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This prospective randomized-controlled trial evaluated the efficacy of sleep-focused Mind-Body Bridging (MBB) compared with sleep education control (SED) for improving sleep in Veterans with a history of mild traumatic brain injury (mTBI) suffering from disturbed sleep. MBB (n=34) and SED (n=34) each comprised three weekly sessions. The primary outcome, Medical Outcomes Study-Sleep Scale was completed at baseline, weekly during treatment, post-intervention and 3- and 6-month follow-up. Additional mTBI-related measures included neurobehavioral symptom inventory (NSI) and quality of life (SF-36V). TBI-related co-morbid measures included PTSD and pain. Secondary (exploratory) outcome measures for depression, resilience, perceived stress, mindfulness, and other psychosocial variables were completed at baseline, post-intervention and 3- and 6-month follow-up. Both MBB and SED groups improved sleep significantly from baseline to post-intervention and there was a significant non-zero linear trend in both groups. More importantly, the rate of change (i.e., improvement) in the MBB group was significantly greater than that in the SED group. Additionally, at 3-month follow-up, those in the MBB reduced PTSD symptoms and perceived stress, while increasing mindfulness, relative to those in the SED. Sleep-focused MBB can improve sleep and possibly also other co-occurring psychological symptoms in mTBI Veterans suffering from disturbed sleep.
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## Abstract

Objective: Mind-Body Bridging (MBB) has been previously shown to be effective for improving disturbed sleep. This prospective randomized-controlled trial evaluated the efficacy of sleep-focused MBB compared with sleep education control (SED) for improving sleep in Veterans with a history of mild traumatic brain injury (mTBI) suffering from disturbed sleep.

Methods: MBB (n=34) and SED (n=34) each comprised three weekly sessions. The primary outcome, Medical Outcomes Study-Sleep Scale (MOS-SS) was completed at baseline, weekly during treatment, post-intervention and 3- and 6-month follow-ups. To supplement this main primary outcome measure, sleep diary and Actiwave Cardio device for sleep were used to gain more information about sleep quality and performance. Additional measures for mTBI condition included neurobehavioral symptom inventory (NSI) and quality of life (SF-36V). TBI-related comorbid measures included PTSD and pain. Secondary (exploratory) outcome measures for depression, resilience, perceived stress, self-compassion, mindfulness, well-being, suicide ideation, introceptive awareness, and distressed personality were completed at baseline, post-intervention and 3- and 6-months follow-up. Salivary samples were collected at four time-points per day over two days at each assessment visit (baseline, post, and 3-month follow-up) for cortisol and alpha-amylase assessment. Clinician-administered medical and psychological assessments of sleep and co-occurring conditions were conducted at baseline and post-intervention.

Results: Both MBB and SED groups improved sleep significantly from baseline to post-intervention ($p=.006$ for SED; $p<.001$ for MBB) and there was a significant non-zero linear trend in both groups ($p=.004$ for SED; $p<.001$ for MBB). More importantly, the rate of change in the MBB group was significantly greater than that in the SED group ($d=8.22$, $p=.017$). Additionally, at 3-month follow-up, those in the MBB reduced PTSD symptoms ($p=.02$) and perceived stress ($p=.004$), while increasing mindfulness ($p=.002$), relative to those in the SED.

Conclusions: Sleep-focused MBB can improve sleep and possibly also other co-occurring psychological symptoms in mTBI Veterans suffering from disturbed sleep. Further development of a complementary treatment modality (such as MBB) may contribute to a personalized medicine approach to polytrauma care. The MBB treatment protocol developed for this study may be helpful for both clinical care and preventive training to improve physical and mental health status of service members returned from their deployment.

## Introduction

This introduction briefly reviews: 1) co-occurring of mental and physical health conditions in Veterans and the role of sleep disturbance as a common factor that cuts across the polytrauma triad of mild traumatic brain injury (mTBI), pain and PTSD; and 2) a novel mind-body intervention program, Mind-Body Bridging (MBB).

### [1] Sleep Disturbance and Polytrauma Clinical Triad Associated with mTBI in OEF/OIF Veterans

Traumatic brain injury represents a dynamic spectrum of physiologic and cognitive dysfunction that exerts effects at multiple levels of human health. Mild traumatic brain injury (mTBI) is a multi-factorial illness that is an increasingly serious public health issue for military and civilian personnel. The assessment of neurocognitive deficits in mTBI has been suggested to be less conclusive, presumably because of the predominating influence of PTSD and other co-existing factors. Recent research suggests that psychological factors play a substantial role in TBI-related impairments in self-reported health and cognition function (NIH, 1999).

The Veterans Health Administration (VHA) has developed a Polytrauma System of Care in response to a new cohort of Veterans back from Iraq and Afghanistan, usually referred to as OEF/OIF Veterans. Recent research has shown that TBI is rarely an isolated finding in military combat settings and that persistent post-concussive symptoms are commonly associated with post-traumatic stress disorder and chronic pain, a constellation of findings that has been termed the “polytrauma clinical triad” (Risdall and Menon, 2011). Indeed, significant numbers of returning Veterans of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) display the polytrauma clinical triad (PCT) of pain, posttraumatic stress disorder (PTSD), and traumatic brain injury (Lew et al., 2008; Otis et al., 2011).

Pain is highly prevalent in Veterans with polytrauma injuries (Dobscha et al., 2008) and headaches are a frequent consequence of TBI (Ruff et al., 2008; Patil et al., 2011). Pain is an impediment to rehabilitation, posing a greater challenge for effective treatment in this group of war-injured, who commonly experience multiple and severe injuries, a high prevalence of brain injuries, cognitive impairments and emotional distress, a prolonged and intensive rehabilitation process, and a frequent need for repeated follow-up surgeries (Clark et al., 2009).

Furthermore, many of these OEF/OIF Veterans suffer from sleep disturbance, defined as difficulty falling or staying asleep (Sayer et al., 2009; Sayer, 2012). Sleep disturbance was highly prevalent (93.5%) in a sample of 200 OEF/OIF Veterans who received a diagnosis of mTBI following evaluation at a polytrauma outpatient clinic (Lew et al., 2010). This same study suggested that posttraumatic stress disorder and pain significantly contributed to sleep disturbance in Veterans with mTBI. Another study (Lew et al., 2009) based on comprehensive review of medical records of 340 OIF/OEF Veterans seen at a Department of Veterans Affairs Polytrauma Network Site indicated a high prevalence of all three PCT conditions in this population, with chronic pain, PTSD,

and postconcussive symptoms (PPCS) present in 81.5%, 68.2%, and 66.8%, respectively. Only 3.5% of the Veterans (n=12) had no chronic pain, PTSD, or PPCS. The frequency at which these three conditions were present in isolation (10.3%, 2.9%, and 5.3%, respectively) was significantly lower than the frequency at which they were present in combination with one another, with 42.1% of the sample being diagnosed with all three conditions simultaneously.

An observational study (Taylor et al., 2012) using national inpatient, outpatient, and pharmacy data from Veterans Health Administration (VHA) datasets determined the prevalence of TBI alone and TBI with other psychiatric disturbances and pain conditions. The sample used consisted of all OEF/OIF VHA users in 2009. Data from this study supported the finding that patients with combat-related TBI also have high rates of psychiatric disturbances and pain. Among 327,388 OEF/OIF Veterans using VHA services in 2009, 6.7% were diagnosed with TBI. Among those with TBI diagnoses, 89% received a psychiatric diagnosis (PTSD being the most frequent at 73%), and 70% had a diagnosis of head, back, or neck pain. The rate of comorbid PTSD and pain among those with vs. without TBI was 54% vs. 11%, respectively.

Sleep as an Undertreated Condition in Veterans: Similarly, sleep disturbance often accompanies post-traumatic stress disorder (PTSD), especially in military populations (Harvey et al., 2003; Lamarche and De Koninck, 2007), and may even be a core feature of PTSD (Spoormaker and Montgomery, 2008). Of the 3 main characteristics of PTSD -- avoidance, hyperarousal and re-experiencing -- the latter two are commonly implicated in sleep disturbances, which include difficulty falling asleep and recurrent nightmares (Lamarche and De Koninck, 2007). Researchers are now considering ways to treat co-existing health conditions using sleep treatments as a potentially fruitful front-loaded approach that might reduce the severity of sleep disturbance and co-existing health conditions. In military populations, this approach could help shed light on how to more effectively treat individuals with co-existing insomnia associated with the polytrauma triad.

More generally, sleep disturbance is highly prevalent in both deployed and post-deployed military personnel; prevalence can vary between 74 - 90% (Peterson et al., 2008; Lewis et al., 2009). Following return to civilian life, many Veterans have great difficulty in overcoming sleep problems, and if this persists, it may lead to reduced quality of life and wellbeing, and may contribute to the worsening of many other health problems. Sleep problems can be more severe in Veterans with co-existing such as PTSD, depression and anxiety (Neylan et al., 1998). Sleep problems may be more severe in those with medical conditions such as obesity and high blood pressure (Mustafa et al., 2005). In addition, pain is a frequent problem among Veterans; if not effectively managed, persistent acute or localized pain could lead to greater risk for developing widespread chronic pain (Eisen et al., 2005; Ang et al., 2006), and associated sleep problems.

Taken together, all these studies point to the high prevalence of co-occurring symptoms associated with the PCT and the pervasive presence of sleep disturbance in these PCT

conditions. As suggested by some investigators (Brenner et al., 2009), current best practices suggest the importance of treating PCT-related symptoms regardless of etiology; this may decrease the burden of adversity in military personnel and Veterans. The present study builds on the premise that focusing on sleep disturbance as a priority domain will afford us an opportunity to intervene and jump-start rehabilitative processes that are necessary for successful integrative care of Veterans with mTBI.

Currently, there is no established viable short-term non-pharmacological intervention program to treat patients with mTBI and its associated co-occurring symptoms. Furthermore, there is no viable short-term clinical intervention program for simultaneously managing multiple co-existing symptoms associated with the polytrauma triad. A pressing need exists to develop and refine a viable intervention program for treating Veterans with this complex web of co-existing physical and mental health conditions, highly prevalent among OEF/OIF Veterans. Sleep-focused behavioral and cognitive-behavioral programs are being considered as adjunct treatments for mTBI sufferers (Halbauer et al., 2009). An effective mind-body intervention that can manage sleep disturbance along with co-existing symptoms would be a valuable breakthrough for people with mTBI and possibly other psychological and physical health conditions. The present study was conceived to explore the usefulness of a novel mind-body intervention program that may have a potential to serve as a front-loaded adjunct intervention program for patients with a history of mTBI who are currently suffering from disturbed sleep.

**[2] Awareness Training Programs, Mindfulness, and Mind-Body Bridging (MBB)**
Awareness Training Program (ATP) is a general term for mind-body interventions that focus on the power of “mental training” in regulating mental and physical health conditions (Begley, 2007). These ATPs include Mindfulness-Based Stress Reduction (MBSR)(Kabat-Zinn, 1991) and Mindfulness-Based Cognitive Therapy (MBCT) (Teasdale et al., 2000; Teasdale et al., 2002), both of which have emerged as effective treatment/management programs for psychological symptoms associated with medical conditions such as cancer as well as symptoms of anxiety and depression. Mindfulness has been described as an awareness of moment-by-moment experiences arising from purposeful attention, along with a non-judgmental acceptance of these present-moment experiences (Kabat-Zinn, 2003). MBSR has incorporated mindfulness meditation in a structured group program to alleviate suffering associated with physical, psychosomatic and psychiatric disorders. The program has a non-religious and non-esoteric orientation, and it is based upon systematic experiential procedures to develop the cultivation of awareness of moment-to-moment experience of mind-body processes. The approach assumes that the cultivation of awareness will provide more veridical perception, reduce negative affect, and improve vitality and coping. Mindfulness training has been previously demonstrated to be effective in managing chronic pain (Kabat-Zinn, 1982; Kabat-Zinn et al., 1985; Morone et al., 2008; Rosenzweig et al., 2010), anxiety (Kabat-Zinn et al., 1992), in the prevention of depressive relapse (Teasdale et al., 1995; Teasdale et al., 2002), and in the management of pain and fatigue symptoms in cancer (Carlson et al., 2003). Furthermore, mindfulness meditation has been shown to help enhance increased prefrontal cortical functioning, both in areas

underlying modulation of positive emotion (Davidson et al., 2003) and improved executive functioning (Lazar et al., 2005). (See Khusid et al., 2016a and Khusid et al., 2016b for systematic reviews of mindfulness-based programs as self-management strategy for depression, PTSD, anxiety, pain, substance misuse, and insomnia.)

A recent addition to ATPs is Mind-Body Bridging (MBB) (Block and Block, 2005, 2007; Tollefson et al., 2009). Like similar modalities such as MBSR (i.e., mindfulness meditation) and cognitive-behavioral therapy, MBB fosters the cultivation of awareness and the reduction in maladaptive thinking. In contrast, MBB does not involve psychotherapy or meditation practice, and its basic techniques can be conveyed in a few hours of training. These features can make MBB more likely to be accepted by a wide spectrum of OEF/OIF Veterans. MBB consists of cognitive and attentional techniques (awareness practice) for cultivating present-focused, non-judgmental awareness of one's body, emotions, and thoughts. MBB also teaches mind-body "mapping" exercises, which are designed to reveal thought patterns known as "requirements." Requirements are expectations about how people and the world should be at particular moments (an example of a requirement is "I should readjust to my civilian life quickly" or "I should not have any trauma-related symptom"). When requirements are not fulfilled, people may develop ruminative storylines that in turn may lead to dysfunctional mind-body states. By using awareness practices and defusing requirements, over time and with practice, MBB practitioners quickly learn to expand their awareness, deal more effectively with daily life's challenges, and foster more balanced, harmonious mind-body states. In this way, MBB carries awareness practices one critical step further by addressing the underlying cause of the resistances to clarity, i.e. mental afflictions caused by an individual's fixed idea of who she/he is, known as the "Identity System" (I-System) in MBB teaching language. If activated when requirements are not satisfied, the I-System produces a self-centered mind-body state and can impede a person's natural functioning. Increased awareness of the I-System may account for MBB's therapeutic usefulness. We postulate that regular practice of MBB can lead to improved well-being, cognitive flexibility, and acceptance of distressing sensations, emotions, and thoughts. MBB is theorized to work by intentionally transforming self-centered cognitive/emotional processing, so that MBB practitioners shift from a ruminative thinking style and instead adopt a more "experiential" present-centered thinking style. This present-centered orientation enables MBB practitioners to respond to sensations, perceptions, emotions, and thoughts with equanimity and flexibility. In actual practice, MBB techniques are easy to learn and benefits may accrue rapidly.

MBB demonstrated strong efficacy in our previous study of 63 Veterans with sleep disturbance, in which sleep-focused MBB reduced both self-reported sleep disturbance and PTSD symptoms (Nakamura et al., 2011). In another recently completed study of Gulf War Veterans, MBB reduced disturbed sleep in the group of Veterans who were suffering from multiple symptoms including disturbed sleep (Nakamura et al., 2017). These results suggest that MBB may serve as a promising adjunct treatment for Veterans with mTBI and sleep disturbance. Integration of MBB into polytrauma and primary care may enhance care of Veterans and others with sleep disturbance and co-existing health conditions.

The main objective of the proposed study was to evaluate the comprehensive benefit of a novel mind-body therapeutic intervention, Mind-Body Bridging (MBB), in Veterans who presented a history of mTBI and disturbed sleep at the VASLCHCS. Evidence for comprehensive benefit includes was indicated by the average difference in outcomes between MBB and an active control, sleep education (SED), both integrated with the usual care for mTBI Veterans. The long-term goal of the proposed project was to introduce, implement and establish a mind-body intervention program as a behavioral health intervention modality that would serve as a generally sustainable health care intervention program before, during, and after deployment for military personnel, especially the OEF/OIF Veterans.

**Study Aims and Hypotheses**

Specific aims of the present study and their corresponding hypotheses are:

Aim 1. Test the impact of MBB on sleep function among individuals with mTBI.
Hypothesis 1: Compared to SED, MBB will more efficaciously improve sleep.

Aim 2. Test the impact of MBB on the polytrauma triad symptoms of pain and PTSD symptoms, along with Quality of Life.
Hypothesis 2: Compared to SED, MBB will more efficaciously reduce pain and PTSD symptoms, and improve Quality of Life.

Aim 3 (exploratory). Test the impact of MBB on mindfulness, perceived stress, self-compassion, depression, resilience, introceptive awareness, distressed personality, and well-being.
Hypothesis 3 (exploratory): Compared to SED, MBB will more efficaciously improve mindfulness, perceived stress, self-compassion, depression, resilience, introceptive awareness, distressed personality, and well-being.

## METHODS

Study Participants

The study population was comprised of combat veterans of Operation Iraqi Freedom (2003-2011) and Operation Enduring Freedom (2001-2014) during the Second Gulf War and the Global War on Terrorism respectively. Prospective participants for the study were OEF/OIF veterans who presented to the Division of Physical Medicine and Rehabilitation Polytrauma Clinic at the VA Salt Lake City Health Care System with: a) self-reported sleep disturbance, defined as a score of 35 or greater on the Medical Outcomes Study Sleep Scale (MOS-SS) Sleep Problem Index-II (SPI-II), and b) clinician-identified history of combat-associated mild Traumatic Brain Injury (mTBI).

Patients were excluded from the study if they had been diagnosed with delayed sleep phase syndrome, advanced sleep phase syndrome, or narcolepsy, were terminally ill, had active suicidal ideation, had any unstable medical or psychiatric condition (any condition requiring hospitalization imminently or within 3 months prior to study), any progressive neurodegenerative diseases (e.g. Parkinson's disease, Alzheimer's disease, Pick's disease etc), dementia of any cause, frequent nocturia, or a substance dependence disorder, as evaluated by the Mini-International Neuropsychiatric Interview (M.I.N.I.), which is a structured interview that allows for the diagnosis of DSM-IV and ICD-10 psychiatric disorders. A clinical evaluation conducted by a physician's assistant at pre-assessment ensured that specific sleep disorder conditions and other symptoms included above were not identified in OEF/OIF Veterans who participated in the study. Participants could be on any sleep medications that were previously prescribed. Lastly, any pregnant female veterans were excluded from the study.

Since the present study aimed to evaluate impacts of the interventions on broadly defined profiles of Veterans with a history of mTBI, participants were not excluded from participating in the study if they presented with: 1) PTSD, 2) chronic pain), or 3) specific sleep disorders (central or obstructive sleep apnea, periodic limb movement disorder, or sleep-disordered breathing with any restrictive or obstructive pulmonary disease), as long as they were already receiving treatment for these conditions. However, these conditions were used as part of a stratified randomization procedure (described in Study Design below), to ensure that the distribution of OEF/OIF Veterans with any of these conditions was not skewed across the two groups.

The Institutional Review Boards at the University of Utah and VASLCHS approved all aspects of this study. The ClinicalTrials.gov Identifier for this study is **NCT01975857.**

Study Design

This study was a prospective, randomized controlled study in which 68 participants were assigned to one of two parallel treatment arms: a) Mind-body Bridging (MBB; experimental condition; n = 34) or b) Sleep Hygiene Education (SED; control condition; n = 34). Participants were computer-randomized in blocks of 4 to one of the interventions, stratified by 1) PTSD, 2) chronic pain), or 3) specific sleep disorders (central or obstructive sleep apnea, periodic limb movement disorder, or sleep-disordered breathing with any restrictive or obstructive pulmonary disease). Participants were only informed about treatment assignment after their arrival to their first MBB or SED session. The study was conducted between March 2014 and February 2018.

Interventions

*Treatment-As-Usual (TAU) programs within VAHCS:* Veterans seen in the Polytrauma Clinic received VA standard of care based on clinical operation guidelines. Following the clinical evaluation performed by the interdisciplinary team in the Polytrauma Clinic, VA clinicians made an appropriate referral for subsequent follow-up care for any

symptom or condition identified. For instance, Veterans with any mental health issue were referred to Mental Health Services within the VAHCS. Likewise, Veterans with disturbed sleep or pain issues were typically referred to the Primary Care that was expected to provide the current standard of care for these symptoms. In the present study, one of the two investigative intervention programs was added to the TAU care of Veterans with mTBI and disturbed sleep: Sleep Hygiene Education (SED) and Mind-Body Bridging (MBB).

Participants were randomized to either MBB +TAU or SED + TAU, comprising three weekly sessions conducted once per week for 3 consecutive weeks. All treatment sessions were in a group format and conducted at VA Salt Lake City Health Care System.

Sleep Education (SED): The SED intervention provided educational lectures and group discussion on sleep hygiene centered on helpful tips to deal with difficulties related to sleep. The program did not involve teaching of any specific experiential skills to deal with pre-sleep arousal, mood, or sleep. The SED program served an active control group, that is, an attention-control group by controlling for the therapist contact hours and perceived social support that group settings often provide. The SED protocol used in this study was based on the protocol previously used in the research team's MBB studies (Nakamura et al., 2011;Nakamura et al., 2017). VA licensed mental health providers conducted all intervention sessions.

Mind-Body Bridging (MBB): MBB and specifically the sleep-focused MBB program have been described previously (Nakamura, Lipschitz, Donaldson, Kida, Williams, Landward, Glover, West, & Tuteja, 2017; Nakamura, Lipschitz, Kuhn, Kinney, & Donaldson, 2013; Nakamura, Lipschitz, Landward, Kuhn, & West, 2011). Briefly, participants were taught MBB concepts and how these could assist them in dealing with persistent sleep problems. The MBB tools included bridging exercises, identifying what expectations they had of the world (Requirements), and recognizing an active Identity System, to help their sleep improve. MBB was taught by licensed clinical social worker(s) who had received certification training in MBB and used MBB in their clinical care for their clients. MBB was focused on teaching experiential skills that participants could use in regulating awareness and reactions to thoughts and emotions that might arise in response to external and/or internal triggers. During Session 1, participants were taught MBB concepts, and learned how to use MBB tools to help them fall asleep quicker and sleep more soundly. These tools included specific 'Bridging' techniques when trying to fall asleep, such as paying attention to sounds or feeling tactile sensations of bed sheets, etc. In Session 2, participants learned how to reduce daytime stress and how to experience themselves free from intrusive thoughts, feelings and emotions. In Session 3, participants learned how to understand and identify Requirements. To be maximally effective, MBB participants were encouraged to understand these principles and practice MBB techniques at any time throughout the day and right up to the time when they went to bed, and after waking up and trying to get back to sleep. Licensed mental health providers with extensive experience in providing MBB sessions conducted weekly sessions for this program.

Study Procedures

Initial screening of participants was conducted at VASLCHCS clinics or over the phone. Prospective Veterans completed a brief screening health history questionnaire, as well as the MOS Sleep Scale sleep problems index II (SPI-II). To be eligible, they needed to score 35 or higher on the SPI-II. After they were determined to be provisionally eligible, they underwent informed consent and were scheduled for a comprehensive physical evaluation and psychological evaluation. During the evaluation, a physician assistant (PA) went through their medical history and performed physical examinations to assure that the participant met study eligibility. A licensed clinical psychologist conducted psychological evaluation to ensure that the participant was eligible to participate in the study. Participants completed self-report questionnaires for sleep and other outcome measures, including depression, PTSD, quality of life (QOL), and mindfulness. (See Table 1B for a complete list of secondary outcome measures.) For sleep, measures were collected at baseline (Pre), weekly during treatment (Week 2, 3), post-intervention (Post), and at the 3- and 6-month follow-up. For the remaining measures, data were collected at Pre, Post and two Follow-ups. In addition, saliva samples were collected to assess cortisol and alpha-amylase as indicators of Hypothalamic-Pituitary-Adrenal axis functioning and sympathetic drive respectively. Salivary samples were collected at four time-points per day over two days at each assessment visit for cortisol and alpha-amylase assessment. Subjects also wore an actigraph at pre, post and 3month follow-up to gain quantitative insight into sleep quality and performance. Prior to the first session, but after participants found out to which group they had been assigned, they answered a question asking what were their expectations of treatment benefit.

During Post assessment, the participants were re-evaluated by a PA administering the same physical evaluation, for sleep and co-occurring symptoms. The assessment also determined if the participant's condition improved, worsened or remained the same as that reported during the baseline assessment. A clinical psychologist used the same evaluation protocol to assess psychological status of the study participants.

Participants who missed two of the three sessions were considered as not completing the treatment program. However, those participants, who dropped out prior to completing treatment, were invited back to both post and follow-up assessments and evaluations.

**Outcome Measures**

Participants in both groups completed all the self-report outcome measures, as described below. The primary outcomes of the study were improvements in sleep in Veterans with a history of mTBI. Secondary outcomes were changes in polytrauma clinical triad symptoms, such as PTSD symptoms, pain, or co-occurring post concussive symptoms. Clinical assessments by a physician assistant and a psychologist were also performed to evaluate Veterans' functionality and QOL, and psychological status. Finally, we assessed participant mindfulness, self-compassion and well-being to

determine if they were influenced by the interventions and if they would show similar improvements to those of sleep and co-occurring health conditions. Additionally, other secondary measures were added to the study for exploratory purpose. Each outcome measure is briefly described below.

Primary outcome measures:

Medical Outcomes Study Sleep Scale (MOS-SS) (Hays et al., 2005): The MOS-SS provides an index of sleep problems, including sleep disturbance, sleep adequacy, daytime somnolence, snoring, waking up short of breath with a headache, and quantity of sleep. The MOS-SS was validated as a retrospective assessment of sleep performance over the previous 4 weeks, and compares favorably with the Pittsburgh Sleep Quality Index (PSQI). We have used a modified version of MOS-SS to assess the subject's sleep patterns over the previous 7 days (Hays et al., 2005). The primary outcome measure for our clinical trial analysis was self-reported rating on the MOS-Sleep Scale, and objective sleep indicators gathered with a physical motion monitoring device served as supplementary measures for sleep. To complement these measures, a sleep diary was used during 7-day period. In addition to the collection time points specified, we will also collect MOS-SS on a weekly basis during the treatment period. For the current study, Cronbach's alpha coefficient was calculated to be .708 for this primary outcome measure at baseline.

Sleep Diary: Study participants were asked to complete a diary of their sleep habits for seven days. For each day during the diary period, participants made entries detailing when they went to bed, when they thought they had fallen asleep, the duration of their nighttime sleep, and any naps during the day. From these entries, nightly sleep onset latency (the time from initially attempting to go to sleep until sleep onset), total sleep time (the total time which the participant slept during the night), sleep efficiency (the proportion of the intended sleep period during which the participant actually slept), number of awakenings after sleep onset and total time out of bed were calculated over the course of a week. Subjects also appraised overall sleep quality each night via a 5 point Likert-like scale, in which 1 indicated very poor quality and 5 indicated excellent quality. The sleep diary was completed on five different occasions: a) prior to the start of the intervention (baseline), b) after the second session, c) one week after the third and final session, and the week prior to the time when participants complete their d) 3-month and e) 6-month follow-up questionnaires.

Actiwave Cardio Device for Sleep: During their sleep, participants wore an Actiwave Cardio device, a small actigraph unit to gain insight into patterns of physical activity during sleep as a measure of sleep quality. Each participant wore the device for 2 consecutive days of home assessment. Participants were asked to wear the device for about 10 minutes during the medical evaluation to obtain the baseline data. The device was worn following the completion of medical and psychological evaluations, comprising the baseline assessment, and at about one week after the final treatment session and at 3-month follow-up. See instructions for the procedure of attaching and wearing the device (Sleep activity monitor Instructions are included in Appendix B). Results based

on the Actiwave Cardio Device are currently being analyzed, and preliminary descriptive data are presented in Table 6.

Neurobehavioral Symptom Inventory (NSI) (King et al., 2012): The NSI is a self-report measure of post-concussive symptoms comprising 22-items. Participants rate the degree of symptom severity on a five-point scale ranging from 0 (none) to 4 (very severe) over the past 2 weeks. The NSI total score is the sum of severity ratings of the 22 symptoms, and ranges from 0 to 88. The NSI reflects a 9 symptom cluster model (Cicerone and Kalmar, 1995), which can be validly reduced to 4 clusters, namely, cognitive, affective, vestibular, and somatic/sensory symptoms, as suggested by (Caplan et al., 2010). Cronbach's alpha coefficient was calculated to be .915 in the present study.

Medical Outcomes Study Short Form-36 for Veterans (MOS SF-36V) (Ware and Sherbourne, 1992): We are interested in determining MBB's relative efficacy using a standard measure of Quality of Life (QOL), such as the SF-36, to assess mental and physical health as well as functional status. An adapted form for Veterans, first called SF-36V and now called VR-36, consists of the same eight sections as the MOS 36-Item Short-Form Health Survey (SF-36) (Kazis et al., 1998). Higher scores indicate better quality of life. The instrument provides a global score, as well as the following subscale scores: functional capacity, physical aspects, pain, general health condition, vitality, social aspects and emotional aspects, and mental health. Cronbach's alpha coefficient was calculated to be .947 in the present study.

Comorbid Symptom Measures:

Table 1A provides a brief summary of the measures used to directly address other comorbid polytrauma symptoms associated with mTBI. Cronbach's Alpha is calculated from the present sample.

**Table 1A : Psychometric Assessments of Comorbid Symptoms**

| Outcome Measure | Description | Cronbach's Alpha | Reference |
|---|---|---|---|
| PTSD Check List – Military Version (**PCL-M**) | The PCL-M is a 17-item reliable self-report measure assessing PTSD severity in veterans experiencing a traumatic event. Total scores above 50 are considered to reflect moderate, and above 65 severe, PTSD symptoms. | .929 | Keen et al., 2008 |
| Brief Pain Inventory (**BPI**) | The BPI assesses clinical pain symptoms and their impacts on multiple patient quality of life domains. | .920 | Cleeland and Ryan, 1994; Tan et al., 2004 |

## Secondary Outcome and Process Measures

Questionnaires and Surveys: Table 1B presents an overview of additional psychometric measures collected before, during and after treatment. Cronbach's Alpha is calculated from the present sample.

**Table 1B : Additional Psychometric Instruments**

| Outcome Measure | Description | Cronbach's Alpha | Reference |
|---|---|---|---|
| Center for Epidemiologic Studies Depression Scale (**CES-D**) | The CES-D is a 20-item survey designed to assess depressive symptomatology during the past week. The CES-D has been employed in investigations of depression in a trauma-exposed military sample. | .705 | Radloff, 1977; Elhai et al., 2011 |
| Connor–Davidson Resilience Scale (**CDRS**) | The CDRS is a 25-item survey which assesses resilience, the ability to positively adapt in the face of stress or trauma. | .950 | Connor and Davidson, 2003 |
| Perceived Stress Scale (**PSS**) | The PSS is a 10-item questionnaire which measures the overall burden of stress on an individual over the course of the last week rather than individual stressors. | .899 | Cohen et al., 1983; Cohen and Williamson, 1988 |
| Self-Compassion Scale (**SCS**) | The SCS comprises 26 items and is used to measure self-compassion, an emotionally positive self-attitude that should protect against the negative consequences of self-judgment, isolation, and rumination. | .860 | Neff, 2003 |
| Five Facet Mindfulness Questionnaire (**FF-MQ**) | The FF-MQ assess five clear, interpretable facets of mindfulness. It is informative as a process measure of quality control to assess the degree to which sleep-focused MBB increased participant mindfulness. | .937 | Baer et al., 2006 |
| Well-Being Index (**WBI**) | The WBI is a five-item scale evaluating both positive and negative aspects of emotional functioning developed by the World Health Organization Collaborating Centre in Mental Health. | .885 | Bech et al., 2003; Henkel et al., 2003 |
| Beck Scale for Suicide Ideation (**BSI**) | The BSI is a self-report scale comprising 21 items used to detect and measure the intensity of a person's attitudes, behaviors, and plans to commit suicide during the past week. | .913 | Beck and Steer, 1991 |
| Multidimension Assessment of Interoceptive Awareness (**MAIA)** | This assessment scale comprising 32 items serves to identify and distinguish beneficial and maladaptive body awareness. The MAIA comprises eight subscales: Noticing, Distracting, Worrying, Attention Regulation, Emotional Awareness, Self-Regulation, Body Listening and Trusting. | .939 | Mehling et al., 2012 |
| Type D Scale-14 (**TYPE-D**) | This assessment is a 14-item survey designed to measure the Type D or Distressed personality construct which comprises a tendency towards both negative affectivity and social inhibition. | .763 | Denollet, 2005 |

Expectation for treatment benefit

After participants completed all baseline screening and knew to which group they had been randomized (but just before attending their respective group), they were asked to what extent they thought that the treatment they would receive would help them improve their sleep problems (and other symptoms). They recorded their responses on an 11 point Likert-like scale in which, 0 reflected that it was not at all likely, and 10 reflected that it was highly likely.

Computerized Cognitive Assessment: Recent work has highlighted that subjective states of the mind such as mind-wandering can play a substantial role in the manner that individuals function in everyday life (for a review of laboratory based research (see (Smallwood and Schooler, 2006; Smallwood and Schooler, 2015). A laboratory paradigm that has been developed to study mind-wandering might be particularly useful for evaluating potential benefits of our clinical intervention programs in Veterans with mTBI. Briefly, participants performed a sustained attention task in which they were required to identify targets (such as the letter 'x') presented in a series of sequential non-targets (such as the digits 1- 9) either in the center or to either side of a fixation point. During this task, participants were asked to report their mental states at intermittent intervals. This occurred in either a probe-caught method in which participants were occasionally asked about the contents of consciousness in response to a probe presented on a computer screen, or using the self-caught method in which participants indicated whenever they voluntarily noticed that their minds wandered from what they were doing. The probe asked participants to indicate the general content of their consciousness (such as whether they were giving the task their full attention or they were thinking about an event from the past or the upcoming future). In this way, participants were asked to report on the specific contents of their mind-wandering episodes. Participants were instructed to give a verbal report or narrative account of the contents of their consciousness at the intermittent probes, as well as any time they caught their mind wandering in task-irrelevant manners. Each testing session lasted about 30 minutes. Participants completed the task at pre-and post-treatment, and at the 3-month follow-up. Results from the cognitive assessment are currently being analyzed.

Biomarker Assessment: We previously investigated the effects of MBB on alterations in salivary biomarkers implicated in hyper-arousal and stress, namely, cortisol and α-amylase (Lipschitz et al. 2013). These substances have been extensively measured and validated and are considered essential players in understanding stress and stress related effects in the field of psychoneuroendocrinology. Participants were trained in the routine collection of saliva samples using Salivettes (Sarstedt, Inc, Germany) and were be asked to collect saliva samples at three specific time points during the study: within a few weeks prior to the first session (pre-study baseline), one week after the last session (post-study), and at the 3-month post-study assessment follow-up (See Saliva Collection, Appendix). Participants were required to collect 8 saliva samples at specified times over the course of 48 hours. Samples were immediately refrigerated at 4°C at participants' homes and thereafter shipped to the Pain Research Center, University of Utah where they were stored in a -80°C freezer until all samples were

collected from all study participants and ready for assaying. Samples were shipped to the Faculty of Psychology at Technische Universität Dresden for analysis (https://tu-dresden.de/mn/psychologie/biopsychologie/forschung/labor/speichel). Results based on the salivary biomarkers are currently being analyzed, and preliminary descriptive data are presented in Table 7.

Clinical Assessments by Physician Assistant and Clinical Psychologist

Prior to (Pre) and following completion (Post) of the interventions, participants were evaluated by a Physician Assistant (PA) and a Clinical Psychologist (CP) to ascertain whether they experienced changes in their status of various symptoms that they have been suffering from.

All participants underwent an in-person comprehensive evaluation by the team of clinicians (PA and CP) specialized in primary care medicine and psychological medicine, including medical and psychological assessment. The evaluation helped us ensure that our protocols were appropriately applied (e.g., eligibility criteria) and to identify co-existing conditions in Veterans with mTBI and disturbed sleep. Participants were assessed at baseline (to determine eligibility) and post-treatment.

Medical Evaluation: A VA health care provider took a detailed medical history and performed the necessary physical examination to ensure that the patient met study eligibility under the supervision of the study VA physicians. Medical evaluation was specifically intended to identify comprehensively other co-existing conditions, especially those conditions involving pain in Veterans who have a history of mTBI as assessed in the Polytrauma Clinic at VASLCHCS. Furthermore, medical evaluation included rigorous assessment of chronic pain and some highly specific sleep disorders (such as sleep apnea and sleep-disordered breathing), and information about these conditions (if they were already properly treated) was used in stratified randomization of patients into the two study intervention groups.

If participants did not receive clear confirmation from their medical provider that they sustained at least one mTBI event during their deployment, they were evaluated using a Structured TBI Diagnostic Interview (STDI) to determine their mTBI status. Those who have been determined not to have a history of mTBI during their deployment were excluded from the study.

Psychological Evaluation: A licensed psychologist conducted a structured interview with each Veteran to ascertain whether they met the criteria for PTSD, major depressive disorder, dysthymia, or depressive disorder not otherwise specified. For this purpose, we used the Mini-International Neuropsychiatric Interview (M.I.N.I.), which is a structured interview that allows for the diagnosis of DSM-IV and ICD-10 psychiatric disorders (Sheehan et al, 1998). Additionally, the psychological evaluation included a semi-structured interview to obtain basic psychosocial history.

## Statistical Analyses

Primary Outcome: For the primary outcome measure of sleep, the MOS-SS Sleep Problems Index II, the measure used to determine subject eligibility for the clinical trial, we utilized a mixed effects model analysis of variance (ANOVA), in which the means of pre-randomization measurements at Pre and Week1 served as a baseline measure. We conducted analyses on both the raw scores and transformed z scores to evaluate if the data were normally distributed.

Our model made use of all data collected from participants after randomization until the completion of treatment: week 2, week 3 and post-intervention to evaluate treatment impact, providing an "intent-to-treat" approach to any missing data. Under the model's assumptions, the algorithm chooses parameter estimates generating the highest probability for all the data observed. The maximum-likelihood effect estimates are fully correct even if there is systematic unequal dropout conditional on baseline observations (Donaldson & Moinpour, 2005; Little & Rubin, 2002).

Initially, we determined the covariance structure for each outcome measure, and used the covariance structure that generated the best Bayesian Information Criterion (BIC; smaller number is better) in the Treatment by Period factorial interaction. The full factorial model comprised Treatment by Period interaction (significant at $p<.05$). Customized contrasts compared mean rate of change in SPI-II across the two groups over the course of treatment. Within-subjects tests were carried out with data collected at 3- and 6-month follow-ups to determine if the treatment gains seen at post were maintained at later time points.

As a further analysis of treatment outcomes, a common language effect size, $P(X>Y)$, was calculated from the pooled changes in SPI-II from pre to post between both treatment groups. A Mann-Whitney U statistic was calculated from these changes across both groups and divided by the product of the sample sizes to give a common language effect size index for the primary outcome variable.

Secondary Outcomes: For all secondary outcome measures, an analysis of covariance was conducted, but with a single covariate (the baseline measurement); the post-randomization time points included post as well as 3- and 6-month follow-ups. Covariance structures were determined by selecting the structure that generated the best Bayesian Information Criterion (BIC) in a Treatment by Period factorial interaction. The full factorial model comprised Treatment (MBB, SED), Period (Post, 3-month Follow-up, and 6-month Follow-up), and Treatment by Period interaction (significant at $p <0.05$). To gain insight into the magnitudes of treatment effects at each time point and within each group, we examined customized contrasts within and between the two treatments at Post and both Follow-ups, adjusted for baseline measures.

Clinical assessment: To evaluate differences in clinician-assessed symptoms between the two groups, we calculated mean proportions of participants exhibiting improvement, worsening, or no change in each symptom at Post in both groups. To ascertain as to

whether or not the two intervention groups differed in terms of observed outcomes, a Mann-Whitney U test was performed.

## Results

### Participant Attendance

844 OEF/OIF veterans were contacted either by letter, phone or by a VASLCHS clinician and were screened for inclusion if they expressed interest. Figure 1 outlines the number of individuals who completed screening (n=187), were enrolled in the study and were present at both post and follow-up for each intervention. Of the randomized participants (n=68), 50 (23 in MBB and 27 in SED) completed the intervention, indicated by attending at least two sessions and completing post assessments.

### Demographics and Baseline Characteristics

**Table 2** provides a breakdown of the demographic characteristics of the study participants by group, ages ranged from 23 to 59 (mean, SD; 36.60, 9.15). Participants were largely white (91.2%) and male (92.6%). Baseline characteristics were generally balanced between these two groups.

### Expectation for treatment benefit before the intervention started

The two groups did not differ in terms of expectation for treatment benefit (MBB: mean=6, SD=2; SED: mean=5, SD=2), based on an independent samples t-test ($t(54) = .686$, $p = .496$). This suggests that both intervention programs were perceived to be credible and effective by study participants at the beginning of the intervention phase.

### Primary Outcome Measures

Sleep - MOS-SS Sleep Problems Index II (SPI-II):

As demonstrated by Figure 2, reductions in SPI-II were observed in both groups over the course of treatment, when compared with the mean of both baseline measurements for both groups (64.84 in this case). The magnitude of reduction at post was greater in MBB than SED, though these differences were slightly diminished at the 3-month and 6-month follow-ups. Table 3A presents SPI-II unadjusted means and 95% Confidence Intervals (CIs) for the two treatment groups at Pre, Week 2, Week 3, Post, and 3- and 6-month Follow-up.

The mixed model analysis revealed a significant treatment by period interaction ($F(8, 141.66) = 211.625$, $p < .001$). Within-group comparisons confirmed that both MBB and SED improved sleep as indexed by SPI-II from pre to post-intervention (SED: $t(194.445)=2.38$, $p = .006$; MBB: $t(196.67)=5.40$, $p <.001$). Additionally, there was a significant non-zero linear trend in both groups ($p=.004$ for SED; $p<.001$ for MBB). Furthermore, more critically, the customized comparison of “rate of change” between the treatment groups were significant ($t(195.206) =2.40$, $p = .017$), reflecting the greater

rate of change (i.e., improvement) in symptom decrease in the MBB group relative to the SED group.

To evaluate longer-term impacts of the intervention programs, for the MBB group, customized tests with follow-up measures at 3 months and 6 months showed that there was no meaningful change from the post assessment ($t = 1.095$, $p = .289$; and $t = 1.347$, $p = .208$), suggesting that benefits of the intervention were basically maintained in MBB. Similarly, for the SED group, customized tests with follow-up measures at 3 months and 6 months showed that there was no meaningful change from post assessment ($t = 1.140$, $p = .266$; and $t = .789$, $p = .437$). Taking together, these findings suggest that following the treatments, the sleep symptoms in both groups remained relatively stable.

To examine the relative magnitude of the intervention benefit, a Mann-Whitney U test was performed on the pooled pre to post changes across both groups, granting a U value of 230.50. This was used to calculate the probability of a patient randomized to MBB experiencing a better outcome than a patient randomized to SED. The resulting P (X>Y) was .5978, indicating a roughly 60% probability that in any random pair of two subjects chosen from the two respective groups (i.e., one from each group), the participant randomized to MBB would experience a greater decrease in SPI-II score over the course of treatment compared with the participant randomized to SED. This 60% probability serves as a common language effect size of MBB benefit relative to SED.

Table 3B presents unadjusted means and 95% CIs for the MOS-SS subscales at the same time points to that of SPI-II. In these subscales, analyses of covariance revealed no significant overall Treatment effect. Customized contrasts at post-intervention, 3 months and 6 months failed to uncover any significant treatment effect for the SPI-I, Daytime Somnolence, Sleep Disturbance, Shortness of Breath or Sleep Adequacy subscales. However, a meaningful contrast was observed in the Snoring subscale at 6 months favoring the MBB participants ($F (1, 183.988) = 5.069$, $p = .026$).

Descriptive data based on participant-completed sleep diaries are presented in Table 5. The two groups looked basically comparable in terms of sleep diary-based measures.

## Comorbid Symptoms Measures

### PTSD Symptoms -- PCL-M

Figure 3A presents the adjusted means of total PCL-M scores at Post and both 3 and 6 months post intervention. PCL-M pre-intervention baseline score is shown as a reference line. Both groups exhibited a net improvement in PTSD symptoms at post and 3 months, though SED returned to baseline at the 6-month follow-up.

Both groups showed slight improvements in PCL-M scores when compared with baseline at post. From baseline measures of 55.26 and 57.29, respectively, SED and

MBB groups showed reductions to 53.11 and 52.83 in their overall PCL-M scores. A further slight reduction was observed in MBB at 3 months to 51.53 while SED rebounded to 55.15.

Based on an analysis of covariance, treatment was found to be statistically significant ($F(1, 55.23) = 4.443$), $p = .04$), suggesting a meaningful difference in reduction in PTSD symptoms between MBB and SED. A significant difference was observed between the groups at 3-month ($F(1, 103.78) = 5.610$, $p = .02$). A Cohen's d of .27 was calculated at the 3-month Follow-up. Overall, these findings suggest that MBB reduced self-reported PTSD symptoms greater than SED did and that the benefits were retained at 3-month post-intervention.

Post-Concussive Symptoms (NSI)

Both the MBB and SED treatment groups showed a slight reduction of symptoms over the course of the trial, as shown in Table 4A. Treatment and Treatment by Period interaction were not found to be significant for the total NSI total score. However, a significant difference was found in favor of the MBB group at 3 months in the Cognitive symptoms subscale of the NSI ($F(1, 64.92) = 5.474$, $p = .022$), perhaps suggesting an improvement in cognitive symptoms in the MBB group relative to the SED group.

Pain (BPI)

Treatment and Treatment by Period interaction were not found to be significant for any of the BPI subscales: Pain Severity, Pain Interference or Pain Relief, suggesting that there was no significant preferential benefit to pain symptoms in either group.

**Secondary Outcome Measures**

Stress (PSS)

**Figure 3B** presents adjusted means and 95% confidence intervals for PSS total scores by treatment group with baseline measures shown as a reference line. The overall effect of treatment was found to be marginally significant **(**$F(1, 52.89) = 3.883$, $p = .054$). However, at the first follow-up measurement (3 months), a significant contrast was observed ($F(1, 157.15) = 8.53$, $p = .004$), suggesting a meaningful reduction in stress among participants assigned to the MBB group relative to those in the SED group.

Mindfulness (FFMQ)

**Figure 3C** presents adjusted means and 95% confidence intervals for FFMQ total scores by treatment group with baseline measures shown as a reference. MBB participants showed an improvement in FFMQ scores at post and at the first follow-up while SED participants did not. From a baseline measure of 112.67, group means for MBB improved to 116.57 at post and further to 119.26 at 3-month. By contrast, from a

baseline of 111.06, SED participants reported a mean score of 109.78 at post and 106.75 at 3-month.

As assessed by an ANCOVA, the overall effect of treatment was found to be significant, (F (1, 52.64) = 4.06, p = .049), reflecting increased mindfulness in the MBB group. Furthermore, a highly significant contrast favoring the MBB group was observed at 3 months (F (1, 84.94) = 5.152, p = .002), suggesting that MBB improved mindfulness relative to the SED at 3-month post-intervention. As a process measure and an index of quality control, this observation supports that MBB did indeed improve mindfulness in the experimental group and that mindfulness might be a possible mechanism by which sleep symptoms were ameliorated.

Quality of Life (SF-36)

Overall, this measure did not differ across the two groups. The overall effect of treatment was not found to be significant (F (1, 52.154) = 3.180, p=.08). However, at the 3-month follow-up, treatment was found to be significant (F (1, 85.601) = 5.162, p = .026), suggesting an improvement in participants assigned to the MBB group relative those in the SED group. (See Table 4B)

Other Secondary Outcome Measures

**Table 4B** presents unadjusted means and 95% confidence intervals for all other secondary outcome measures and their subscales if applicable. As shown in the Table, these secondary measures did not differentiate the two intervention groups on the basis of the ANCOVAs for Depression (CESD), Resiliency (CDRS), Well-Being (WBI), Suicidality (BSS) or Introspective Awareness (MAIA). However, a meaningful improvement in the Social Inhibition subscale of the TDS was seen in the MBB group relative to the SED group at 3 months (F (1, 183.337) = 5.932, p = .016) and at 6 months (F (1, 188.998) = 9.84, p = .002). A meaningful difference was also observed in the Negative Affect subscale of the TDS at 3 months for the MBB group (F (1, 116.104) = 5.339, p =.023). Together, these findings suggest some lasting improvement in social inhibition and negative affectivity that may have been modified by MBB.

Physical and Psychological Evaluations

The results of the clinician-administered sleep and psychological symptom evaluations are presented in Table 8. These data document the proportion of participants who completed the intervention who experienced worsening, no change, or improvement in symptoms over the course of the trial. Results indicated that a large percentage of veterans randomized to either the SED or MBB groups showed improvement across a range of physical and psychological symptoms. There was no statistically significant difference in any variable examined in terms of the proportions of participants falling into one of these three categories, with one exception. For psychological health, a Mann-Whitney U test found a statistically significant difference (U = 192.00, p=.006) between

the two groups, indicating that those in the MBB group improved significantly better than those in the SED group.

## Summary and Conclusion

The main objective of this exploratory RCT study was to document potential benefits of a mind-body intervention program to improve sleep symptoms for returning OEF/OIF Veterans who suffered a combat-related TBI and presented with ongoing disturbed sleep. As one of the few studies that evaluated impacts of a complementary mind-body intervention program (MBB), the study produced several encouraging findings.

First, both MBB and SED groups improved sleep significantly from baseline to post-intervention and there was a significant non-zero linear trend in both groups. More importantly, the rate of change in the MBB group was significantly greater than that in the SED group, suggesting that MBB is more efficacious in improving sleep than SED over the period of 5-6 weeks (from baseline assessment to post-intervention assessment).

Second, at 3-month follow-up, those in the MBB reduced PTSD symptoms and perceived stress, while increasing mindfulness, relative to those in the SED. These findings seem to suggest that a mind-body intervention program like MBB should receive further consideration as a complementary adjunct modality in polytrauma care.

Third, the present study did not find any preferential advantage of MBB over SED for other measures designed to assess the status of TBI-related conditions (such as NSI). There may be several reasons for this absence of finding a meaningful difference across the two intervention groups. First, the final sample size ended up being smaller than what we originally envisioned to have (for a number of reasons). Second, what was evaluated in the study is the efficacy of sleep-focused MBB program that lasted for only 3 weeks. It may be highly likely that we would need to provide a much longer, more comprehensive MBB-based program to produce measurable impacts on all other clinically important measures that would define the overall status of Veterans with mTBI and other co-existing symptoms.

Polytrauma care is undoubtedly very challenging. More consorted effort will be needed to figure out the scope of an optimal program that can help mTBI Veterans heal in an most effective way. The heterogeneity of Veterans' mental and physical health conditions, coupled with varying military and personal life experience, makes it challenging to provide them with optimal care. Further development of a complementary treatment modality (such as MBB) may contribute to a personalized medicine approach to polytrauma care. The MBB treatment protocol developed for this study may be helpful for both clinical care and preventive training to improve physical and mental health status of service members returned from their deployment.

**Figure 1: Study Flow**

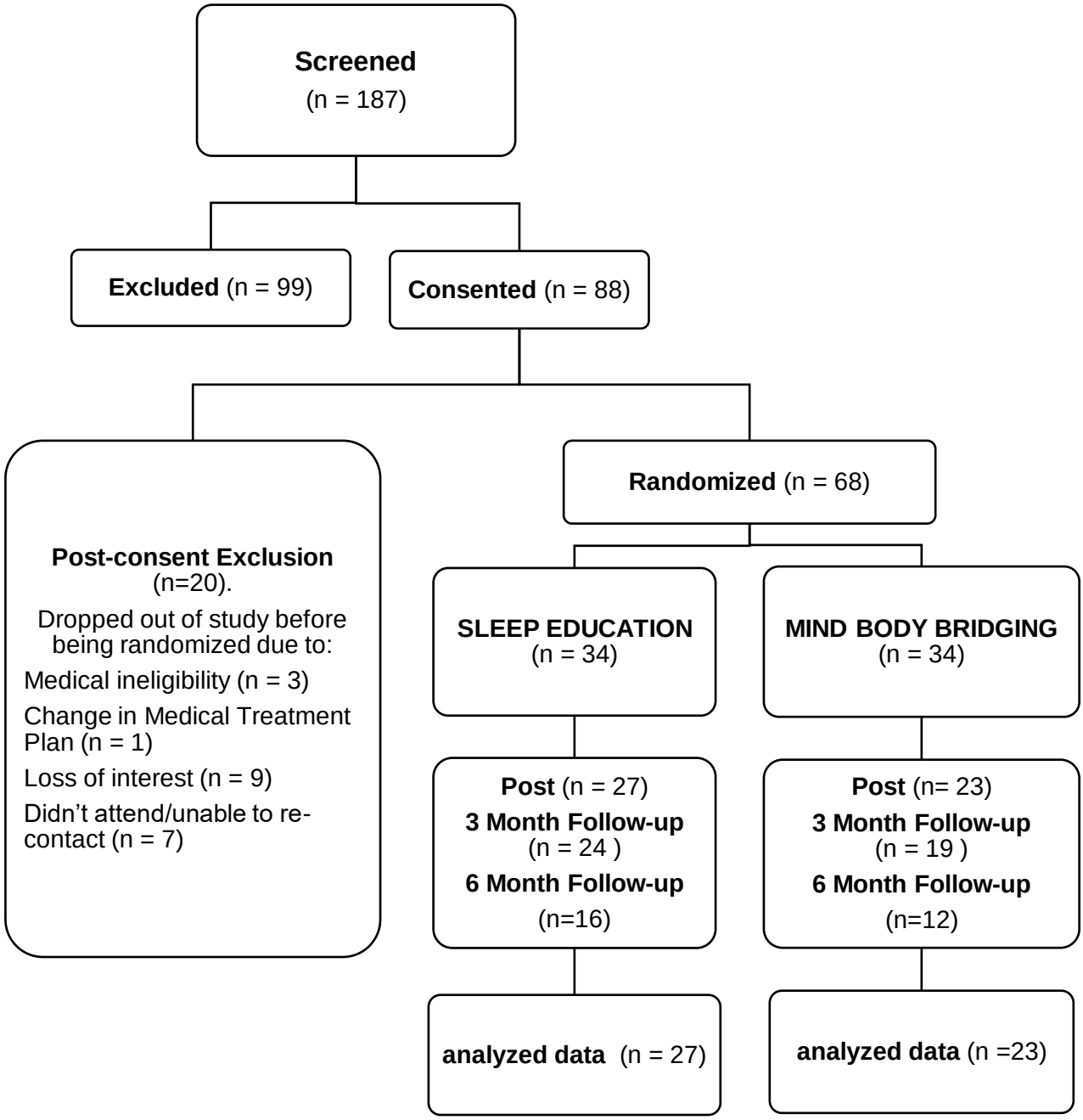

**Figure 2.**

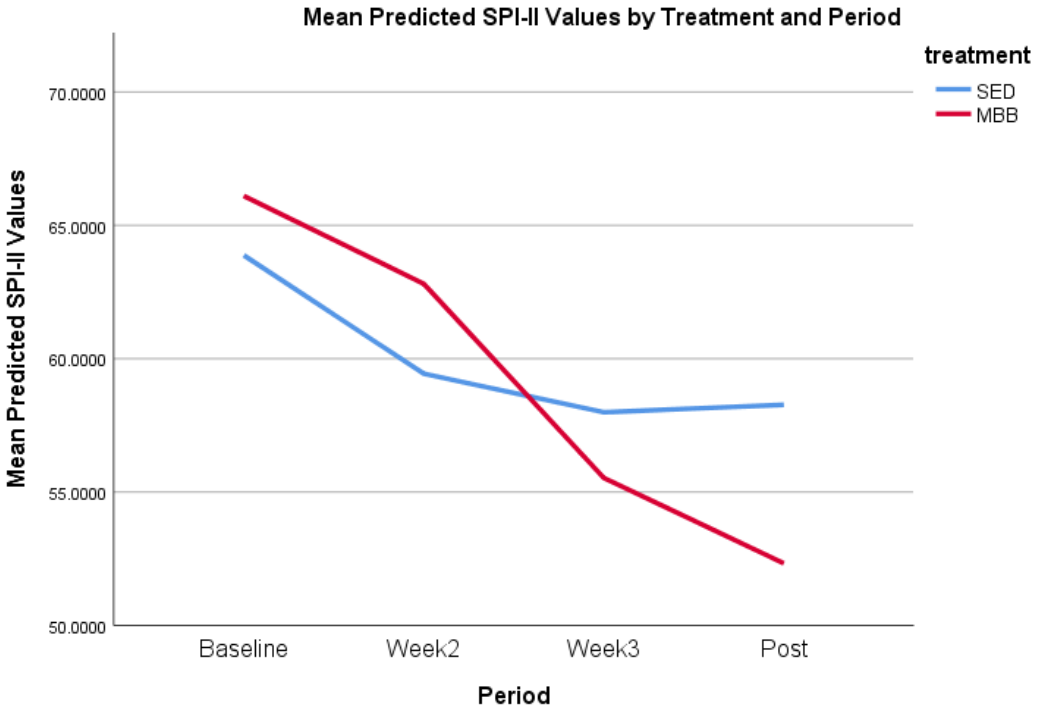


**Figure 2.** Effects of SED and MBB interventions on SPI-II (sleep outcome).

Predicted mean values by period are shown along with pre-intervention baseline (Pre) scores.

SED = Sleep Education; MBB = Mind–Body Bridging; SPI-II – Sleep Problem Index-II in MOS-SS

**Figure 3A**

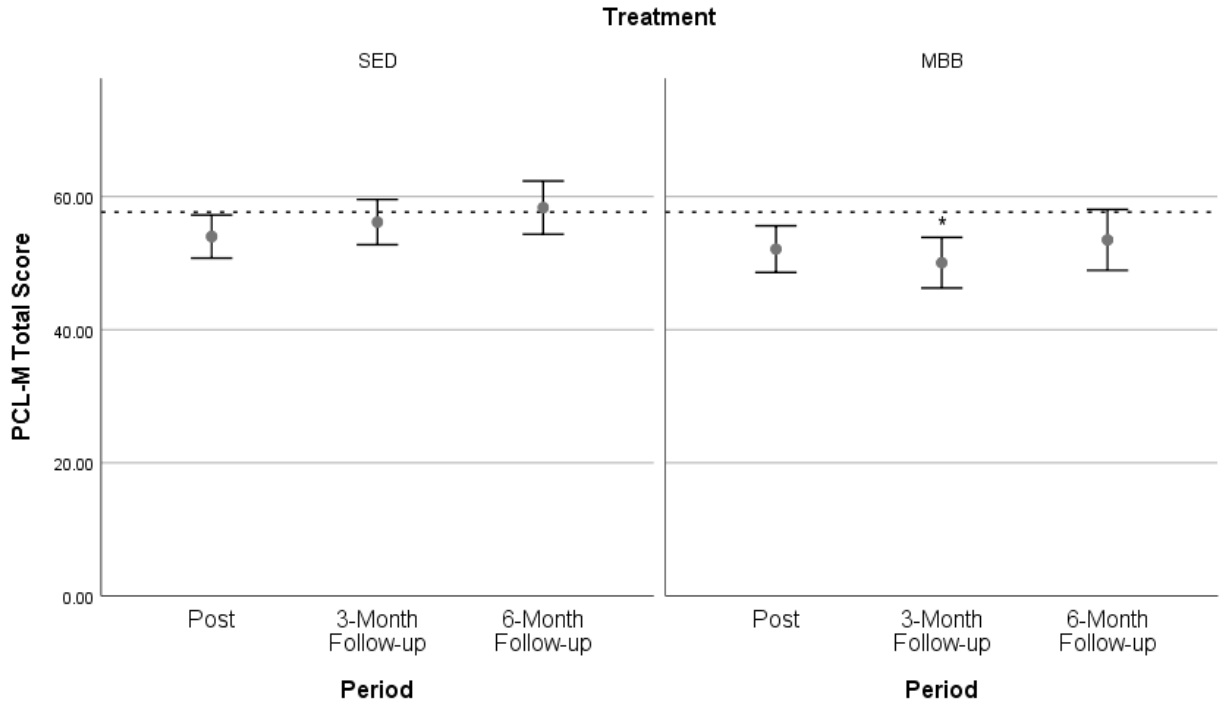


**Figure 3B**

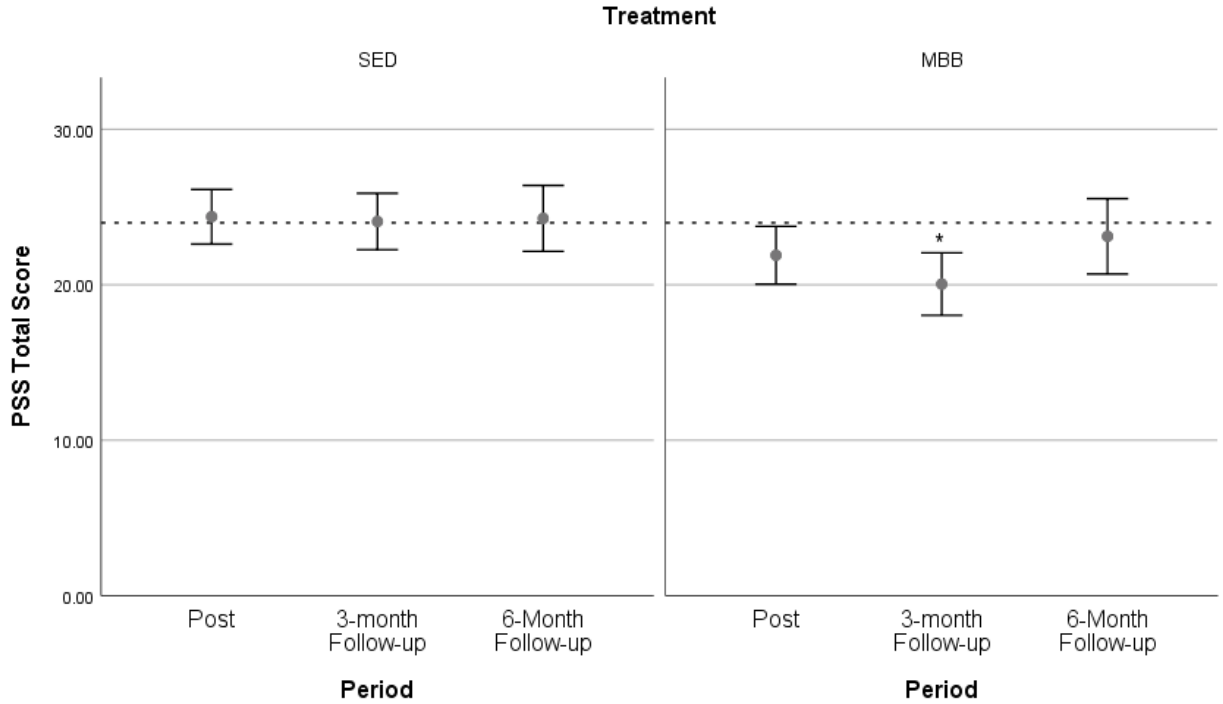

**Figure 3C**

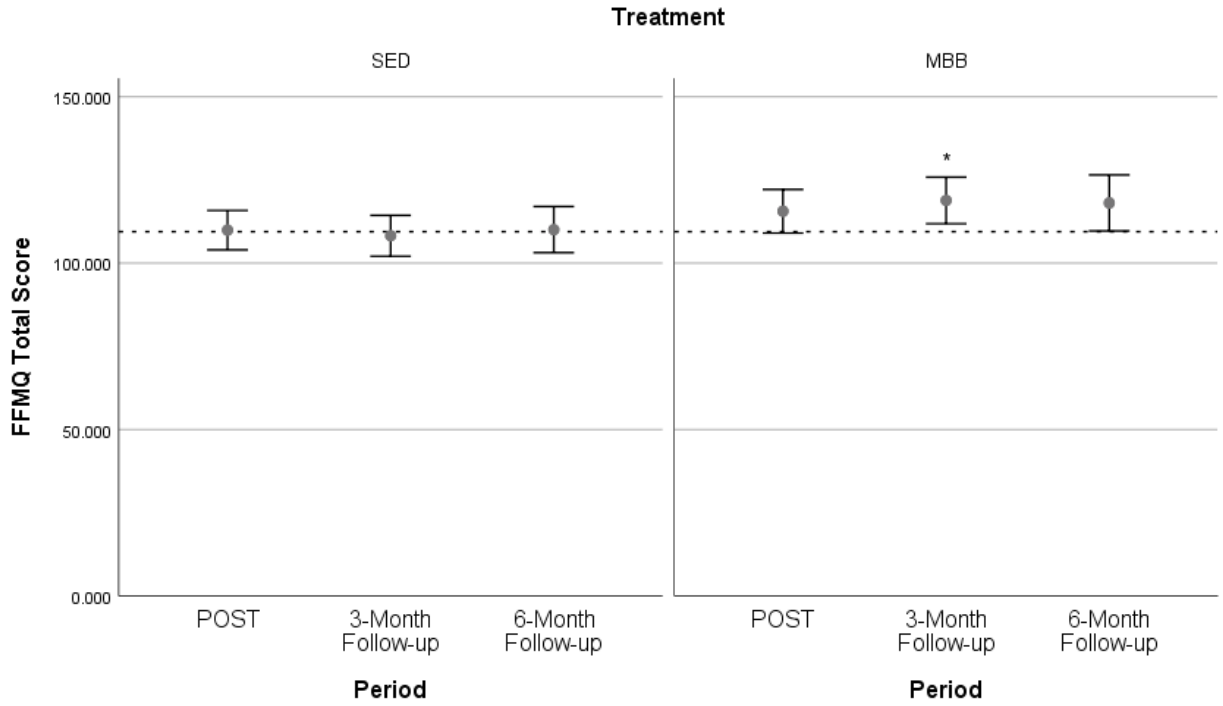


**Figure 3.** Effects of SED and MBB interventions on (A) PTSD (PCL-M Total score), B) Stress (PSS Total core), and C) Mindfulness (FFMQ Total Score)

*Note.* Estimated means (with 95% Confidence Intervals; CIs), adjusted for pre-intervention baseline (Pre) scores are shown. The dashed horizontal line represents the mean baseline covariate value of each scale, representing a common baseline reference across the two intervention groups. SED = Sleep Education; MBB = Mind–Body Bridging; PCL-M = PTSD Checklist – Military; PSS= Perceived Stress Scale; FFMQ = Five Face Mindfulness Questionnaire; *MBB compared with SED ($p < .05$).

## Table 2: Baseline demographics for participants

| | SED | | MBB | |
|---|---|---|---|---|
| **N** | 34 | | 34 | |
| | **Mean (SD)** | | **Mean (SD)** | |
| **Age** | 35.56 (8.42) | | 39.15 (8.30) | |
| **Years in Military** | 11.25 (8.42) | | 13.78 (8.32) | |
| | **Number of participants** | **%** | **Number of participants** | **%** |
| **GENDER** | | | | |
| Female | 2 | 5.9 | 3 | 8.8 |
| Male | 32 | 94.1 | 31 | 91.2 |
| **BRANCH OF MILITARY** | | | | |
| Army | 26 | 76.5 | 22 | 64.7 |
| Air Force | 3 | 8.8 | 5 | 14.7 |
| Navy | 2 | 5.9 | 1 | 2.9 |
| Marine | 2 | 5.9 | 6 | 17.6 |
| Other/No Response | 1 | 2.9 | 0 | 0 |
| **ETHNICITY** | | | | |
| Hispanic/Latino | 3 | 8.8 | 4 | 11.8 |
| Not Hispanic/Latino | 31 | 91.2 | 30 | 88.2 |
| **RACE** | | | | |
| Asian | 0 | 0 | 0 | 0% |
| White | 32 | 94.1 | 30 | 88.2 |
| Native Hawaiian/Pacific Islander | 0 | 0 | 0 | 0 |
| African American/Black | 1 | 2.9 | 1 | 2.9 |
| American Indian/Alaska Native | 0 | 0 | 3 | 8.8 |
| Other | 1 | 2.9 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| **EDUCATION** | | | | |
| Less than High School | 0 | 0 | 0 | 0 |
| High School Graduate | 5 | 14.7 | 2 | 5.9 |
| Associate Degree | 4 | 11.8 | 2 | 5.9 |
| Some College | 16 | 47.1 | 16 | 47.1 |
| College Degree | 7 | 20.6 | 10 | 29.4 |
| Masters or Higher | 2 | 5.9 | 4 | 11.8 |
| | | | | |
| **MARITAL STATUS** | | | | |
| Singe (never married) | 9 | 20.6 | 4 | 11.8 |
| Married | 18 | 52.9 | 24 | 70.6 |
| Separated/Divorced | 7 | 20.5 | 6 | 17.6 |
| Widowed | 0 | 0 | 0 | 0 |
| | | | | |
| **LIVING SITUATION (could be living with spouse and children/other)** | | | | |
| Alone | 5 | 14.7 | 7 | 20.6 |
| Spouse | 22 | 64.7 | 25 | 73.5 |
| Children | 11 | 32.4 | 19 | 55.9 |
| Other | 7 | 20.6 | 3 | 8.8 |
| | | | | |
| **EMPLOYMENT** | | | | |
| Full time | 19 | 55.6 | 16 | 47.1 |
| Part time | 2 | 5.9 | 5 | 14.7 |
| Unemployed | 7 | 20.6 | 1 | 2.9 |
| Homemaker | 0 | 0 | 0 | 0 |
| Retired | 4 | 11.8 | 5 | 14.7 |
| Other | 2 | 5.9 | 7 | 20.6 |
| | | | | |
| **WORKERS COMPENSATION AND DISABILITY DATA** | | | | |
| **Receiving Workers Compensation** | 0 | 0 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| **Receiving Long-term Disability** | | | | |
| Yes | 20 | 58.8 | 24 | 70.6 |
| No | 14 | 14.2 | 10 | 29.4 |
| Missing | 0 | 0 | 0 | 0 |
| | | | | |
| **Source of Disability Compensation** | | | | |
| VA | 20 | 58.8 | 23 | 67.7 |
| Other | 0 | 0 | 1 | 2.9 |
| Responding No to previous item | 14 | 14.2 | 10 | 29.4 |
| | | | | |
| **Pending Disability** | | | | |
| Yes | 11 | 32.4 | 8 | 23.5 |
| No | 23 | 67.6 | 26 | 76.5 |
| Missing | 0 | 0 | 0 | 0 |
| | | | | |
| **Source of Pending Disability** | | | | |
| VA | 9 | 26.5 | 7 | 20.6 |
| Other | 2 | 5.9 | 1 | 2.9 |
| Responding No to previous item | 23 | 67.6 | 26 | 76.6 |

**Table 3A: UNADJUSTED MEANS and 95% Confidence Interval (CI) for the primary outcome measure, MOS-SS SPI2.**

| | | SED | | MBB | |
|---|---|---|---|---|---|
| **OUTCOME MEASURE** | **Period** | **Mean** | **95% CI (lower, upper)** | **Mean** | **95% CI (lower, upper)** |
| **MOS-Sleep Scale: Sleep Problems Index-II** | PRE | 63.50 | (59.39, 67.60) | 65.34 | (60.43, 70.25) |
| | Week 1 | 64.13 | (60.37, 68.25) | 67.07 | (62.62, 71.52) |
| | Week 2 | 59.44 | (52.23, 66.65) | 62.62 | (55.78, 69.83) |
| | Week 3 | 57.99 | (50.49, 65.49) | 55.53 | (46.93, 64.13) |
| | POST | 58.27 | (52.09, 64.46) | 52.33 | (43.56, 61.10) |
| | 3Mo | 53.80 | (46.46, 61.13) | 56.61 | (45.01, 68.21) |
| | 6Mo | 62.64 | (53.07, 72.20) | 55.83 | (40.85, 70.81) |

**Table 3B: UNADJUSTED MEANS and 95% Confidence Interval (CI) for other sleep outcome measures, as assessed by MOS Sleep Scale**

| | | SED | | MBB | |
|---|---|---|---|---|---|
| **OUTCOME MEASURE** | **Period** | **Mean** | **95% CI (lower, upper)** | **Mean** | **95% CI (lower, upper)** |
| **MOS-Sleep Scale: Sleep Problems Index-I** | PRE | 60.98 | (56.51, 65.45) | 63.43 | (58.53, 68.34) |
| | POST | 56.17 | (49.62, 62.72) | 52.38 | (43.54, 61.22) |
| | 3Mo | 51.67 | (44.05, 59.29) | 55.61 | (44.39, 66.84) |
| | 6Mo | 62.08 | (52.62, 71.55) | 53.33 | (38.09, 68.58) |
| **MOS-Sleep Scale: Sleep Disturbance** | PRE | 66.25 | (60.24, 72.26) | 68.83 | (61.45, 76.20) |
| | POST | 57.04 | (48.83, 65.25) | 55.12 | (43.65, 66.59) |
| | 3Mo | 55.42 | (46.72, 64.12) | 59.21 | (44.18, 74.24) |
| | 6Mo | 61.25 | (48.03, 74.47) | 59.79 | (39.81, 79.77) |
| **MOS-Sleep Scale: Sleep Adequacy** | PRE | 25.29 | (19.65, 30.94) | 20.61 | (14.40, 26.81) |
| | POST | 30.00 | (22.48, 37.52) | 33.33 | (22.25, 44.42) |
| | 3Mo | 35.83 | (27.30, 44.36) | 28.95 | (16.94, 40.96) |
| | 6Mo | 20.63 | (13.48, 27.77) | 30.00 | (14.20, 45.80) |
| **MOS-Sleep Scale: Daytime Somnolence** | PRE | 46.47 | (39.88, 53.06) | 48.48 | (41.69, 55.28) |
| | POST | 47.41 | (40.69, 54.12) | 40.63 | (30.67, 50.60) |
| | 3Mo | 42.50 | (33.80, 51.20) | 40.35 | (29.51, 51.19) |
| | 6Mo | 45.83 | (35.47, 56.20) | 38.33 | (23.76, 52.91) |
| **MOS-Sleep Scale: Snoring** | PRE | 51.18 | (38.07, 64.25) | 55.00 | (42.18, 67.82) |
| | POST | 52.59 | (38.35, 66.84) | 47.62 | (29.08, 66.16) |
| | 3Mo | 50.83 | (35.49, 66.18) | 54.44 | (37.45, 71.43) |
| | 6Mo | 60.00 | (41.75, 78.25) | 43.33 | (19.82, 66.85) |
| **MOS-Sleep Scale: Shortness of Breath** | PRE | 42.35 | (32.67, 52.04) | 37.58 | (25.98, 49.17) |
| | POST | 36.30 | (24.89, 47.71) | 26.67 | (12.76, 40.57) |
| | 3Mo | 28.33 | (16.15, 40.51) | 33.68 | (16.97, 50.40) |
| | 6Mo | 43.75 | (26.69, 60.81) | 31.67 | (12.54, 50.79) |
| **MOS-Sleep Scale: Sleep Duration** | PRE | 5.44 | (5.09, 5.79) | 4.97 | (4.55, 5.39) |
| | POST | 5.63 | (5.23, 6.03) | 5.45 | (4.91, 6.00) |
| | 3Mo | 5.73 | (5.17, 6.29) | 5.37 | (4.86, 5.88) |
| | 6Mo | 5.81 | (5.19, 6.43) | 5.35 | (4.45, 6.26) |

**Table 4A: Unadjusted means (and 95% Confidence Intervals) of Self-Reported Comorbid Symptom Measure Comparisons between Mind-Body Bridging (MBB) and Sleep Education (SED) in OEF/OIF veterans with mTBI.**

| | | SED | | MBB | | | |
|---|---|---|---|---|---|---|---|
| **OUTCOME MEASURE** | **Period** | **Mean** | **95% CI (lower, upper)** | **Mean** | **95% CI (lower, upper)** | **p-value** | **Effect size[a]** |
| **PTSD** (PCL-M Total Score) | PRE | 55.26 | (50.67, 59.86) | 57.29 | (52.60, 61.99) | .04* | |
| | POST | 53.11 | (47.46, 58.77) | 52.83 | (47.38, 58.27) | .44 | |
| | 3Mo | 55.04 | (49.64, 60.44) | 51.53 | (44.98, 58.07) | .02# | .27 |
| | 6Mo | 57.94 | (49.66, 66.21) | 54.42 | (42.57, 66.26) | .12 | |
| **Post-Concussive Symptoms** (NSI Total Score) | PRE | 38.41 | (34.46, 42.37) | 38.74 | (33.36, 44.11) | .29* | |
| | POST | 35.92 | (31.28, 40.57) | 34.65 | (29.06, 40.24) | | |
| | 3Mo | 38.29 | (32.53, 44.06) | 34.79 | (37.55, 42.03) | | |
| | 6Mo | 40.46 | (32.61, 48.52) | 38.42 | (28.20, 48.63) | | |
| NSI - Affective Subscale | PRE | 13.47 | (11.96, 14.98) | 14.35 | (12.65, 16.05) | .40* | |
| | POST | 12.15 | (10.47, 13.83) | 12.30 | (10.30, 14.31) | | |
| | 3MO | 13.25 | (11.42, 15.08) | 12.05 | (9.50, 14.60) | | |
| | 6MO | 14.06 | (11.60, 16.53) | 14.06 | (9.24, 17.59) | | |
| NSI - Cognitive Subscale | PRE | 8.79 | (7.63, 9.96) | 8.24 | (6.83, 9.64) | .22* | |
| | POST | 8.26 | (6.88, 9.64) | 7.78 | (6.39, 9.17) | | |
| | 3MO | 8.92 | (7.37, 10.46) | 7.67 | (5.63, 9.11) | .022# | .42 |
| | 6MO | 9.25 | (7.30, 11.20) | 8.67 | (6.12, 11.21) | . | |
| NSI - Somatic Subscale | PRE | 9.38 | (8.08, 10.68) | 9.94 | (8.01, 11.87) | .43* | |
| | POST | 9.22 | (7.76, 10.68) | 8.78 | (6.52, 11.05) | | |
| | 3MO | 9.41 | (7.48, 11.35) | 9.26 | (6.95, 11.58) | | |
| | 6MO | 10.37 | (7.56, 13.19) | 10.00 | (7.52, 12.48) | | |
| NSI - Vestibular Subscale | PRE | 3.74 | (3.10, 4.37) | 3.03 | (2.29, 3.77) | .82* | |
| | POST | 3.37 | (2.46, 4.28) | 3.26 | (2.38, 4.14) | | |
| | 3MO | 3.38 | (2.24, 4.51) | 3.31 | (2.35, 4.28) | | |
| | 6MO | 3.94 | (2.88, 4.99) | 3.41 | (1.92, 4.91) | | |
| **PAIN** (BPI-Pain Severity) | PRE | 15.76 | (13.09, 18.44) | 17.15 | (14.55, 19.74) | .98* | |
| | POST | 17.26 | (14.13, 20.39) | 18.39 | (15.17, 21.62) | | |
| | 3Mo | 15.20 | (12.23, 18.19) | 18.63 | (15.78, 21.48) | | |
| | 6Mo | 16.25 | (12.61, 19.89) | 18.08 | (14.29, 21.88) | | |
| **PAIN** (BI-Pain Interference) | PRE | 27.74 | (21.17, 34.30) | 31.44 | (25.34, 37.55) | .37* | |
| | POST | 30.44 | (23.69, 37.20) | 31.87 | (24.33, 39.41) | | |
| | 3Mo | 28.17 | (22.18, 34.15) | 35.37 | (28.08, 42.65) | | |
| | 6Mo | 32.50 | (23.54, 41.46) | 32.50 | (19.25, 45.75) | | |
| **PAIN** (BI-Pain Relief) | PRE | 5.53 | (4.18, 6.88) | 4.15 | (2.97, 5.33) | .48* | |
| | POST | 4.93 | (3.51, 6.34) | 4.17 | (3.03, 5.32) | | |
| | 3Mo | 5.46 | (3.96, 6.96) | 4.42 | (3.08, 5.76) | | |
| | 6Mo | 4.62 | (2.85, 6.40) | 4.17 | (1.73, 6.60) | | |

**Table 4B: Unadjusted means (and 95% Confidence Intervals) of Self-Reported Secondary Outcome Measure Comparisons between Mind-Body Bridging (MBB) and Sleep Education (SED) in OEF/OIF veterans with mTBI.**

| OUTCOME MEASURE | Period | Mean | 95% CI (lower, upper) | Mean | 95% CI (lower, upper) | p-value | Effect size[a] |
|---|---|---|---|---|---|---|---|
| **PSS** (STRESS) | PRE | 22.79 | (20.35, 20.35) | 22.30 | (19.44, 25.17) | .054* | |
| | POST | 23.65 | (20.43, 26.88) | 22.35 | (19.74, 24.95) | | |
| | 3Mo | 23.33 | (20.50, 26.17) | 20.95 | (17.59, 24.31) | .004# | .35 |
| | 6Mo | 24.38 | (20.57, 28.18) | 25.08 | (19.26, 30.90) | | |
| **MINDFULNESS** (FFMQ-TOTAL) | PRE | 111.06 | (105.19, 116.93) | 112.67 | (104.62, 120.71) | .049* | |
| | POST | 109.78 | (100.87, 118.68) | 116.57 | (106.35, 126.78) | | |
| | 3Mo | 106.75 | (97.15, 116.35) | 119.26 | (105.58, 135.92) | .026# | .49 |
| | 6Mo | 109.25 | (95.30, 123.20) | 113.45 | (86.55, 140.36) | | |
| **QUALITY OF LIFE** (SF-36 TOTAL) | PRE | 51.45 | (46.66, 56.23) | 50.61 | (45.34, 55.88) | .08* | |
| | POST | 51.21 | (44.77, 57.65) | 54.80 | (47.50, 62.10) | | |
| | 3Mo | 50.21 | (44.81, 55.62) | 54.19 | (45.83, 62.54) | .026# | .26 |
| | 6Mo | 35.53 | (35.53, 54.53) | 47.10 | (34.34, 59.89) | | |
| **DEPRESSION** (CESD) | PRE | 24.18 | (21.90, 26.45) | 27.41 | (24.74, 30.08) | .10* | |
| | POST | 24.63 | (21.27, 27.99) | 24.91 | (22.28, 27.54) | | |
| | 3Mo | 23.38 | (20.60, 26.15) | 25.26 | (21.96, 28.57) | | |
| | 6Mo | 24.19 | (20.11, 28.27) | 25.75 | (19.76, 31.74) | | |
| **RESILIENCY** (CDRS) | PRE | 63.53 | (58.02, 69.04) | 66.55 | (60.15, 72.94) | .187* | |
| | POST | 59.81 | (53.70, 65.91) | 62.58 | (55.61, 69.56) | | |
| | 3Mo | 57.71 | (50.55, 64.87) | 63.89 | (54.37, 73.42) | | |
| | 6Mo | 57.13 | (47.50, 66.75) | 58.33 | (43.59, 73.08) | | |
| **WELL-BEING** (WBI) | PRE | 9.00 | (7.40, 10.60) | 9.18 | (7.51, 10.84) | .719* | |
| | POST | 9.78 | (7.83, 11.73) | 8.52 | (7.13, 11.91) | | |
| | 3Mo | 9.71 | (7.66, 11.76) | 9.89 | (7.01, 12.76) | | |
| | 6Mo | 8.19 | (5.38, 11.00) | 9.50 | (5.04, 13.96) | | |
| **SUICIDALITY** (BSS) | PRE | 2.97 | (1.29, 4.65) | 2.91 | (1.06, 4.76) | .555* | |
| | POST | 1.96 | (.19, 3.74) | 2.52 | (.37, 4.67) | | |
| | 3Mo | 2.17 | (.45, 3.88) | 2.78 | (.63, 4.93) | | |
| | 6Mo | 2.81 | (.37, 5.25) | 2.17 | (.25, 4.08) | | |
| **INTROSPECTIVE AWARENESS** (MAIA) | PRE | 10.45 | (9.69, 11.21) | 11.36 | (10.50, 12.21) | .115* | |
| | POST | 10.27 | (9.26, 11.28) | 11.96 | (10.86, 13.06) | | |
| | 3Mo | 10.18 | (9.06, 11.31) | 12.06 | (10.72, 13.40) | | |
| | 6Mo | 9.86 | (8.35, 11.37) | 11.32 | (9.12, 13.52) | | |
| **MOOD** (TDS-Negative Affectivity) | PRE | 11.15 | (9.56, 12.75) | 12.53 | (10.65, 14.40) | .052* | |
| | POST | 10.96 | (9.28, 12.65) | 11.91 | (9.92, 13.91) | | |
| | 3Mo | 12.33 | (10.39, 14.28) | 11.89 | (9.52, 14.27) | | |
| | 6Mo | 13.13 | (10.36, 15.89) | 11.58 | (7.39, 15.78) | .023# | .26 |
| **MOOD** (TDS-Social Inhibition) | PRE | 17.03 | (15.45, 18.61) | 14.69 | (12.28, 17.09) | .109* | |
| | POST | 16.48 | (14.31, 18.65) | 13.91 | (11.14, 16.68) | | |
| | 3Mo | 17.67 | (15.89, 19.44) | 13.42 | (9.90, 16.94) | .016# | .709 |
| | 6Mo | 18.75 | (16.49, 21.01) | 15.33 | (9.78, 20.89) | .002# | .497 |

[a]Effect size (Cohen's d) calculated for the difference between the two interventions at (change from baseline) Post or Follow-up, respectively

*For Overall Effect of Treatment; # Time-Dependent Pairwise Comparisons

**Table 5: Unadjusted means (and 95% Confidence Intervals) of Sleep Diary Metric Comparisons between Mind-Body Bridging (MBB) and Sleep Education (SED) in OEF/OIF veterans with mTBI.**

| | | SED | | MBB | |
|---|---|---|---|---|---|
| **OUTCOME MEASURE** | **Period** | **Mean** | **95% CI (lower, upper)** | **Mean** | **95% CI (lower, upper)** |
| **Number of Awakenings** | PRE | 2.31 | (1.66, 2.95) | 2.55 | (2.05, 3.07) |
| | POST | 1.83 | (1.47, 2.21) | 2.37 | (1.78, 2.98) |
| | 3Mo | 2.09 | (1.46, 2.72) | 2.22 | (1.55, 2.90) |
| | 6Mo | 1.96 | (1.5, 2.36) | 2.59 | (1.71, 3.47) |
| **Time out of Bed** (minutes) | PRE | 43.10 | (24.49, 61.72) | 64.49 | (46.56, 82.41) |
| | POST | 49.69 | (31.69, 67.70) | 59.33 | (37.84, 80.82) |
| | 3Mo | 48.04 | (26.11, 69.98) | 58.41 | (30.18, 86.65) |
| | 6Mo | 47.47 | (21.39, 74.18) | 58.83 | (24.79, 82.88) |
| **Sleep Onset Latency** (minutes) | PRE | 70.15 | (53.66, 86.64) | 54.60 | (44.91, 64.30) |
| | POST | 77.21 | (53.96, 100.46) | 53.95 | (34.69, 73.21) |
| | 3Mo | 47.92 | (24.95, 70.90) | 47.45 | (36.03, 58.88) |
| | 6Mo | 68.66 | (37.97, 99.37) | 44.12 | (28.83, 59.48) |
| **Sleep Duration** (hours:min) SD in minutes | PRE | 6:04 | (319.8, 409.05) | 5:46 | (315.00, 378.59) |
| | POST | 6:18 | (335.81, 421.48) | 5:47 | (338.00, 422.73) |
| | 3Mo | 7:13 | (373.11, 494.30) | 6:12 | (309.11, 436.09) |
| | 6Mo | 6:04 | (325.11, 402.04) | 6:23 | (320.28, 446.96) |
| **Sleep Efficiency** (sleep duration/time tried to sleep) | PRE | 71.16 | (64.37, 77.95) | 67.67 | (62.34, 72.99) |
| | POST | 69.86 | (63.57, 76.16) | 71.04 | (63.04, 79.04) |
| | 3Mo | 74.95 | (66.69, 83.21) | 70.02 | (61.39, 78.67) |
| | 6Mo | 72.10 | (62.11, 82.09) | 71.87 | (62.87, 80.88) |
| **Sleep Quality** | PRE | 2.44 | (2.18, 2.72) | 2.47 | (2.12, 2.83) |
| | POST | 2.49 | (2.08, 2.92) | 3.02 | (2.56, 3.49) |
| | 3Mo | 2.85 | (2.29, 3.43) | 3.26 | (2.47, 4.05) |
| | 6Mo | 2.54 | (1.75, 3.34) | 2.55 | (1.48, 3.74) |

**Table 6: Unadjusted means (and 95% Confidence Intervals) of Sleeping Actigraphy Data Comparisons between Mind-Body Bridging (MBB) and Sleep Education (SED) in OEF/OIF veterans with mTBI.**

| | | SED | | MBB | |
|---|---|---|---|---|---|
| **OUTCOME MEASURE** | **Period** | **Mean** | **95% CI (lower, upper)** | **Mean** | **95% CI (lower, upper)** |
| **Time in Bed** | PRE | 8:30 | (7:18, 9:42) | 7:30 | (6:27, 8:33) |
| | POST | 7:44 | (6:52, 8:35) | 7:22 | (5:53, 8:51) |
| | 3Mo | 6:20 | (5:33, 7:07) | 7:30 | (6:13, 8:47) |
| **Actual Sleep Time** | PRE | 7:22 | (6:40, 8:04) | 7:04 | (6:03, 8:05) |
| | POST | 7:01 | (6:14, 7:48) | 6:50 | (5:32, 8:09) |
| | 3Mo | 5:52 | (5:07, 6:38) | 6:40 | (5:11, 8:09) |
| **Longest Sleep Time** | PRE | 1:02 | (0:51, 1:12) | 1:18 | (0:37, 1:59) |
| | POST | 0:56 | (0:50, 1:03) | 1:26 | (0:51, 2:01) |
| | 3Mo | 1:04 | (0:51, 1:16) | 1:50 | (0:25, 3:14) |

**Table 7: Unadjusted means (and 95% Confidence Intervals) of Salivary Alpha-Amylase and Cortisol Secretion between Mind-Body Bridging (MBB) and Sleep Education (SED) in OEF/OIF veterans with mTBI.**

| | | Cortisol (nmol/L) | | | sAA (Umol/mL) | | |
|---|---|---|---|---|---|---|---|
| **Intervention** | **Collection time** | **PRE** | **POST** | **3Mo** | **PRE** | **POST** | **3Mo** |
| **SED** | Awake | 9.56 (7.56, 11.56) | 7.42 (5.57, 9.27) | 7.32 (5.50, 9.14) | 49.47 (30.50, 68.43) | 43.86 (23.48, 64.23) | 43.34 (28.98, 57.71) |
| | Post-awake | 11.26 (8.28, 14.24) | 10.16 (6.81, 13.51) | 10.52 (6.69, 14.34) | 53.00 (33.66, 72.35) | 43.11 (22.30, 63.91) | 42.35 (17.95, 66.75) |
| | Noon | 2.65 (2.05, 3.25) | 2.66 (1.97, 3.36) | 2.28 (1.59, 2.97) | 104.24 (73.15, 135.54) | 100.79 (55.15, 146.44) | 80.74 (47.21, 114.28) |
| | Evening | 1.01 (.55, 1.47) | 0.87 (.54, 1.19) | 1.19 (0.46, 1.92) | 72.59 (54.32, 90.87) | 86.99 (38.97, 135.00) | 55.83 (35.93, 75.72) |
| **MBB** | Awake | 6.57 (5.18, 7.96) | 7.45 (5.54, 9.37) | 7.32 (5.50, 9.14) | 106.71 (56.73, 156.68) | 66.92 (40.76, 93.08) | 81.00 (34.46, 125.55) |
| | Post-awake | 11.02 (8.58, 13.46) | 9.32 (6.66, 11.97) | 9.29 (6.78, 11.81) | 61.33 (31.42, 91.25) | 59.95 (28.35, 91.55) | 40.44 (23.51, 57.35) |
| | Noon | 3.72 (2.89, 4.56) | 4.18 (2.06, 6.30) | 4.23 (3.10, 5.35) | 119.81 (75.40, 164.23) | 124.71 (86.08, 163.35) | 98.98 (55.94, 141.91) |
| | Evening | 2.01 (.99, 3.02) | 1.42 (.60, 2.24) | 1.79 (.78, 2.80) | 83.51 (59.93, 107.09) | 92.41 (71.35, 113.50) | 101.94 (51.49, 152.39) |

**Table 8: Comparison of changes in physical and psychological symptoms at post-intervention clinical evaluation between SED and MBB in OEF/OIF Veterans.**

| | SED | | MBB | |
|---|---|---|---|---|
| | No. participants | Percentage | No. participants | Percentage |
| **PHYSICAL CONDITION** | | | | |
| **Worsened** | 1 | 4.35 | 1 | 5.26 |
| **No Change** | 17 | 73.91 | 16 | 84.21 |
| **Improved** | 5 | 21.74 | 2 | 10.53 |
| **No Assessment** | (+3) | | (+5) | |
| **TOTAL** | 23(+3) | | 19(+5) | |
| **SLEEP** | | | | |
| **Worsened** | 1 | 4.00 | 2 | 8.70 |
| **No Change** | 11 | 44.00 | 8 | 34.78 |
| **Improved** | 13 | 52.00 | 13 | 56.52 |
| **No Assessment** | (+1) | | (+1) | |
| **TOTAL** | 25(+1) | | 23(+1) | |
| **PAIN** | | | | |
| **Worsened** | 0 | 0.00 | 0 | 0.00 |
| **No Change** | 5 | 19.23 | 8 | 33.33 |
| **Improved** | 21 | 80.77 | 16 | 66.67 |
| **TOTAL** | 26 | | 24 | |
| **POSTCONCUSSIVE SYMPTOMS** | | | | |
| **Worsened** | 4 | 16.00 | 2 | 9.09 |
| **No Change** | 15 | 60.00 | 11 | 50.00 |
| **Improved** | 6 | 24.00 | 9 | 40.91 |
| **No Assessment** | (+1) | | (+2) | |
| **TOTAL** | 25(+1) | | 22(+2) | |

| | | | | |
|---|---|---|---|---|
| **PSYCHOLOGICAL STATE** | | | | |
| **Worsened** | 2 | 7.69 | 0 | 0 |
| **No Change** | 12 | 46.15 | 4 | 16.67 |
| **Improved** | 12 | 45.15 | 20 | 83.33 |
| **TOTAL** | 26 | | 24 | |

# APPENDIX A. SALIVA COLLECTION

## Procedure and times of collection

For this saliva collection, you will use the saliva collecting device (Salivette) that is made up of two plastic vials one inside the other, and a plastic cap. The inner vial holds a cotton swab that is removed from the vial and placed in your mouth to collect saliva. You will replace the cotton swab in the inner vial. You will collect saliva 8 times over 2-day period as shown below.

**Before collecting saliva, we ask that you follow the instructions carefully.**

*Please try to follow these precautions:*

- **No eating or drinking (besides water)** one hour before each collection.
- If you **mistakenly eat or drink** something, please rinse your mouth thoroughly with water immediately thereafter (**this must be at least ten minutes prior to saliva collection**).
- **Especially critical to avoid are: high sugar foods (e.g., sodas), acidic foods** (e.g., orange juice), and **dairy products**.
- **No alcohol** 24 hours before and during saliva collection (72 hours total).
- **Do not brush teeth** before collection.
-

Procedure:

1. Remove the cap.
2. Take the cotton swab out of the inner container and place it in your mouth.
3. Swish it around in your mouth for 2 minutes, being sure to move it from side to side, and up and down (do not chew on it).
4. Take the cotton swab out your mouth and place it in the inner tube of the salivette. With practice you will be able to insert the cotton swab into the inner tube without the use of your hands.
5. Replace the cap and as soon as possible place the saliva container in the Ziploc bag provided and put the bag in the freezer.
6. **On the day of the FIRST STUDY SESSION, please bring with you the Ziploc bag containing all 8 collecting tubes and give it to a study team member.**

Collection Times of Day

The collection times are as follows and we appreciate you sticking to these as close as possible. Again, please write the collection time on the corresponding tube.

Collection Times:

| | | |
|---|---|---|
| **Day1:** | **Container 1** | Morning, immediately upon a wakening, before getting out of bed<br><br>Approx. Time Collected:_____ |
| | **Container 2** | Morning, 30 minutes after getting out of bed<br><br>Approx. Time Collected:_____ |
| | **Container 3** | Noon 12 PM<br><br>Approx. Time Collected:_____ |
| | **Container 4** | Evening 10 PM<br><br>Approx. Time Collected:_____ |
| **Day2:** | **Container 5** | Morning, immediately upon a wakening, before getting out of bed<br><br>Approx. Time Collected:_____ |
| | **Container 6** | Morning, 30 minutes after getting out of bed<br><br>Approx. Time Collected:_____ |
| | **Container 7** | Noon 12 PM<br><br>Approx. Time Collected:_____ |
| | **Container 8** | Evening 10 PM<br><br>Approx. Time Collected:_____ |

## Appendix B. Actiwave Cardio Device Participant Instructions:

After the medical and psychological evaluations have finished, you will be given a non-invasive sleep activity and heart rate monitor that you will wear for **two consecutive nights**. This will be used to measure your nighttime sleep and activity patterns. You will wear this monitor at the same time that you will do your sleep diary and collect your saliva samples (see below).

*Procedure*: After the medical and psychological evaluations, the study team will attach the monitor to your chest (see picture). If you are a male and have hair on your chest, we would like you to shave your chest before you attend the evaluation. If you have not done so, the study team can do this for you or give you a razor to do so yourself. We need to shave only two sections of your chest where we place the monitor as shown in the picture. Please note that we cannot attach the monitor if you don't agree to shave your chest.

The first thing we will do is to clean the skin with an alcohol prep pad. After it dries, we will stick on two electrode pads to your skin. One electrode pad will be stuck onto the middle of the chest lower down close to the breastbone (or sternum), as in the picture. The second electrode pad will be attached below the left breast towards the left side of your body. For female Veterans, we will have a female study team member attach the electrodes and the monitor. You will wear the monitor for two nights. We will set the monitor to start recording on the first night. It will record for the whole of the next day and night. The recording will end by the evening of the 3rd day. We will make arrangements with you for someone to come collect the monitor and take off the electrode pads. If this is not feasible, we will make other arrangements with you.

The electrode pads should not cause any discomfort when worn. There is a possibility of some slight temporary itchiness around the attachment site, but this should subside quickly. In the event that you experience severe discomfort, you should remove the electrode pads immediately. If you have sensitive skin, please let us know so that we can make other arrangements or find more suitable electrode pads for you to wear.

It is critically important that the device is attached to the pads and doesn't loosen from your body over the two-night period. Please make sure that the device is properly attached at all times during data collection period.

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**Addendum for W81XWH-12-1-0385_FinalReport**

We would like to submit an Addendum for the final report (W81XWH-12-1-0385_FinalReport.pdf) that was submitted on May 31, 2018 at https://ers.amedd.army.mil/.

The following two sections, Key Research Accomplishments and Reportable Outcomes, were identified as missing from the above final report, and therefore we wish to submit this addendum document to complete the final report requirements.

## KEY RESEARCH ACCOMPLISHMENTS

The key research accomplishments emanating from this project includes the following:

- To date there are only a few studies in the published literature reporting impacts of mind-body interventions on various symptoms experienced by Veterans suffering from mind Traumatic Brain Injury (mTBI). Our project aimed to help expand this knowledge base, by conducting a randomized controlled trial of a mind-body sleep-focused intervention against an active control intervention (patient education program for sleep management, combined with support group format).
- Our project needed to identify an effective identification strategy for recruitment of Veterans with mTBI. We collaborated with the Poly-Trauma Clinic at the VA Salt Lake City Health Care System (VASLCHCS) to seek and identify mTBI Veterans who were suffering from disturbed sleep at the time of our screening process. This strategy was adequate, although the number of Veterans recruited into this study was smaller than we originally aimed for.
- The project was awarded a no-cost extension year in order to continue patient recruitment and allow for study-related operations for interventions and assessments.
- Although the project did not receive the requested second no-cost extension year, the project was awarded a no-cost closeout extension during which all study-related operations and patient recruitment could be terminated, while completing data collection form those Veterans who were participating in certain specific phases of the study operation (post-assessment, follow-up assessment, etc.).
- Despite a smaller-than-planned sample size of our completed study (as of Feb, 2018), our research was able to generate findings that two brief intervention programs were able to improve sleep among mTBI Veterans, even though these programs are only 3 weeks long.

- The mind-body intervention improved sleep more significantly than the control intervention, suggesting that this mind-body intervention program should be further investigated in future clinical studies.
- Where resources are limited, our brief patient education program for sleep management might serve as an effective psychosocial treatment program for mTBI Veterans suffering from disturbed sleep.
- Lastly, our mind-body intervention had additional impacts by improving other co-occurring symptoms that were typically experienced by mTBI Veterans.
- Targeting disturbed sleep might serve as an effective front-loaded intervention program for returning OEF and OIF Veterans.

## REPORTABLE OUTCOMES

We here present a list of reportable outcomes that have resulted from this research including:

- Manuscripts, abstracts, presentations: None yet. A manuscript reporting study findings is under development.
- Patents and licenses applied for and/or issued: Not applicable.
- Degrees obtained that are supported by this award: Not applicable.
- Development of cell lines, tissue, or serum repositories: Not applicable.
- Informatics such as databases and animal models: Not applicable.
- Funding applied for based on work supported by this award: None yet.
- Employment or research opportunities applied for and/or received based on experience/training supported by this award: A research data analyst who worked on the awarded project during the last year has been accepted into a neuroscience program at the University of Iowa, and he will be starting his graduate study in the Fall of 2018.