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TITLE: Investigating Clinical Benefits of a Novel Sleep-focused Mind-body Program on Gulf War Illness Symptoms: An Exploratory Randomized Controlled Trial

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Subjects are being recruited for the proposed study and the study is still ongoing. Thus, there is no finding to report from the study as of 30/06/2012.

15. SUBJECT TERMS
mind-body intervention, awareness training, mindfulness, insomnia, sleep disturbance, Gulf War Illness

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Introduction

The purpose of this study is to conduct an exploratory randomized controlled trial, evaluating clinical benefits of a novel mind-body intervention program for primary care management of Gulf War Veterans with sleep disturbance and unrelieved GWI symptoms. The main 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 sleep and co-morbid Gulf War related symptoms. MBB consists of cognitive and attentional (experiential) techniques for cultivating present-focused, non-judgmental awareness of one's body, emotions, and thoughts. We will recruit 72 Gulf War veterans, who first will undergo a comprehensive screening assessment performed by our medical 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 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 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 by using a biomarker of stress as a proxy indicator of intermediate mechanisms activated by MBB.

Body

The project team completed all the items listed under *Milestone 1 specified in SOW* during Year 1 (12 months). First, we refined and finalized clinical protocols for screening and treatment and we obtained both local IRB and HRPO IRB approval for the study. Second, we completed hiring and training of VA providers who will provide screening sessions (physician assistants) and study intervention sessions (licensed clinical social workers). With respect to *Milestone 2 specified in SOW*, we have begun to recruit Gulf War 1 Veterans who have self-reported sleep problems and conduct screening sessions. During Year 1 period, eligible veterans who completed screening were assigned to the MBB group and the three treatment sessions were completed. We are continuing our recruiting and screening effort and we will run two groups (one group for MBB and one group for control) in August 2012.

Key Research Accomplishments

We do not have anything yet to list here.

Reportable Outcomes

The study is currently ongoing and we do not have anything yet to report here.

Conclusion

As eligible veterans will be recruited into the ongoing study during Year 2 period, 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.

References

None

Appendices

None