Award Title: Evaluating a Novel Sleep-Focused Mind-Body Rehabilitative Program for Veterans with mTBI and Other "Polytrauma" Symptoms: An RCT Study
Principal Investigator: Nakamura, Yoshio
Institution Receiving Award: University of Utah
Program: PH-TBI
Proposal Number: PT110717
Funding Mechanism: Applied Neurotrauma Research Award with Clinical Trial
Award Amount: $2,750,397.00

Summary: We propose to conduct a randomized controlled trial comparing a novel sleep-focused mind-body intervention with more traditional patient education, for adjunct treatment of Veterans with mild traumatic brain injury (mTBI), sleep disturbance, and co-morbid conditions such as pain and PTSD. mTBI is a complex multi-factorial condition that is increasingly common among military and civilian personnel. Significant numbers of returning veterans of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) display the “polytrauma clinical triad” of traumatic brain injury, pain, and post-traumatic stress disorder (PTSD). Many of these OEF/OIF Veterans also suffer from sleep disturbance, defined as difficulty falling or staying asleep. Because poor sleep may exacerbate co-morbid physical and psychiatric conditions, treatment that improves sleep may also attenuate co-morbid symptoms. The major objective of this proposed 4-year project is to evaluate the comprehensive benefit of a brief sleep-focused Mind-Body Bridging (MBB) rehabilitative program for mTBI sufferers on 1) reducing sleep disturbance and 2) attenuating other psychological or medical co-morbid symptoms (such as pain and PTSD). Building on our prior work, this application seeks funding to conduct a prospective randomized clinical trial, to evaluate treatment efficacy of MBB integrated with usual care for veterans with mTBI and sleep disturbance. Supportive education (SED) integrated with usual care will serve as an active control in the study. A total of 142 patients will be recruited from the VASLCHCS and randomized to one of the two intervention programs (MBB or SED), stratified by pain and PTSD diagnosis in randomly varying block sizes of 4, 6, and 8. The primary outcome measures will be self-reported rating on the MOS-Sleep Scale and objective sleep indicators gathered with an ActiGraph monitoring device. In line with our data analytic approach, repeated assessments of primary and secondary outcomes will take place at pre- and post-study as well as three follow-ups at 2, 4, and 6 months after the completion of the study interventions.