

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

REPORT DATE: February 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				Form Approved OMB No. 0704-0188	
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 Feb 2019		2. REPORT TYPE Annual		3. DATES COVERED 23 JAN 2018 - 22 JAN 2019	
4. TITLE AND SUBTITLE Adaptive Disclosure: A Combat-Specific PTSD Treatment				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-17-1-0041	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Brett Litz, Ph.D. Stephanie Larew, Ph.D.; Alanna Coady, MDiv.; Jessica Carney, B.A. E-Mail: brett.litz@va.gov; stephanie.larew@va.gov; alanna.coady@va.gov; jessica.carney@va.gov				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Boston VA Research Institute, Inc. 150 South Huntington Avenue Boston, MA 02130				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 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.					
15. SUBJECT TERMS Active-duty, Marine Corps, Posttraumatic stress disorder, Cognitive Therapy					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
U	U	U	UU	9	USAMRMC

Table of Contents

	<u>Page</u>
Introduction	1
Keywords	1
Key Research Accomplishments	1
Impact	3
Changes/Problems	3
Products	3
Participants and Other Collaborating Organizations	3
Quad Chart	5
References	6
Appendices	N/A
Supporting Data	N/A

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: 56%

- Our target enrollment is 266 participants by February 2018
- We have enrolled 148 participants total, 27 of whom were enrolled in 2018
- 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: 56%
 - Assessed 27 new participants in 2018
- 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 in 2017, 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: 55% (148 out of target 266 participants)
 - San Diego has sent 148 deidentified data packets to Boston
 - They are stored securely in locked file cabinets
 - We will not enter or collect any further data. We have closed the trail to data collection and will use these 148 participants for all data analysis.
- Goal: Ongoing Data Entry and data quality monitoring (Timeline: Months 1-24)
 - % Completion: 90%
 - 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
 - 90% of the 148 participants' data has been double entered. 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: 20%
 - An initial non-inferiority analysis revealed the following: Performing a repeated measures mixed model regression analysis (predicting the change in CAPs between AD and CPT over the two time points) yielded a predicted estimated difference in mean CAP scores (AD-CPT) of -2.1644, with a 95% CI of [-11.3908, 7.0620].

- Since 10 points falls outside of that confidence interval, we can safely reject the null hypothesis that AD is intolerably worse than CPT in reducing CAPs scores = non-inferiority is met.
- This preliminary analysis was based on the smaller than expected (N=147; expected N=266). The fact that we were able to detect the effect (of non-inferiority) from the smaller sample – and that it is a robust statistically significant result means that there is no evidence that N=147 vs. N=266 de-legitimizes the results.
- 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 ORGNIZATIONS

Boston Personnel:	Dr. Brett Litz, PhD.	Project manager
Project Role:	Principal Investigator	Independent Evaluator
Researcher Identifier (ORCID ID):	n/a	n/a
Nearest person month worked:	6% effort, .72 PM worked	47.75% Effort, 5.73 PM worked
Contribution to Project:	Oversee all aspects of assessments and interventions	CAPS assessments, project management
Funding Support:	Dr. Litz is funded through the Massachusetts Veterans Epidemiology And Information Center (MAVERIC). Six percent effort is paid for by this grant.	Project manager's effort is supported by this grant.

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
 - Selena Baca, B.A., Research coordinator at San Diego site

QUAD CHART



PI: Brett Litz, PhD
Partnering PI: Ariel Lang (VMRF)

Adaptive Disclosure: A Combat-Specific PTSD Treatment Contract No. W81XWH-17-1-0041/ BA160047

DMRDP

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 in military-relevant functioning over 8 weeks of treatment.

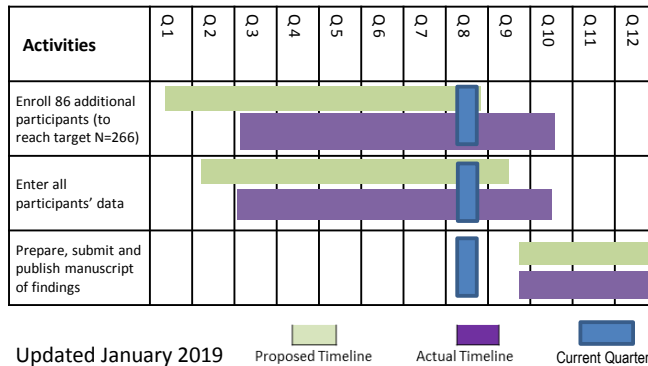
Approach

- 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

- Recruitment and enrollment completed
- Data entry is 90% complete

Timeline



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 continues to send de-identified data to Boston for entry and secure storage
- ☒ Ongoing Data Entry and data quality monitoring

Budget Expenditure to Date

Projected Expenditure: \$133,168
Actual Expenditure: \$86,127

REFERENCES:

- Hoge, C.W., Castro, C.A., Messer, S.C., McGurk, D., Cotting, D.I., & Koffman, R.L. (2004). Combat duty in Iraq and Afghanistan, mental health problems, and barriers to care. *New England Journal of Medicine*, 351, 13-22.
- Kessler, R.C., Sonnega, A.; & Bromet, E. (1995). Posttraumatic stress disorder in the National Comorbidity Survey. *Archives of General Psychiatry*, 52, 1048-1060.
- Kulka, R. A., Schlenger, W. E., & Fairbank, J.A. (1990). Trauma and the Vietnam War generation: Report of findings from the National Vietnam Veterans Readjustment Study. Philadelphia: Brunner/Mazel.
- Litz, B. T., & Bryant, R. A. (2009). Early cognitive-behavioral interventions for adults. In E. B. Foa, T. M. Keane, M. J. Friedman, J. A. Cohen, E. B. Foa, T. M. Keane, ... J. A. Cohen (Eds.) , *Effective treatments for PTSD: Practice guidelines from the International Society for Traumatic Stress Studies (2nd ed.)* (pp. 117-135). New York, NY US: Guilford Press
- Litz, B. T., & Schlenger, W. E. (2009). PTSD in service members and new veterans of the Iraq and Afghanistan wars: A bibliography and critique. *PTSD Research Quarterly*, 20, 1–8.
- Prigerson, H. G., Maciejewski, P. K., & Rosenheck, R. A. (2001) Combat trauma: Trauma with highest risk of delayed onset and unresolved posttraumatic stress disorder symptoms, unemployment, and abuse among men. *Journal of Nervous and Mental Disease*, 189, 99-108.
- Steenkamp, M., Litz, B. T., Gray, M., Lebowitz, L., Nash, W., Conoscenti, L., Amidon, A., & Lang, A., (2011). A Brief Exposure-Based Intervention for Service Members with PTSD. *Cognitive and Behavioral Practice*, 18, 98-107.