

AD_____

Award Number: W81XWH-07-2-0006

TITLE: Online Early Resilience Intervention for Combat-Related PTSD in Military Primary Healthcare Settings: A Randomized Trial of "DESTRESS-PC"

PRINCIPAL INVESTIGATOR: Charles Engel

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation
Rockville, MD 20852

REPORT DATE: August 2010

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 (DD-MM-YYYY) 01-08-2010		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 2 JUL 2007 - 1 JUL 2010	
4. TITLE AND SUBTITLE Online Early Resilience Intervention for Combat-Related PTSD in Military Primary Healthcare Settings: A Randomized Trial of DESTRESS-PC				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-07-2-0006	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) COL Charles C. Engel, MD, MPH * e-mail: cengel@usuhs.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry M. Jackson Foundation Rockville, MD 20852				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research Materiel Command Fort Detrick, Maryland 21702-5016				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 Over the course of the last year, recruitment has continued at the three study recruitment sites--Savannah, Charleston/Goose Creek, and Womack Army Medical Center (WAMC). This time last year, we successfully instituted several strategies to boost study recruitment, and we have since seen an increase in the rate of participant enrollment. In order to further maximize participant enrollment, we requested an extension of the study through March 2011. This extension will allow us to continue recruiting through September 2010, and then provide participants with enough time to complete the intervention and 18 weeks of follow-up prior to the new study end date. Thus far, we have consented 116 participants and randomized 67-30 at Savannah, 27 at WAMC, and 10 at Charleston VA/Goose Creek. Forty-four participants have completed the study through the 18-week follow-up.					
16. Subject Terms - None provided.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT:	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	7	19b. TELEPHONE NUMBER (include area code)
					Standard Form 298 (Rev. 8-98) Prescribed by ANSI Std. Z39.18

Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	1
Reportable Outcomes.....	1
Conclusion.....	1
References.....	1-2
Appendices.....	2-4
Supporting Data.....	----

INTRODUCTION:

This randomized controlled trial will compare a cognitive-behavioral online self-management intervention (DESTRESS-PC) designed for primary care-delivered treatment of war-related PTSD to a control intervention, “optimized usual primary care PTSD treatment”. Optimized usual primary care will consist of PTSD diagnosis and referral back to the soldier’s primary care provider (PCP) followed by usual PCP guided treatment. Participants in both conditions will have scheduled check-ins with a study nurse to monitor their progress. The long term objective of the proposed research is to: 1) improve the readiness and resilience of military personnel who have symptoms from recent combat-related stressors; and 2) empower military primary care providers to assist personnel with PTSD symptoms following combat operations.

We expect that DESTRESS-PC will significantly decrease anxiety, depression, and physical symptoms, and improve overall health and occupational functioning relative to the optimized primary care condition. If this research project is successful, a provider-efficient model of care could be instituted in all DoD and VA primary care settings. By increasing the presence of available and effective PTSD treatment delivered in a primary care clinic with online psycho-education and therapeutic interventions, fewer military personnel will develop chronic PTSD. This is expected to improve the overall health of our patients and increase the military readiness of our service men and women.

BODY:

Over the last year of the study, we have continued Task 3 (“Conduct study”), as laid out in the Statement of Work. In terms of specific accomplishments relating to Task 3, we have actively continued with participant recruitment and enrollment, and have completed a large number of follow-up assessments. We have seen an increase in the rate of participant enrollment over the last year due to some of the changes we instituted to boost recruitment (detailed on the 2009 annual report). We have also extended the study through March 2011 in order to allow recruitment to continue for a few additional months. We anticipate that this additional time will allow us to enroll 10-15 more participants, putting our total enrollment at 75-90. Thus far, we have consented 116 participants and randomized 67—30 at Savannah, 27 at Womack Army Medical Center (WAMC), and 10 at Charleston VA/Goose Creek. Forty-four participants have completed the study through the 18-week follow-up. Please see the appended Consort diagram for a detailed breakdown of recruitment and follow-up. We plan to begin the fourth and fifth tasks on the Statement of Work (“Data verification and analysis” and “report preparation”) over the next 7 months, to be completed prior to the March 2011 study end date.

KEY RESEARCH ACCOMPLISHMENTS:

There are not yet any clear scientific findings resulting from this research because recruitment and data collection are still underway. Results are expected in March, 2011.

REPORTABLE OUTCOMES:

A presentation was given to the Mental Health Research Forum in September, 2009. The abstract is appended to this report.

CONCLUSION:

There are no conclusions to report, as recruitment and data collection are still underway.

REFERENCES:

Litz, BT, Williams, L, Wang, J, Bryant, R, Engel, CC (2004). A therapist-assisted internet self-help program for traumatic stress. *Professional Psychology: Research and Practice*, 35, 628-634.

Litz, B, Engel, CC, Bryant, R, Papa, A (2007). A randomized, controlled proof of concept trial of an internet-based therapist-assisted self-management treatment for PTSD. *American Journal of Psychiatry*, 164, 1-8.

Kuehn, BM (2008). VA, military seek office-based PTSD care. *JAMA*, 299, 1885-1886.

APPENDICES:

Abstract for the September 2009 presentation to the Mental Health Research Forum (Appendix 1).

Consort diagram showing participant recruitment and follow-up (Appendix 2).

SUPPORTING DATA:

N/A

Appendix 1.

BACKGROUND – Iraq and Afghanistan war veterans often report PTSD symptoms and related impairment. Only a minority of those affected receive mental health services. Improved access to effective primary care-based psychosocial interventions for PTSD may reach a larger fraction of these underserved service members. Our group has developed a web-based therapist-assisted PTSD treatment called DESTRESS (**DE**livery of **Self-TR**aining and **E**ducation for **Stressful Situations**). A small controlled trial of DESTRESS in service members with PTSD found greater improvements in PTSD, depression, and high end-state functioning versus web-based supportive care. DESTRESS is a potential way of delivering high fidelity PTSD therapy in primary care.

PURPOSE – To review the intervention, design, and status of a study to determine the effectiveness of DESTRESS-PC (DESTRESS for Primary Care).

HYPOTHESES – Primary care patients with PTSD after returning from deployment to the Iraq or Afghanistan conflicts will experience significantly improved PTSD (primary outcome), depression, anxiety, somatic symptoms, physical health status, and occupational function in response to DESTRESS-PC versus optimized usual PTSD treatment.

STUDY DESIGN – The study is a multi-site two parallel arm randomized controlled trial comparing DESTRESS-PC to optimized usual primary care. Blinded raters assess PTSD symptoms, depression, anxiety, somatic symptoms, physical health status, and occupational functioning at 6 weeks, 12 weeks, and 18 weeks post-randomization.

SAMPLE - US service members or veterans returning from deployment to the Iraq or Afghanistan conflicts with PTSD who are visiting primary care with PTSD at one of three VA and four DoD clinics. The goal is to randomize 184 participants, 92 from DoD sites and 92 from VA clinics.

INTERVENTION – DESTRESS-PC is a web-based, nurse-assisted, Cognitive Behavioral Therapy (CBT) informed self-management intervention designed for primary care patients with PTSD. DESTRESS-PC is briefer (six weeks instead of eight) and less intensive (3 logons per week instead of daily) than DESTRESS and employs a nurse, rather than a therapist. Participants log on to a secure website for self-CBT and receive RN nurse care manager (“DESTRESS Nurse”) contact every two weeks. DESTRESS Nurses introduce the approach, monitor, answer questions, and insure primary care provider collaboration. The control intervention is optimized usual primary care. All study participants receive RN care management and are under the care of a primary care provider trained in evidence-based PTSD treatment who receives status reports from the DESTRESS nurse to include baseline psychiatric status.

RESULTS – Recruitment of participants is underway in all clinics. Trial completion is anticipated in August, 2010.

CONCLUSIONS – DESTRESS-PC is a promising way of empowering primary care providers to offer patients an acceptable, widely available, and effective psychosocial treatment for PTSD.

Total Referred (n=434): S=197, C=172, FB=65

Not consented (n=293):

Unreachable (n=66)
 Too busy (n=19)
 Not interested (n=76)
 Moving (n=15)
 No internet (n=2)
 Referred to Savannah (n=1)
 Deployed (n=1)
 Screened, found ineligible (n=113):
 Not OIF/OEF (n=9)
 Not on stable treatment regimen (n=9)
 Engaged in specialty MH care (n=18)
 Psychosis (n=3)
 No trauma (n=3)
 Ineligible on CAPS (n=41)
 Substance Dependence (n=8)
 Suicidal Ideation (n=2)
 Medication exclusion (n=4)
 No email (n=2)
 No PTSD (n=2)
 No combat (n=8)
 Active bipolar (n=1)
 Failed Tx (n=2)

Total Consented (n=116): S=45, C=27; FB=44*M (n=96) F (n=20) W(n=59) AA(n=45) H(n=7) Oth (n=5)*

Excluded (n=38):

Ineligible on CAPS (n=14)
 Homicidal ideation (n=2)
 Suicidal ideation (n=1)
 Engaged in specialty mental health care (n=4)
 Unreachable to complete eligibility interview (n=3)
 Medically unstable (n=3)
 Substance dependence (n=8)
 Not Interested (n=1)
 Medication exclusion (n=2)
 Eligible, dropped out pre-randomization (n=9)—S (2); FB (2); C (5)
 Waiting for baseline (n=2) FB

Randomized (n=67)**Treatment Group
(n=38)**

Male (n=30)
Female (n=8)

**6-week follow-up
(n=16)**

**12-week follow-up
(n=15)**

**18-week follow-up
(n=21)**

Dropped Out (n=8)

(No follow-up obtained)
 5—prior to treatment (3 S; 2 C)
 3—following treatment (FB)

Dropped Out (n=1)

(No follow-up obtained)
 Immediately post-randomization--C

**Optimized Care
(n=29)**

Male (n=24)
Female (n=5)

**6-week follow-up
(n=18)**

Missing (n=1) S

**12-week follow-up
(n=16)**

**18-week follow-up
(n=23)**

Key:

S=Savannah site (VA) M=Male W=White
 C=Charleston site (VA) F=Female AA=African American
 FB=Ft. Bragg site (DoD) H=Hispanic
 Oth=Other