Award Number: W81XWH-10-1-1021

TITLE: Post-Traumatic Headache and Psychological Health: Mindfulness Training for Mild Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: Sutapa Ford, Ph.D.

CONTRACTING ORGANIZATION: University of North Carolina at Chapel Hill
Department of Physical Medicine and Rehabilitation
Chapel Hill, NC 27599

REPORT DATE: October 2012

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**

<table>
<thead>
<tr>
<th>1. REPORT DATE</th>
<th>October 2012</th>
<th>2. REPORT TYPE</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. DATES COVERED</td>
<td>27 September 2011 – 26 September 2012</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TITLES AND SUBTITLE**

Post-Traumatic Headache and Psychological Health: Mindfulness Training for Mild Traumatic Brain Injury

**AUTHOR(S)**

Sutapa Ford, Ph.D.

**E-Mail:** FordS@carolinaheadacheinstitute.com

**PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

University of North Carolina at Chapel Hill
Department of Physical Medicine and Rehabilitation
Chapel Hill, NC 27599

**SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

**DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**ABSTRACT**

Traumatic brain injury has been coined the signature injury of OIF/OEF, with posttraumatic headache being a cardinal symptom found to be as high as 36% of soldiers with MTBI. Combat-related headaches are undertreated, associated with high sick calls, missed days, negative psychological/mood states, and impair overall quality of life. Comorbid anxiety, depression, PTSD and other psychological, psychosocial, and health stressors portend poorer TBI/headache outcomes, supporting the need for integrative health care. Development, evaluation, and integration of a specialized posttraumatic headache treatment program into a comprehensive TBI rehabilitation effort is critical to restoration of function, health, and quality of life of our soldiers. This project addresses multiple FY09 TBI/PH topic areas by validating an evidence-based, mind-body approach for prevention and treatment of post-TBI headache, stress, and associated psychological health issues in order to restore function, enhance well being, prevent post-TBI headache chronification, develop psychological resilience, and promote long-standing health benefits. The focus of this project is on evaluation of mindfulness based stress reduction as one, potentially critical component of a comprehensive rehabilitative effort for this group of MTBI patients.

**SUBJECT TERMS**

None provided.

**SECURITY CLASSIFICATION OF:**

<table>
<thead>
<tr>
<th>a. REPORT</th>
<th>U</th>
</tr>
</thead>
<tbody>
<tr>
<td>b. ABSTRACT</td>
<td>U</td>
</tr>
<tr>
<td>c. THIS PAGE</td>
<td>U</td>
</tr>
</tbody>
</table>

**LIMITATION OF ABSTRACT**

UU

**NUMBER OF PAGES**

5

**NAME OF RESPONSIBLE PERSON**

USAMRMC

**TELEPHONE NUMBER (include area code)**

U
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Body</td>
<td>4</td>
</tr>
<tr>
<td>Key Research Accomplishments</td>
<td>4</td>
</tr>
<tr>
<td>Reportable Outcomes</td>
<td>4</td>
</tr>
<tr>
<td>Conclusion</td>
<td>5</td>
</tr>
<tr>
<td>References</td>
<td>5</td>
</tr>
<tr>
<td>Appendices</td>
<td>5</td>
</tr>
</tbody>
</table>
Introduction

Traumatic brain injury has been coined the signature injury of OIF/OEF, with posttraumatic headache being a cardinal symptom found to be as high as 36% of soldiers with MTBI. Combat-related headaches are undertreated, associated with high sick calls, missed days, negative psychological/mood states, and impair overall quality of life. Comorbid anxiety, depression, PTSD and other psychological, psychosocial, and health stressors portend poorer TBI/headache outcomes, supporting the need for integrative health care. Development, evaluation, and integration of a specialized posttraumatic headache treatment program into a comprehensive TBI rehabilitation effort are critical to restoration of function, health, and quality of life of our soldiers. This project addresses multiple FY09 TBI/PH topic areas by validating an evidence-based, mind-body approach for prevention and treatment of post-TBI headache, stress, and associated psychological health issues in order to restore function, enhance well being, prevent post-TBI headache chronification, develop psychological resilience, and promote long-standing health benefits. The focus of this project is on evaluation of mindfulness based stress reduction as one, potentially critical component of a comprehensive rehabilitative effort for this group of MTBI patients.

Body

This project marks collaboration between the University of North Carolina at Chapel Hill (UNC), Womack Army Medical Center (WAMC), and the Carolina Headache Institute (CHI). During Year 2 (Oct 2011-Sept 2012), we progressed through the goals in the Statement of Work. Specifically, Dr. O’Garo is active as our lead/WAMC principal investigator, data entry and tracking system was established (using RedCap for data storage), the mindfulness meditation intervention was finalized, and the randomization protocol completed. Renewal of the study by both IRBs was completed (WAMC in August 2012, and UNC October 2012). We continue twice monthly meetings at UNC with conference call access. The study coordinator (Coble) and research assistant at WAMC (Lynch) completed security access through the Department of Defense. Ms. Lynch travels to WAMC each week to screen/recruit subjects. Drs. Mann and Calhoun were approved to provide headache care (baseline assessment) at WAMC.

Our projected timeline was delayed in Year 2 especially due to the lengthy security clearances for the on-site research assistant/local WAMC study coordinator (Lynch). We consequently projected that initial screening and recruitment of potential participants would begin by the end of the 4th quarter/Year 1; however, recruitment did begin in August 2012. Due to the delay, we will identify board members of the DSMB in the upcoming months.

Key Research Accomplishments

- Credentialing/security clearances for all personnel completed
- IRB approvals from WAMC, UNC and HRPO.
- Recruitment initiated
- Baseline assessments initiated

Reportable Outcomes

Considering examples provided in instructions, we consider this not applicable to our project at this time.
Conclusion

We have accomplished the majority of the tasks outlined in the SOW. Subject recruitment began in August 2012. Pending is identifying DSMB members and continuing recruitment. A recruitment system has been established at WAMC and we anticipate ongoing subject recruitment. We have established good inter-institutional communication and a regular research meeting structure. These achievements offer a good foundation for the proposed research project.

References

N/A

Appendices

N/A