

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: University of Utah  
Utah State Office Building

REPORT DATE: 10/2013

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.**

<b>1. REPORT DATE</b> 09/2013		<b>2. REPORT TYPE</b> Annual Report		<b>3. DATES COVERED</b> 1 September 2013-31 August 2013	
<b>4. TITLE AND SUBTITLE</b> Evaluating a novel sleep-focused mind-body rehabilitative program for Veterans Veterans with mTBI and other "polytrauma" symptoms: An RCT study				<b>5a. CONTRACT NUMBER</b> W81XWH-12-1-0385	
				<b>5b. GRANT NUMBER</b> W81XWH-12-1-0385	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Yoshio Nakamura, Ph.D.  E-Mail: yoshi.nakamura@utah.edu				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  University of Utah 201 Presidents Cir. Rm 408 Salt Lake City, UT 84112-9023				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b>  We obtained IRB approval for the study from the University of Utah IRB, VA SLC HCS and DoD HRPO and we have been preparing to start recruiting study participants for the study.					
<b>15. SUBJECT TERMS</b> mind-body intervention, awareness training, mindfulness, insomnia, sleep disturbance, mTBI, PTSD, chronic pain					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC
<b>a. REPORT</b> U	<b>b. ABSTRACT</b> U	<b>c. THIS PAGE</b> U			<b>19b. TELEPHONE NUMBER (include area code)</b>
			UU	4	

Annual Report

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

**Table of Contents**

	<u>Page</u>
<b>Introduction .....</b>	<b>1</b>
<b>Body .....</b>	<b>2</b>
<b>Key Research Accomplishments .....</b>	<b>2</b>
<b>Reportable Outcomes .....</b>	<b>2</b>
<b>Conclusion.....</b>	<b>2</b>
<b>References.....</b>	<b>2</b>
<b>Appendices.....</b>	<b>2</b>

**4. Introduction**

The objective 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 disturbed sleep and comorbid symptoms in Veterans with mild Traumatic Brain Injury (mTBI). We will recruit 142 OEF/OIF veterans with mTBI, who first will undergo comprehensive medical and psychological evaluations and then will be randomly assigned to one of the two programs (MBB or SED). Each veteran will receive a total of 6 hours of treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each Veteran will be evaluated again after treatment has been completed. 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 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 heart rate variability and a biomarker of stress as proxy indicators of intermediate mechanisms presumably activated by MBB and SED.

## **5. Body**

We obtained approval for the study from the University of Utah IRB, VA SLC HCS and DoD HRPO and started planning study logistics and refined them by meeting with the Polytrauma clinic to inform their personnel about the study and to obtain the Polytrauma clinic TBI database to start contacting Veterans.

We also started the process to hire project staffers, including personnel to conduct the medical and psychological evaluations (physician's assistant, psychologists) and MBB and sleep control group instructors.

Other tasks accomplished during Year 1 include putting together the sleep control program, purchasing motion detection device and setting up online survey (REDCap).

## **6. Key Research Accomplishments**

- Obtained approval from the UU IRB, VASLCHCS and DoD HRPO
- Started planning study logistics
- Obtained database with Veterans' contact information
- Started hiring staffers
- Put together the sleep control program
- Purchased motion detection device
- Setting up online survey (REDCap)

## **7. Reportable Outcomes**

We have not started recruiting the study participants as of Sep. 30, 2013, and thus we do not have any result yet to report here.

## **8. Conclusions**

We have not started recruiting the study participants. 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 1.

## **9. References**

None

## **10. Appendices**

None

## **11. Supporting Data**

None