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

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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.						
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# **Table of Contents**

## Page

Introduction	4
Body	4
Key Research Accomplishments	4
Reportable Outcomes	4
Conclusion	4
References	5
Appendices	5

#### 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 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.

## Body

This project marks the collaboration between the University of North Carolina at Chapel Hill (UNC), Womack Army Medical Center (WAMC), and the Carolina Headache Institute (CHI). During these last 12 months, we accomplished the majority of the goals proposed in the Statement of Work. Specifically, we contacted 121 potential subjects. We screened 58 and enrolled 33 subjects. We have randomized three cohorts, finishing cohorts 1 and 2 and are in the follow-up phase of cohort 3. We renewed both UNC and WAMC IRBs.

Our projected timeline was delayed due to the sequestration. Furloughs have been implemented which constrain select WAMC personnel to four day work weeks. This impacted the referrals from the WAMC Concussion Care Clinic. The government shutdown has slowed administrative processing time. The study team is adapting to changes in clinic operations and SOP. To increase enrollment, we hired two new research staff personnel; one full-time on-site coordinator to help increase recruitment and one another back-up coordinator to assist with recruitment and cover UNC's administrative responsibilities. The new staff are working very efficiently and effectively to make the transition as smooth as possible. Recruitment will continue shortly when they are fully cleared and credentialed by WAMC.

#### **Key Research Accomplishments**

- Completion of two cohorts. The third cohort arm is in progress.
- Weekly research meetings with agenda and minutes.
- Data collection, scoring, and entry are in progress.
- Received a No-Cost extension on 6/28/13
- Continuing review approved by WAMC IRB

#### **Reportable Outcomes**

- 1. Randomized Cohort 3. Completed baseline and the Intervention phase. They are in the 2 week follow up phase.
- 2. Research Assistant (Bernice Jordan) was hired on 9/18/2013. She passed WAMC security clearances and completed training. She is WAMC IRB approved.
- 3. Backup research assistant (Paula Anderson) was hired on 8/21/2013. She is credentialed for WAMC as of 12/2/13. She is WAMC IRB approved.
- 4. Backup instructor (Hugh Harling) was hired to teach the Education group. We are processing his IRB approval.
- 5. Subject Recruitment (Goal: 120 subjects)
  - 121 Contacted
    - 58 Screened
    - 33 Enrolled
      - \*Cohort 1: 5 enrolled \*Cohort 2: 8 enrolled \*Cohort 3: 12 enrolled
      - \*Cohort 4: 6 enrolled

-4 Completers

## Conclusion

We have accomplished the majority of the tasks outlined in the SOW. We have hired two full-time, on-site WAMC coordinators to offset delays due to government furloughs and shutdown. We have completed enrollment for Cohort 4 and will soon initiate the baseline phase.

### References

Not applicable

## Appendices

Not applicable