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TITLE: Adaptive Disclosure: A Combat-Specific PTSD Treatment

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Many troops return from deployment with mental health problems related to their experiences. One such problem is posttraumatic stress disorder (PTSD), which involves symptoms such as persistent unwanted memories of traumatic events, avoidance of reminders of the events, excessive watchfulness, jumpiness and irritability. Current therapies for PTSD focus chiefly on fear related to life-threat and were developed chiefly on civilians. We developed and piloted tested an early psychological treatment for PTSD designed specifically for service members who suffer not only life-threat, but traumatic loss and inner conflicts from morally injurious experiences. AD is an eight-session treatment that helps Marines to identify unhelpful beliefs about a traumatic event and find ways to move forward. Preliminary data suggests that AD is acceptable to Marines, safe and feasible to implement, and that it reduces PSTD and depression. The primary objective of this randomized controlled non-inferiority trial is to determine whether Adaptive Disclosure (AD), a new combat-specific psychotherapy for PTSD, is comparable in efficacy to Cognitive Processing Therapy, cognitive only version (CPT-C) in terms of its impact on deployment-related psychological problems (specifically PTSD and depression) and functioning. As secondary aims, we have specified some comparisons in which we believe that AD will be superior to CPT-C (degree of change in posttraumatic grief, moral injury, resilience, and posttraumatic growth, as well as degree of treatment acceptability) and we propose to evaluate a posited mechanism of change (trauma-related cognition). There are no up-to-date findings as data collection has not yet begun.

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 comborbid 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.

BODY

Statement of Work (SOW)

Preparatory Phase (Months 1 – 6)

- **Regulatory Review and IRB Approval (Months 1-6)**:
  (1) Prepare and submit human subjects protection application to UCSD IRB, VA Research and Development (R&D) Committee, IRB for Camp Pendleton, Boston IRB/R&D and Army ORP. IRBs have been submitted to and approved by UCSD IRB, VA Boston IRB/R&D, and Camp Pendleton IRB. Due to a longer than expected review process and changes required to the IRB submissions, the study has not yet received approval from the Navy IRB or CRADA. Subsequently, HRPO approval has been delayed.
  (2) Establish weekly meetings for principal investigators for study planning and initiation. Biweekly meetings and conference calls with principal investigators have been established; they are currently occurring on an as-need basis but will be attended weekly once recruitment begins.

- **Database Development (Months 4 – 6)**: **Establish study database.** Database has been established.

- **Hire and Train Study Personnel (Months 1-6):**
  (1) Hire and credential study staff. All Boston study staff have been hired and credentialed.
  (2) Train and certify study personnel on all study procedures. Boston staff have been trained.
  (3) Train assessors in CAPS administration. CAPS assessors at the Boston VA site have been trained to administer CAPS phone interviews.

- **Miscellaneous Preparatory Tasks (Months 1-6):**
  (1) Purchase necessary supplies and transport to study sites. Necessary supplies have been purchased.
  (2) Develop study manual of operation and randomization procedures. An SOP for procedures to be carried out by Boston personnel has been created.
  (3) Establish oversight committee to monitor study progress and safety. This has not been done yet because data collection has not started. We will generate this local committee in the next quarter.
  (4) Develop and test standardized audio recording procedures for independent evaluators. Assessors at the Boston VA have established ways to audio record CAPS phone assessments and received necessary permissions to do so.

Patient Recruitment & Enrollment (Months 7 – 36): **1) Identify and recruit potential participants; (2) monitor enrollment progress at clinics; (3) provide ongoing supervision for therapists; (4) collect data from study participants [pre-treatment through 32 weeks]; (5) conduct audio recording for on-going adherence and provide prompt feedback to assessors and therapists; (6) collect and report adverse events and serious adverse events; (7) transport deidentified data to Boston for entry and secure storage; (8) ongoing data quality monitoring.**

Due to a longer than expected review process, patient recruitment has not yet begun and no data have been collected.

Site Location Information

Site 1: San Diego [Veterans Medical Research Foundation (VMRF)]
9500 Gilman Dr. (MC 0855)
La Jolla, CA 92093-0855
PI: Ariel J. Lang, Ph.D., M.P.H.
Human use at Camp Pendleton.

Site 2: Boston [Boston VA Research Institute (BVARI)]
150 South Huntington Avenue,
Room 11B-60
Boston, MA 02130
PI: Brett Litz, Ph.D.
No human or animal use at this site.

Site 3: UCSD
9500 Gilman Dr.
La Jolla, CA 92093
PI: William Nash, M.D.
No human or animal use at this site.

Gantt Chart for SOW

	Year 1	Year 2	Year 3	Year 4
Preparatory Phase: Set-up, Regulatory Review and Approvals				
IRB and VA R&D Committee approvals	VMRF, Boston			
Army ORP approval	VMRF			
Hire and train staff	VMRF, Boston, UCSD			
Develop database	Boston			
Recruitment, Enrollment and Intervention				
Recruit and enroll participants		VMRF, UCSD		
Deliver AD and CPT-C		VMRF		
Data collection		VMRF, Boston		
Supervise assessors and therapists		VMRF, Boston, UCSD		
Data quality monitoring		VMRF, Boston		
Data Collection and Close-out				
Complete data collection			VMRF, Boston	
Complete database			Boston	
Analysis, Writing & Dissemination				
Complete data analysis				Boston
Prepare reports, manuscripts, presentations				VMRF, Boston, UCSD

KEY RESEARCH ACCOMPLISHMENTS

Recruitment has not yet begun. No data have been collected in the past year.

REPORTABLE OUTCOMES

None at this time.

CONCLUSION

Recruitment has not yet begun. No data have been collected in the past year.

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