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Award Number: W81XWH-08-2-0031

TITLE: Identification of an At-Risk Interventions for Pre-Deployment Psychophysiologic Predictors of Post-Deployment Mental Health Outcomes

PRINCIPAL INVESTIGATOR: Jeffrey M. Pyne, M.D.

CONTRACTING ORGANIZATION: Biomedical Research Foundation, Little Rock
Little Rock, AR 72205

REPORT DATE: October 2011

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;
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REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
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1. REPORT DATE October 2011		2. REPORT TYPE Annual		3. DATES COVERED 15 September 2010 – 14 September 2011	
4. TITLE AND SUBTITLE Identification of an At-Risk Interventions for Pre-Deployment Psychophysiological Predictors of Post-Deployment Mental Health Outcomes				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0031	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Jeffrey M. Pyne, Regina Stanley E-Mail: Jeffrey.Pyne@va.gov				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Biomedical Research Foundation, Little Rock Little Rock, AR 72205				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 <i>Objectives and Rationale:</i> The primary objectives of this proposal are to develop objective pre-deployment predictors of PTSD and test two pre-deployment resiliency interventions. Objective predictors include: 1) physiologic reactivity to combat-related virtual reality environments and white noise startle and 2) cognitive bias assessment. We also will test two pre-deployment resiliency interventions: 1) video game-based heart rate variability biofeedback training and 2) computerized cognitive bias training. Objective assessment and training measures are more reliably measured and could be early indicators of resilience/vulnerability. <i>Study Design:</i> We will collect pre-deployment physiologic reactivity and cognitive bias data from Army National Guard and/or Reserve members within 12 months of OIF/OEF deployment. We plan to consent up to 600 soldiers in order to complete 500 pre-deployment assessments. Subjects will be randomized to one of three groups: heart rate variability biofeedback training, cognitive bias training, or no additional training. Follow-up data will be collected at 3- and 12- months post-deployment. <i>Major Findings:</i> There are no findings to report at this time. <i>Project Status:</i> Pre-deployment baseline assessments are completed and the data is being prepared for analysis. <i>Potential Impact:</i> The products from this study will include an objective model for PTSD risk assessment and evidence to support specific pre-deployment PTSD resiliency training.					
15. SUBJECT TERMS PTSD, Mental Health, Prevention, Projection, Prediction					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)
			UU	9	

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Introduction

The purpose of this research study is to identify objective pre-deployment predictors for post-deployment post-traumatic stress disorder (PTSD) and to test two pre-deployment interventions designed to reduce post-deployment mental health problems. A total of 500 Army National Guard or Reserve members who are planning to deploy for Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) operations within the next 12 months will be recruited for the study.

Body

The tasks outlined below were completed during the current reporting period.

Task 6: Modify existing cognitive attribution bias training for use in the proposed study (Mos. 1-6):

- Modify existing cognitive bias modification training for use in military population (Mos.1-5). Constans, SLVHCS
- Load cognitive bias modification training software on laptop computers and hand-held devices (Mos.6). Wiederhold, VRMC

Progress: Complete. The final laptop and handheld versions of the cognitive attribution bias training are complete and have been loaded onto laptop computers and handheld devices (iPod Touch). The training programs (Breath Pacer and IMAT apps) are available for downloading at the Apple Store.

Task 9: Collect pre-deployment physiologic reactivity and cognitive attribution bias data from Army National Guard and/or Army Reserve members (N=500) (Mos. 9-15):

- Recruit and consent National Guard and/or Army Reserve subjects within 12 months of OIF/OEF deployment (Mos. 9-15). Pyne, CAVHS
- Collect pre-deployment physiologic reactivity and cognitive attribution bias data (Mos. 9-15). Pyne, CAVHS

Progress: Complete. A total of 600 subjects were recruited from two Army National Guard units. Consenting took place during pre-deployment Soldier Readiness Check (SRC) weekends. Of the 600 subjects that consented to be in the study, 427 completed pre-deployment baseline assessments during pre-deployment training. The remaining 173 subjects either voluntarily dropped from the study or did not contact research personnel to schedule appointments for their assessment.

All baseline assessments were completed on an Army National Guard training base (Ft. Pickett, VA) during the time that the soldiers were completing their pre-deployment training. The major barrier to completing the assessments was the soldier's rigorous training schedules. That being said, soldiers were willing to complete assessments well into the early morning hours.

- Define baseline physiologic reactivity variables (Mos. 7-18). Tan, MEDVAMC
- Refine analysis plan for pre-deployment data (Mos. 7-18). Williams, UAMS

Progress: Data collection was completed in May 26, 2011. Analyses of these data are currently underway.

Task 10: Randomize pre-deployment National Guard and/or Army Reserve members to resiliency training or no intervention (Mos. 9-15):

- Use block randomization design to randomize pre-deployment National Guard and/or Army Reserve members to physiologic reactivity training, cognitive attribution training, or no intervention (Mos. 9-15). Pyne, CAVHS

Progress: Complete. See attached randomization procedures (Appendix A) and randomization results (Appendix B).

The tasks outlined below are scheduled to be completed prior to post-deployment data collection.

Task 13: Train research assistants to collect post-deployment data (Mos. 21-27):

- Train research assistants to collect post-deployment interview data (Mos. 21-27) Kramer, UAMS
- Train research assistants to collect post-deployment physiologic reactivity data (Mos. 21-27) Kimbrell, UAMS
- Train research assistants to collect cognitive bias data (Mos. 21-27) Constans, SLVHCS

Task 14: Collect post-deployment data (Mos. 27-42):

- Collect 3-month post-deployment physiologic reactivity, cognitive attribution bias, and interview data (Mos. 27-33). Pyne, CAVHS
- Collect 12-month post-deployment physiologic reactivity, cognitive attribution bias, and interview data (Mos. 36-42). Pyne, CAVHS
- Define post-deployment physiologic reactivity variables (Mos. 27-42). Tan, MEDVAMC
- Refine analysis plan for post-deployment data (Mos. 27-42). Williams, UAMS

Task 15: Data analysis and report writing (Mos. 42-48):

- Complete data analysis and report writing (Mos. 42-48). Pyne, CAVHS

Key Research Accomplishments

- Training apps approved by Apple Store - Getting new apps into the Apple Store was more difficult than anticipated due to criteria for acceptance changed while we were in the process of submitting the apps for approval. We were told that the apps were not entertaining enough and that they did not appeal to a wide enough audience. With more justification (e.g. potential use by thousands of soldiers), we succeeded in getting approval.
- Collecting data from 427 soldiers during their pre-deployment training was a huge accomplishment. Contributing factors included 1) Use of iPod Touch device; 2) Willingness of research team to collect data on soldiers whenever they were available; 3) Support of commanders – providing space and allowing soldiers time to participate in the study.

Reportable Outcomes

None to report.

Conclusion

The following tasks outlined in the SOW were completed during this reporting period.

- Consented/enrolled 600 participants
- Completed pre-deployment data collection on 427 participants
- Provided resilience training to 252 soldiers

Appendix A

Randomization Procedures

- Participants were randomized to one of three training arms: breath pacing, cognitive bias, or no additional training.
- The unit of randomization was the smallest naturally occurring unit that was most likely be in close proximity during deployment (e.g. squad or platoon). This was done in order to limit training intervention cross-over that is very likely if soldiers who work in close proximity are assigned to different training intervention arms. The precise unit of randomization was decided in consultation with command leadership. The randomization scheme was 1:1:1 by unit across training intervention arms and was based on results from a random number generator.
- Randomization was stratified by company or troop under the assumption that there may be factors that could affect outcomes that were specific to a given company or troop, e.g., assignment, culture, etc. Headquarter companies were randomized separately. We monitored the number of subjects who were recruited into each arm and modified randomization strategies such that at the end of recruitment we had equal numbers of subjects in each of the training arms. A larger number of subjects was in the no additional training arm and this will enhance our power to detect outcome differences between the training arms and the control group.

Appendix B

Randomization Results

Arm	Battalion 1	Battalion 2	Totals
Biofeedback	40	86	126
Cognitive	31	95	126
Control	47	128	175
Totals	118	309	427