to identify and recruit potential participants; monitor enrollment progress at clinics; provide ongoing supervision for therapists; collect data from study participation (Months 1-18)
  - % Completion: 45%
Our target enrollment is 266 participants by February 2018
We have enrolled 121 participants total, 6 of whom were enrolled in 2017
Actual timeline for enrollment shifted from Q1-Q3 due to recruitment difficulties at San Diego site

Goal: Collect CAPS data from study participants over the phone (pre- and post-treatment) (Timeline: Months 1-21)
  % Completion: 45%
  Assessed 7 new participants in 2017

Goal: Conduct audio recording for on-going adherence and provide prompt feedback to assessors and therapists (Timeline: Months 1-24)
  % Completion: 100%
  All CAPS Assessments are recorded using Phillips DPM8000 recorders
  One participant did not assent to audio recording, so their assessment was not recorded.

Goal: Collect and report adverse events (Timeline: Months 1-24)
  % Completion: 100%
  There were no Adverse Events during the reporting period.

Goal: San Diego will send de-identified data to Boston for entry and secure storage (Timeline: Months 1-24)
  % Completion: 47% (127 out of target 266 participants)
  San Diego has sent 127 deidentified data packets to Boston
  They are stored securely in locked file cabinets

Goal: Ongoing Data Entry and data quality monitoring (Timeline: Months 1-24)
  % Completion: 50%
  Due to delay in enrollment, the actual timeline for data entry also had to shift accordingly, from Q2 to Q3
  All CAPS collected during the reporting period were entered on an ongoing basis, and have been double entered and cross-checked to ensure data integrity
  All other data has been entered once, and data entry infrastructure was designed to double enter all data in order to conduct data integrity checks
  An unpaid student volunteer has been hired to double-enter all remaining data.

Goal: Conduct data analysis according to proposed plans; summarize study results, prepare manuscripts and present findings at conferences; prepare and submit final report to DoD (Timeline: Months 22-24)
  % Completion: 0%
  Nothing to report

Opportunities for training and professional development provided by the project:
  Nothing to report

How results were disseminated to communities of interest
  Nothing to report

IMPACT
While we do not currently have any results, the findings generated in this study will impact the field of clinical psychology by increasing understanding of whether AD is as least as effective as CPT, cognitive only version (CPT-C), in terms of its impact on deployment-related psychological
health problems (specifically PTSD) and functioning. These findings may contribute to a better understanding of treatments for military-related PTSD.

- Impact on other disciplines:
  - Nothing to report
- Impact on technology transfer:
  - Nothing to report
- Impact on society beyond science/tech:
  - Nothing to report

**CHANGES/PROBLEMS**
- Actual timeline for enrollment shifted from Q1 to Q3 due to recruitment difficulties at the San Diego site
  - Associate Investigator at Naval Medical Center increased referrals in order to resolve these difficulties
- Due to the delay in enrollment, the actual timeline for data entry also had to shift accordingly, from Q2 to Q3
- These delays did not impact our expenditures

**PRODUCTS**
- Nothing to report

**PARTICIPANTS and OTHER COLLABORATING ORGANIZATIONS**

<table>
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<tr>
<th>Boston Personnel:</th>
<th>Dr. Brett Litz, PhD.</th>
<th>Postdoc</th>
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<tbody>
<tr>
<td>Project Role:</td>
<td>Principal Investigator</td>
<td>Independent Evaluator</td>
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<tr>
<td>Researcher Identifier (ORCID ID):</td>
<td>n/a</td>
<td>n/a</td>
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<td>Nearest person month worked:</td>
<td>6% effort, .72 PM worked</td>
<td>47.72% Effort, 5.73 PM worked</td>
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<tr>
<td>Contribution to Project:</td>
<td>Oversee all aspects of assessments and interventions</td>
<td>CAPS assessments, project management</td>
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<tr>
<td>Funding Support:</td>
<td>Dr. Litz is funded through the Massachusetts Veterans Epidemiology And Information Center (MAVERIC). Six percent effort is paid for by this grant.</td>
<td>Postdoc’s effort is supported by this grant and the Massachusetts Veterans Epidemiology And Information Center (MAVERIC)</td>
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Other organizations involved in helping with the project:

- University of Wyoming
  - Matt Gray, Ph.D., Independent Contractor
- San Diego [Veterans Medical Research Foundation (VMRF)]
  - Ariel Lang, Ph.D., site PI at San Diego site
  - Carrie Rogers, Ph.D., Treatment Supervisor
  - Shiva Ghaed, Ph.D., Associate Investigator
  - Amy Lansing, Ph.D., study therapist at San Diego site
  - Toni Robinson and Maureen Hallett, M.A., Research coordinators at San Diego site
Adaptive Disclosure: A Combat-Specific PTSD Treatment
Contract No. W81XWH-10-1-0810

PI: Brett Litz, PhD
Partnering PI: Ariel Lang (VMRF)
Org: Veterans Medical Research Foundation
Award Amount: $499,739 (Boston: $133,172)

Study/Product Aim(s)

• Determine if AD is at least as effective as CPT-C in terms of change in PTSD and Depression symptoms over an 8-week treatment period.
• Determine if AD is at least as effective as CPT-C in terms of change in military-relevant functioning over 8 weeks of treatment.

Approach

• Randomized, controlled non-inferiority trial (n=266) comparing Adaptive Disclosure to Cognitive Processing Therapy, cognitive only version.
• Marines/Sailors with PTSD will be followed during the intervention and for 6 months after treatment.
• Primary outcomes include PTSD severity, depression and military-relevant functioning.

New Accomplishments

• Finished conducting data integrity checks for primary outcome data (CAPS-IV)
• Assessed 7 new participants and enrolled 6 new participants
• Study therapist and study assessor obtained access to intervention delivery site

Goals/Milestones

☑ Conduct audio recording for on-going adherence and provide prompt feedback to assessors and therapists
☐ Collect and report adverse events
  □ Have not had any adverse events to report
☐ San Diego site to send de-identified data to Boston for entry and secure storage
☐ Ongoing Data Entry and data quality monitoring

Updated February 2018

<table>
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<tr>
<th>Activities</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Q5</th>
<th>Q6</th>
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<td>Enroll 86 additional participants [to reach target N=266]</td>
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<td>Enter all participants’ data</td>
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<td>Prepare, submit and publish manuscript of findings</td>
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Budget Expenditure to Date
Projected Expenditure: $133,168
Actual Expenditure: $58,502

Updated February 2018

Proposed Timeline
Actual Timeline
Current Quarter
REFERENCES:


