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TITLE: : Using Complementary and Alternative Medicine (CAM) to Promote Stress Resilience in those with Co-Occurring Mild TBI and PTSD

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14. ABSTRACT Mild traumatic brain injury (mTBI) and post-traumatic stress disorder (PTSD) co-occur at a high rate in Soldiers and Veterans. Despite this, there is a paucity of evidence-based treatments for those dealing with mTBI/PTSD symptoms and their exacerbation by stress. Using a placebo-controlled, randomized, blinded design, the current study is testing the following hypothesis: active acupressure (more than Placebo) will reduce the adverse effects of stress in Veterans with co-occurring mTBI/PTSD, which will be evident in measures of anxiety, perceived stress, distress, psychiatric health, memory and in a laboratory stress task. Veterans have been recruited since regulatory approval was obtained (August 2012) and enrolled in the study in an ongoing manner, with several having already completed the study protocol or being in process. Because the study is ongoing, there are no data to report as of yet. The findings of the present study hold significant military significance: a safe, portable, low-cost, efficacious and accessible treatment strategy would benefit Veterans, family members and the military/VA health care systems. Results of the ongoing study will determine if acupressure is such a treatment strategy.					
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Introduction

The currently funded study assessed the efficacy of acupressure, a type of complementary and alternative medicine (CAM) in the Veteran population. Veterans with co-occurring mild traumatic brain injury (mTBI) and post-traumatic stress disorder (PTSD) were recruited, consented and randomly assigned to either an active or placebo acupressure treatment series of 8 sessions. From these data, we are assessing the degree to which acupressure affects aspects of day-to-day function, such as memory, sleep, mood, psychiatric health and stress resilience. This information will help identify potential treatment strategies to improve quality of life and overall function in this particular Veteran population.

Body

Objective 1

- Task 1: The human subjects research protocol received approval from all regulatory agencies (the VA, COMIRB and HRPO/Human Research Protections Office) beginning in August 2012, and has continued to be approved annually by all of these entities. Regulatory approval will be continued through at least the next 12 months as we finalize data analyses and prepare results for dissemination.

Objective 2

- Tasks 1-4: The study coordinator was hired, study measures received, and study coordinator fully trained on study specific protocols, including consenting, outcome measures, equipment usage etc. Acupressure practitioner is in place and fully trained on study specific protocols. All personnel were fully trained and everything in place to begin recruiting upon final approval for the research from all regulatory agencies.

Objective 3

- Task 1: With all regulatory approvals and study personnel in place, we recruited and consent participants. A total of 60 individuals were consented, of which 10 were found to be ineligible at secondary screen.

Objective 4

- Task 1: After enrollment, participants were randomly assigned to either the active or placebo acupressure treatment condition. Over the life of the funding period, 50 consented individuals were enrolled and of these 22 completed and 28 withdrew after consent or were lost to follow.

Objective 5

- Task 1: The data entry and checking are complete for the majority of the measures, and are being done blinded to treatment condition. This will continue until complete and then be prepared for publication and dissemination via conference proceedings.

Objective 6

- Task 1: Prepare manuscript/s and presentation at scientific conference. This will be done as soon as data analyses are completed.

Key Research Accomplishments

- Conducting a placebo-controlled, randomized, blinded trial of acupressure in Veterans with co-occurring mTBI and PTSD in a VA Medical Center setting.

Reportable Outcomes

- None at this time

Conclusions

Initiating a research study from the funding stage to first data collection poses a known challenge that scientists understand and expect. Initiating a research study that assesses an innovative treatment strategy like acupuncture in a Federal hospital setting (Denver VA Medical Center/VAMC) poses additional challenges that the PI (Hernández) is familiar with and anticipated. While there were a few unanticipated challenges that impacted recruitment pace, these were dealt with systematically and effectively and through the appropriate regulatory channels. This successful ability to respond to challenge stems in part from the PI's experience in this type of research, as well as the significant infrastructure support from the VISN 19 MIRECC (co-PI Brenner, Director, Veterans Integrated Services Network 19, Mental Illness Research, Education and Clinical Center) and the Denver VAMC in general, has resulted in the research team successfully navigating the process, conducting the funded research and successfully completing the study: a placebo-controlled, randomized, blinded trial of acupuncture in Veterans with co-occurring mTBI and PTSD.

References

None at this time.

Appendices

None at this time.