

AD _____

Award Number: W81XWH-12-1-0385

TITLE: Evaluating a Novel Sleep-Focused Mind-Body Rehabilitative Program for Veterans with mTBI and Other Polytrauma Symptoms: An RCT Study

PRINCIPAL INVESTIGATOR: Yoshio Nakamura, Ph.D.

CONTRACTING ORGANIZATION: The University of Utah
Salt Lake City, UT 84112

REPORT DATE: September 2014

TYPE OF REPORT: Annual Report

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 September 2014		2. REPORT TYPE Annual Report		3. DATES COVERED 31 Aug 2013 – 30 Aug 2014	
4. TITLE AND SUBTITLE Evaluating a Novel Sleep-Focused Mind-Body Rehabilitative Program for Veterans with mTBI and Other "Polytrauma" Symptoms: An RCT Study				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER: W81XWH-12-1-0385	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Yoshio Nakamura, Ph.D. E-Mail: yoshi.nakamura@utah.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The University of Utah Salt Lake City, UT 84112-9023				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 Subjects are being recruited for the proposed study and the study is still ongoing. There is no finding to report from the study as of 30/09/2014.					
15. SUBJECT TERMS mind-body intervention, awareness training, mindfulness, insomnia, sleep disturbance, mild Traumatic Brain Injury (mTBI), OEF/OIF					
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	4	19b. TELEPHONE NUMBER (include area code)

Annual Report

1. Front Cover
2. Standard Form (SF 298)
3. Table of Contents

Table of Contents

	<u>Page</u>
Introduction.....	3
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	4
Conclusion.....	4
References.....	4
Appendices.....	4

4. Introduction

The purpose of the study is to evaluate and compare the clinical benefit of two sleep-focused therapeutic interventions: Mind-Body Bridging (MBB) and Supportive Education (SED) on sleep and comorbid mild Traumatic Brain Injury (mTBI) symptoms. We will recruit 142 OEF/OIF veterans with mTBI, who first will undergo a comprehensive evaluation performed by our medical and psychological staff, and then will be assigned to one of the two programs (MBB or SED). Each veteran will receive a total of 6 hours of sleep-focused treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each patient will be evaluated again after treatment has ended. Three months after treatment ends, patients will have another evaluation. Six months after treatment ends, patients will complete follow-up questionnaires. These assessments will help us to evaluate both the efficacy of the therapy programs and document any differences in individual treatment response. Additionally, the project will explore underlying mechanisms of action involved in treatment benefits resulting from MBB and SED by using a biomarker of stress as a proxy indicator of intermediate mechanisms activated by MBB and SED.

5. Body

We hired psychologists to do psychological evaluation, a Physician Assistant to do physical evaluation and LCSWs to do interventions.

We hired a research assistant.

We started recruitment. We screen the patients lists obtained from Polytrauma Clinic at VA, send recruitment letters and make phone calls to follow-up with the letters we sent.

The list was smaller than we expected to have a large number of subjects for the study during the shorter time period. This may mean that the study may take longer than it was originally projected to last. We are currently exploring more options for recruitment.

We will post flyers and brochures at Salt Lake VA and other approved locations, and distribute study information to OEF/OIF resource groups.

First intervention groups started in April and the participants who completed the groups also completed the post-intervention evaluation and 3 month follow-up evaluation.

Second intervention groups are scheduled to start in October.

6. Key Research Accomplishments

- Hired Psychologists, LCSWs and Physician Assistants
- Started recruitment
- Completed first intervention groups and post and 3 month evaluations for those who completed the intervention
- 13 Veterans consented to participated in the study
- 2 Veterans completed intervention sessions
- 2 Veterans completed post-intervention and 3 month follow-up evaluation
- Setting up online survey (REDCap)

7. Reportable Outcomes

Study enrollment is still currently ongoing. We do not have any result yet to report here.

8. Conclusions

Study enrollment has started during Year 2. We are currently not in a position to reach any conclusion regarding study aims and hypothesized benefits of the experimental intervention program (MBB) at the end of Year 2.

9. References

None

10. Appendices

None

11. Supporting Data

None