

AD _____

Award Number: W81XWH-061-0573

TITLE: Identification of Risk Factors for Chronic Posttraumatic Stress Disorder (PTSD)

PRINCIPAL INVESTIGATOR: M. Tracie Shea, Ph.D.
Norman J. Hebert

CONTRACTING ORGANIZATION: Brown University
Providence RI 02912

REPORT DATE: July 2007

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 01-07-2007		2. REPORT TYPE Annual		3. DATES COVERED 1 Jul 2006 – 30 Jun 2007	
4. TITLE AND SUBTITLE Identification of Risk Factors for Chronic Posttraumatic Stress Disorder (PTSD)				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-06-1-0573	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) M. Tracie Shea, Ph.D. Norman J. Hebert Email: M_Shea@Brown.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Brown University Providence RI 02912				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 The primary research aims are to examine the early longitudinal course of PTSD symptoms and test hypotheses regarding risk factors for chronic PTSD in military personnel returning from Iraq or Afghanistan. Recruitment of study subjects began in mid-December 2006 following human subjects' approval. Experience with recruitment efforts has been positive. Eighty-three subjects have participated to date, all completing baseline interviews averaging 3 to 4 hours. Six month and 12 month post-return follow-up data has been collected on 78 and 14 subjects. Data from the comprehensive interviews are undergoing editing and data entry. Data analyses have not yet begun, given the early phase of the research. The P.I. collaborated with Dr. Audrey Tyrka to procure funding for an add-on study to assess biological markers (genetics and cortisol) as risk factors. Dr. Tyrka's study was funded by the USAMRMC, and recruitment for the add-on study has begun. 41 subjects (91% of those invited) have participated in the biomarkers study.					
15. SUBJECT TERMS Posttraumatic Stress Disorder, mental health, longitudinal research					
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	5	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	2
Reportable Outcomes.....	2
Conclusion.....	2
References.....	none
Appendices.....	none

Introduction: The purpose of this first phase of longitudinal research is to examine the early longitudinal course of PTSD in military personnel after their return from Iraq or Afghanistan, and to test hypotheses regarding risk factors for chronic PTSD. The study aims to recruit and comprehensively assess 300 National Guard and Reserve troops recently returning from deployment, and to obtain follow-up assessments of symptomatic course, functional outcomes, treatment utilization, and ongoing social support and life stress at six and twelve months post return.

Body: During the first three months of the funding period staff were hired, the assessment battery was finalized, and interviewers were trained to reliably administer the key interviews (Clinician Administered PTSD Survey – CAPS, Structured Diagnostic Interview for DSM-IV Disorders – SCID). Protocols were submitted to local IRBs (Brown University and the Providence Veterans Affairs Medical Center), and to the Human Research Protections Office, USAMRMC. Approval to begin recruitment was granted by the USAMRMC HRPO in mid December of 2006, and recruitment for the study began.

Eighty three subjects have agreed to participate, signed informed consent, and completed baseline interviews (Task 1—in progress). Our window for recruitment was approximately 6 months following return from deployment. For subjects who had been back 6 months at the time of recruitment, we were able to complete baseline and 6 month interviews at the same point. Otherwise, subjects receive a separate interview at 6 months. We now have complete 6 month data for 78 Subjects (Task 2—in progress), and have completed fourteen 12 month interviews (Task 2). The response to the study has been excellent in terms of command support (willingness to allow us to speak to the soldiers to present the study) and in terms of the interest and response among soldiers. Recruitment has taken place primarily during redeployment debriefings held by the National Guard and Reserves.

Several local National Guard and Reserve units with large numbers of troops are scheduled to return in early fall, and we anticipate sizeable recruitment for the study during the upcoming fall and winter months.

Clinical editing of the data is underway. Programming for data entry has been completed, and data are now being entered for the baseline interviews. Data processing includes further computer based verification and editing. (Task 3 a.)

Given the early phase of the data collection and processing, data analyses have not yet been conducted. Thus, there are no scientific results or findings at this point to report.

Reviewers of the proposal for the current study strongly suggested adding biological measures as risk factors. This was not possible within the existing budget. The P.I. approached an investigator (Dr. Audrey Tyrka) with the relevant expertise, and Dr. Tyrka submitted a proposal to the USAMRMC for an add-on study to collect data for genetic

and stress hormone (cortisol) factors as risk factors. This study has been funded and is now underway. Forty-one subjects (of 44 invited) have participated in the add-on study to date.

Key Research Accomplishments:

- Human Subjects Approval
- Ongoing subject recruitment
- Completion of 83 baseline interviews
- Completion of 78 6 month follow-up interviews
- Completion of 14 12 month follow-up interviews
- Collaboration resulting in funding for add-on study of biomarkers as risk factors

Reportable Outcomes:

Data not yet analyzed; no reportable scientific findings to date from this study.

Funding received for add-on study (biomarkers of risk)

Related publications and presentations by P.I. during period of report:

Schnurr PP, Friedman MJ, Engel CC, Foa EB, Shea MT, Chow BK, Resick PA, Thurston V, Orsillo SM, Haug R, Turner C, Bernardy N. Cognitive Behavioral Therapy for Posttraumatic Stress Disorder in Women. A Randomized Controlled Trial. Journal of the American Medical Association. 2007; 297:820-830.

Shea MT, McDevitt-Murphy MM, Ready D, Schnurr P. Group Therapy. In Foa EB, et al. (Eds.) Effective Treatments for PTSD: Practice Guidelines from the International Society for the Study of Traumatic Stress. NY, NY: Guilford Press, in press.

Shea MT, Lambert J, Howard J, Davis N. Implementation of Present-Centered Therapy in the CSP-494. Presentation at the International Society for the Study of Traumatic Stress, November, 2006.

Conclusion: The study is receiving a favorable response and recruitment is going well.