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Maximizing Energy After Traumatic Brain Injury: A Novel Intervention

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<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> Purpose: The purpose of this randomized clinical trial is to test the effect of a fatigue management program (MAX intervention) compared to a control intervention for decreasing the impact and severity of post-traumatic brain injury (TBI) fatigue, increasing participation in everyday life and physical activity, and reducing work disability. Scope: Up to 73% of TBI patients endorse fatigue as their most challenging symptom hindering reintegration into society. The MAX intervention will train individuals to better manage their fatigue. Thirty-eight participants will be randomized to MAX Intervention control groups. All participants will receive the appropriate intervention in two 1:1 sessions/week for 8 weeks via the internet. Outcome measures will be collected at baseline, intervention completion, and 4 weeks and 8 weeks after intervention completion. Study Progress: The study is currently ongoing. Forty participants have consented to participate in the study. Nineteen participants in the experimental group and 16 participants in the control group have completed the intervention phase of the study. An additional 2 participants in the control group are currently in the intervention phase. Data analysis will be completed once all participants have completed the study protocol.						
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## **INTRODUCTION:**

The proposed project aims to study the effects of an intervention designed to address chronic pathological fatigue in patients with traumatic brain injury (TBI). TBI is the signature injury of the wars in Iraq and Afghanistan, affecting about 10-20% of returning soldiers. Chronic pathological fatigue, one of the most distressing symptoms following TBI, is not associated with injury severity. Indeed, approximately 44% of soldiers diagnosed with TBI report feeling fatigued. Post-TBI fatigue is associated with problems in emotional, social, physical, and cognitive functioning; reduced participation in everyday life; and slower return to active duty and work. Thus, post-TBI fatigue hinders patients' reintegration into the community. The aim of this 2-year single-blind randomized clinical trial is to test the effect of the MAX intervention for decreasing the impact and severity of post-TBI fatigue, increasing participation in everyday life and physical activity, and reducing work disability. In the MAX intervention, an occupational therapist (OT) will use web camera technology to teach participants on a one-to-one basis to apply Energy Conservation Strategies to solve their fatigue-related problems. This teaching will be individualized for each participant using the framework inherent within Problem Solving Therapy. We hypothesize that participants randomized to the MAX Intervention will demonstrate significantly lower fatigue impact and severity; greater participation in everyday life and physical activity; and lower work disability at intervention completion and 4 and 8 weeks after intervention completion compared to baseline; compared to participants randomized to the Health Education Intervention. Thirty-eight participants will be randomly assigned to MAX Intervention or Health Education groups. All participants will receive the appropriate intervention in two 1:1 sessions/week for 8 weeks via web cameras. Outcome measures will be collected at baseline, intervention completion, and 4 weeks and 8 weeks after intervention completion.

## **BODY:**

We have been able to accomplish a majority of the goals for year 1 and some goals for year 2 from the approved Statement of Work. Below is a description of the accomplishments for each of the goals:

### **YEAR 1**

1. Obtain approval for conduct of research from the University of Pittsburgh Institutional Review Board and the Office of Research Protections at USAMRMC.  
We have obtained regulatory approval from the University of Pittsburgh Institutional Review Board and from the Office of Research Protections at USAMRMC. Hence, we have obtained all the necessary regulatory approvals for the conduct of this study.
2. Hire the Research Coordinator for the study.  
Ms. Amanda Baucom has been hired to serve as the research coordinator for the study.
3. Train the Research Coordinator to: (a) conduct all assessments independently and reliably; (b) troubleshoot computer-related problems that arise during the intervention, (c) complete day-to-day administration of the study competently, and (c) manage study data competently.

Ms. Amanda Baucom has been trained and is competent in the following: (a) conduct all assessments independently and reliably; (b) troubleshoot computer-related problems that arise during the intervention, (c) complete day-to-day administration of the study competently, and (c) manage study data competently.

4. Train the Occupational Therapist to administer the Maximizing Energy (MAX) intervention competently. The occupational therapist's adherence to intervention will be checked regularly throughout the study. Any protocol drifts will be discussed with the OT. Reasons for deviations from the protocol will be discussed and strategies to avoid deviations in the future will be discussed.

We have trained 2 occupational therapists – Dr. Denise Chisholm and Dr. MaryLou Leibold to administer the MAX intervention competently. Both Dr. Chisholm and Dr. Leibold have been administering the intervention to the experimental group. Treatment fidelity is being continuously monitored by the PI and Dr. Jennifer Morse.

5. Conduct chart reviews of the University of Pittsburgh Department of Physical Medicine and Rehabilitation Research Registry to identify potential participants. Mail letters to potential participants in waves of 10, until 50 participants have been recruited for the study.

We have identified several recruitment strategies for our study. We use a 4 step process to maximize recruitment and ensure that we recruit an heterogeneous population for our study.

Step 1: Participants are recruited through the Department of Physical Medicine and Rehabilitation Research Registry. We contact participants through mailings and follow-up the mailings with a phone call.

Step 2: Participants are enrolled through clinics within the University of Pittsburgh Department of PM&R, Neurology, Neurosurgery, the University of Pittsburgh Medical Center Rehabilitation Institute (RI) and affiliated clinical services.

Step 3: We have placed several copies of the study fliers in waiting rooms of the outpatient clinics, TBI support group venues, etc. Potential participants contact us directly after viewing the advertisement flyer.

Step 4: We have also been able to recruit through current and ongoing research being conducted by research staff within the Dept. of PMR, Neurosurgery and The School of Health and Rehabilitation Sciences. If, while completing research related procedures on another project, a potential participant is identified, the research staff member who already has contact with the potential participant will inform the individual of the additional research opportunity.

Step 5: We have been very successful in recruiting participants from local area Traumatic Brain Injury support groups.

These recruitment strategies have been very successful. We have consented 40 individuals to participate in the study.

6. Recruit participants that meet inclusion/exclusion criteria in the study and administer the intervention as per the research protocol approved by the local Institutional Review Board and Office of Research Protections at USAMRMC.

We have been successful with our recruitment strategies. We have consented 40

individuals to participate in the study. Nineteen participants in the experimental group and 16 participants in the control group have completed the intervention phase of the study.

7. Collect baseline and follow-up data at the following four time points: Time 1 (baseline), Time 2 (at intervention completion), Time 3 (4 weeks after intervention completion) and Time 4 (4 weeks after booster session completion).

We have been able to collect baseline and follow-up data for participants in the study. Thirty participants have completed all study-related assessments.

8. Concurrently develop a database for data entry and verification.

The database for data entry has been developed. We have developed policies for verifying data to prevent data entry errors.

## YEAR 2

We have not been able to accomplish all Year 2 goals related to the study. Hence, we had requested and have received a one-year no-cost extension for the study.

Following is our summary of our Year 2 goals:

1. Continue to recruit participants that meet inclusion/exclusion criteria in the study and administer the intervention as per the research protocol approved by the local Institutional Review Board and Office of Research Protections at USAMRMC. We continue to recruit participants for the study and complete all study-related procedures based on the protocol.
2. Continue to collect baseline and follow-up data.  
We continue to collect baseline and follow-up data as per study protocol.
3. Conduct data analyses to examine the specific aim of the study: (a) to test the effect of the MAX intervention for decreasing the impact and severity of post-TBI fatigue, increasing participation in everyday life and physical activity, and increasing the ability to return to work.  
We will conduct data analysis as we complete the all data collection for the study.
4. Disseminate the finding of the study through: (a) presentations at military rehabilitation-specific meetings as well as annual scientific meetings; (b) presentations at rehabilitation and occupational therapy annual scientific meetings, and (c) publications submitted to scientific journals.  
Findings from the study will be disseminated, once data analysis is completed.

## **KEY RESEARCH ACCOMPLISHMENTS:**

Our key research accomplishments are as follows:

- Regulatory approvals for the study have been obtained.
- The research coordinator and occupational therapists who will deliver the interventions for the study have been trained.

- A collaborative multi-pronged system has been successful in recruiting participants for the study.
- Participants are successfully completing the study protocol.

**REPORTABLE OUTCOMES:**

At this time we do not have reportable outcomes in terms of publications, abstract presentations, etc.

**CONCLUSION:**

We have participants currently undergoing research-related procedures. As we complete our recruitment for the study, we will be able to examine the effect of the Maximizing Energy intervention for decreasing the impact and severity of post-TBI fatigue, increasing participation in everyday life and physical activity, and reducing work disability.

**REFERENCES:**

None at this time.

**APPENDICES:**

None at this time.

**SUPPORTING DATA:**

None at this time.