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Adaptive Disclosure: A Combat-Specific PTSD Treatment

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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					
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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, Posttraumatic stress disorder, Cognitive Therapy, Moral Injury

KEY RESEARCH ACCOMPLISHMENTS:

Goals of the project:

The primary objective of this study is to determine whether Adaptive Disclosure (AD), a new combat-specific psychotherapy for PTSD, is as least as effective as Cognitive Processing Therapy, cognitive only version (CPT-C), in terms of its impact on deployment-related psychological health problems (specifically PTSD and depression) and functioning. The project has several secondary objectives. First, because AD was developed to be consonant with the Marine Corps culture, we aim to test whether AD will be better accepted by Marines than CPT-C. Second, we will examine whether AD will be superior to CPT-C in terms of changing constructs that are uniquely targeted by AD, namely traumatic grief and moral injury. Third, we examine whether AD will be superior to CPT-C in terms of increasing resilience and posttraumatic growth. Finally, we will examine trauma-related cognition as a mediator of symptom and functioning changes.

Accomplishments:

Major activities:

1. Preparatory Phase (Months 1 – 29)

- a. Regulatory Review and IRB Approval (Months 1-6): All necessary IRB approvals have been obtained.
 - b. Database Development (Months 4 – 6): A study database has been established.
 - c. Hire and Train Study Personnel (Months 1-29): All necessary hiring, credentialing, training, and certification of study personnel is complete.
 - d. Miscellaneous Preparatory Tasks (Months 1-29): All miscellaneous preparatory activities have been successfully completed.
2. Patient Recruitment & Enrollment (Months 30-58, 68+): This report has been revised to acknowledge that recruitment began in 2013 after extensive unanticipated legal and regulatory hurdles. We have had two approved extensions (adding a fifth year and a sixth year) and have received a plus-up for year six. To date, we have recruited 106 of the 266 planned participants. Through year five, the Boston site has conducted 124 pre-treatment assessments, and 62 post-treatment assessments (186 total). No adverse events occurred. These assessments were audio-recorded and a random subsample was sent to Dr. Matt Gray, University of Wyoming, for adherence monitoring. We provided ongoing therapy supervision to study therapists. We also received and stored de-identified data from San Diego. We were awarded continuation funding to complete the trial (adding a seventh and eighth year). We have used these funds to support the re-initiation of patient recruitment. We will continue to recruit subjects until our target goal of 266 participants has been reached over the next two years.
3. Preparatory Phase for Continuation Funding (Months 65-68): We used the plus-up funding we were awarded in preparation for completion of the trial. We have hired a new study therapist and she has been trained in Adaptive Disclosure. We have an agreement to see patients at the Naval Hospital San Diego and we are negotiating about space. We have trained a new RA and two new postdocs to manage the study from the Boston site. We have purchased new equipment (voice recorders) to replace models that had broken during the previous years of the AD trial. Additionally, we have received a two-year Broad Agency Announcement award to complete the project, which began in January 2017. We have hired new staff members to re-initiate data collection and are waiting for their hiring to be processed in order to begin recruitment. Space negotiations are ongoing and we are on track to complete them by the time study staff are fully hired in order to begin data collection as quickly as possible. Furthermore, we have trained two new postdoctoral fellows in giving CAPS assessments. Postdoctoral fellows have been trained to administer this gold-standard assessment with fidelity and have gained skills to reliably assess PTSD symptoms, allowing accurate assessment of the primary outcome of interest in the current study. Through scoring reliability consultations with Dr. Matt Gray, the postdocs have developed a capacity to make nuanced clinical determinations regarding the presence of psychiatric symptoms in keeping with the standards of the CAPS-IV.
4. Follow-Up Data Collection & Patient Closeout (Months 37- 64, 68+): To date, the Boston site conducted 124 pre-treatment assessments, and 62 post-treatment assessments (186 total). No adverse events have occurred. These assessments are audio-recorded and a random subsample has been sent to Dr. Matt Gray, University of Wyoming, for adherence monitoring. We are providing ongoing therapy supervision to study therapists. We are

receiving and storing de-identified data from San Diego. We created a study database and have entered participant data.

Data Analysis & Report Writing, Dissemination (Months 68+): N/A

Specific Objectives: Nothing to report.

Key outcomes and findings: Nothing to report.

Other achievements: Nothing to report.

Stated goals not met: Due to significant recruitment barriers at the site, we were unable to recruit our goal of 266 participants in order to complete data collection and move into the Data Analysis phase. As such, we applied for and received continuation funding through the Broad Agency Announcement in order to complete the trial. We have not been able to examine treatment outcomes in order to remain blind to the data. Our previously stated goals will be met after the additional two years of funding that have been granted to us through the BAA.

Opportunities for training and professional development: Nothing to report.

Dissemination of results: Nothing to report.

What do you plan to do in the next reporting period? Nothing to report (final report).

IMPACT:

- i. Impact on the development of the principal discipline of the project: Nothing to report.
- ii. Impact on other disciplines: Nothing to report.
- iii. Impact on technology transfer: Nothing to report.
- iv. Impact on society beyond science and technology: Nothing to report.

CHANGES/PROBLEMS:

Brett should complete this section outlining problems with recruitment for AD. Answer the following:

- i. Changes in approach or reason for change: Nothing to report.
- ii. Actual or anticipated problems or delays and actions or plan to solve them: We have come up against significant problems with regards to patient recruitment. Our recruitment site has presented substantial institutional barriers that have delayed our ability to start recruiting. We are working with administrators to re-initiate the recruitment process as quickly as possible.
- iii. Changes that had a significant impact on expenditures: The aforementioned recruitment delay had a significant impact on expenditures. Money that we intended to use for data

analysis was, instead, used to continue patient recruitment and to maintain study therapists, site coordinators, and independent evaluators throughout the funding period.

- iv. Significant changes in use or care of human subjects: Nothing to report.
- v. Significant change in use or care of vertebrate animals: Not Applicable.
- vi. Significant changes in the use of biohazards and/or select agents: Not Applicable.

PRODUCTS:

- i. Publications, conference papers, presentations: Nothing to report.
- ii. Websites or other internet sites: Nothing to report.
- iii. Technologies or techniques: Nothing to report.
- iv. Inventions, patent applications, and/or licenses: Nothing to report.
- v. Other products: Nothing to report.

PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS:

The following individuals have worked on the project since its inception:

Name	Brett Litz	Yonit Schorr	Maria Steenkamp	Angela Nickerson	Jonathan Larson
Project Role	Principle Investigator	Postdoctoral Fellow	Postdoctoral Fellow	Postdoctoral Fellow	Research Technician
Research Identifier	N/A	N/A	N/A	N/A	N/A
Person Months:	2	2	1	1	1
Contribution to the project:	Dr. Litz has designed and implemented the project.	Dr. Schorr served as a project manager and conducted CAPS evaluations.	Dr. Steenkamp served as a project manager and conducted CAPS evaluations.	Dr. Nickerson served as a project manager and conducted CAPS evaluations.	Mr. Larson served as a project coordinator and assisted with scheduling, randomization, and data collection
Funding Support:	MAVERIC, BU	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA

Name	Alexander Jordan	Carol Hundert	Charla Rhodes	Jennifer Wortmann	Danielle Berke
Project Role	Postdoctoral Fellow	Research Technician	Research Technician	Postdoctoral Fellow	Postdoctoral Fellow
Research	N/A	N/A	N/A	N/A	N/A

Identifier					
Person Months:	2	1	1	2	1
Contribution to the project:	Dr. Jordan served as a project manager and conducted CAPS evaluations.	Ms. Hundert served as a project coordinator and assisted with scheduling, randomization, and data collection and entry.	Ms. Rhodes served as a project coordinator and assisted with scheduling, randomization, and data collection and entry.	Dr. Wortmann served as a project manager and conducted CAPS evaluations.	Dr. Berke served as a project manager and conducted CAPS evaluations.
Funding Support:	MAVERIC, BU	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA	Adaptive Disclosure, IPA

Name	Julie Yeterian
Project Role	Postdoctoral Fellow
Research Identifier	N/A
Person Months:	1
Contribution to the project:	Dr. Yeterian served as a project manager and conducted CAPS evaluations.
Funding Support:	MAVERIC, BU

Change in active support of the PI: There has been no change in the active other support of the PI since the last reporting period.

There was an initiating partner award to Ariel Lang (San Diego). However, we did not pay any other organizations or award any sub-awards.

CONCLUSION: The Boston site has actively trained new personnel to manage the study, and has trained postdocs to conduct independent evaluations, assess study participants, and enter data. We are poised to reinitiate the recruitment necessary for completion of the data collection phase. Though this is our final report (due to funding), the study is still underway. We will

complete data analysis and dissemination activities after recruitment has been completed using the funding we received from the Broad Agency Announcement. If desired, we will submit another report to HRPO upon completion of the study with updated information on achievements, impact, and outcomes.

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.

APPENDICES: None