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UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science

ACUPUNCTURE FOR SLEEP DISTURBANCE IN VETERANS WITH POST TRAUMATIC
STRESS DISORDER

by

Heather C. King

A dissertation presented to the
FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCES
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In partial fulfillment of the
requirements for the degree
DOCTOR OF PHILOSOPHY IN NURSING
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Abstract

Post Traumatic Stress Disorder (PTSD) has emerged as a significant problem among Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans. Disturbed sleep is one of the most frequently reported symptoms among OEF/OIF veterans with PTSD. PTSD itself is impairing, but the burden of this disorder is likely heightened when accompanied by sleep disturbances. Sleep disturbances have been associated with a 75-90% increased risk of co-morbid conditions, increased levels of depression and anxiety, daytime sleepiness and fatigue, reduced psychomotor performance, diminished work productivity, and decreased quality of life. These consequences of disturbed sleep emphasize the critical need for additional evidence based therapies to treat PTSD related sleep disturbances among OEF/OIF veterans with PTSD.

Increasingly, non-pharmacologic therapies are being investigated for sleep disturbance among PTSD patients. However, few investigations have examined the efficacy of Complementary and Alternative (CAM) therapies on sleep disturbances among veterans with PTSD. CAM practices are emerging in the Department of Defense, yet, there are a limited number of well designed methodologically sound studies to investigate CAM therapies.

The overall purpose of this study was to conduct a small scale feasibility study to examine whether the use of an auricular acupuncture regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. Our approach was to conduct a small scale feasibility study to test the acceptability of an auricular acupuncture regimen for sleep disturbance, examine feasibility of study design, and test efficacy of an auricular acupuncture regimen for sleep disturbance among OEF/OIF veterans with PTSD.

Keywords: auricular acupuncture, OEF.OIF veterans, PTSD, sleep disturbance

Dedication

This work is dedicated to veterans who served in Operation Iraqi Freedom and Operation Enduring Freedom. These veterans embody honor, courage, and commitment. Their service and sacrifice allows our country and its citizens to enjoy living in a free country. Unfortunately, many of these veterans suffer from Post Traumatic Stress Disorder (PTSD) and Sleep Disturbances. The ramifications of this PTSD can be devastating to veterans and their families. New and improved treatments for veterans with PTSD are discovered only through scholarly inquiry, and my dissertation research is dedicated to improving the health of those veterans with PTSD entrusted to our care.

Acknowledgements

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Table of Contents

Chapter 1: PROBLEM

Page

Significance.....	1
Theoretical Perspective.....	8
Purpose, Specific Aims & Hypothesis.....	11

Chapter 2: REVIEW OF THE LITERATURE

Background.....	14
Sleep Disturbance among Veterans with PTSD.....	15
Auricular Acupuncture History.....	16
Proposed Mechanisms of Action for Acupuncture.....	18
Previous Research of Auricular Acupuncture as a Sleep Directed Intervention.....	20
Military Relevance.....	21

Chapter 3: METHODOLOGY

Research Design & Specific Aims.....	23
Sample.....	24
Setting.....	26

Subject Recruitment.....	26
Informed Consent.....	27
Data Collection Procedures.....	28
Sham Acupuncture.....	32
Instrumentation.....	32
Statistical Analysis.....	44
Protection of Human Subjects.....	47
Protection of Patient Privacy.....	47
Study Limitations.....	48
References.....	49

Chapter 4: **MANUSCRIPTS**

Manuscript I: Tri-Service Nursing Research Program Graduate Award Proposal....	70
Manuscript I: Abstract.....	71
Manuscript I: Research Plan.....	73

Manuscript I: References.....	103
Manuscript II: Auricular Acupuncture: A Brief Introduction for Military Providers.....	120
Manuscript II: Abstract.....	121
Manuscript II: Reference.....	122
Manuscript III: Auricular Acupuncture for Sleep Disturbance in Veterans with Post Traumatic Stress Disorder: A Feasibility Study.....	123
Manuscript III: Abstract.....	124
Manuscript III: References.....	158

List of Tables and Figures

Chapter 1, Figure 1: Symptom Management Theory.....	8
Chapter 1, Figure 2: Adapted Symptom Management Theory.....	11
Chapter 3, Figure 3: Insomnia Auricular Acupuncture Protocol.....	30
Chapter 3, Table I: Definition of Sleep Measures.....	42
Chapter 3, Table II: Instrumentation for Study.....	43
Manuscript I, Figure 1: Symptom Management Theory.....	81
Manuscript I, Figure 2: Adapted Symptom Management Theory.....	82
Manuscript I, Figure 3: Insomnia Auricular Acupuncture Protocol.....	89
Manuscript I, Table I: Definition of Sleep Measures.....	97
Manuscript I, Table II: Instrumentation for Study.....	98
Manuscript III, Table I: Demographic Data.....	138
Manuscript III, Figure 1: Consort Diagram.....	140
Manuscript III, Figure 2: Acceptability of Auricular Acupuncture.....	142
Manuscript III, Table II: Actigraphy and Sleep Diary Analysis.....	143

Manuscript III, Table III: PSQI Mean Scores at Week Five.....	144
Manuscript III, Figure 3: PSQI Global Scores Between Groups.....	145
Manuscript III, Figure 4: PSQI Component Sleep Quality Interaction.....	146
Manuscript III, Figure 5: PSQI Component Day Time Dysfunction Interaction.....	147
Manuscript III, Figure 6: PCL Group Means at Week Five.....	148
Manuscript III, Figure 7: PHQ Group Means at Week Five.....	149
Manuscript III, Figure 8: PCL Group Means at Three Time Points.....	150
Manuscript III, Figure 9: PHQ Group Means at Three Time Points.....	151

List of Appendices

Appendix A: Research Participant Consent Form.....	167
Appendix B: Demographic Questionnaire.....	176
Appendix C: STOP Bang Questionnaire.....	178
Appendix D: Consensus Sleep Diary.....	180
Appendix E: Pittsburgh Sleep Quality Index.....	181
Appendix F: Post Traumatic Stress Disorder Checklist Military Version.....	185
Appendix G: Patient Health Questionnaire.....	187
Appendix H: Feedback Questionnaire.....	188
Appendix I: Approval of Clinical Investigation Study NMCS.D.2012.0053	189

Chapter 1: INTRODUCTION AND SIGNIFICANCE

Since September 11, 2001 approximately 2 million troops have deployed to the Middle East in support of the Global War on Terrorism as a part of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF).¹ Among troops returning from OEF/OIF, Post Traumatic Stress Disorder (PTSD) has emerged as a significant health problem. Although estimates of PTSD prevalence vary widely from 1.4%–43% (depending on PTSD assessment method and sampling methods utilized),²⁻⁷ estimates of the overall prevalence of PTSD following deployment in support of OEF/OIF appear to be approximately 15% or greater in non-treatment seeking individuals.⁸ A majority of these veterans (70-90%) will report difficulty maintaining or initiating sleep,⁹ and significant sleep disturbances can have a considerable impact on health status,¹⁰ as well as overall quality of life.^{11, 12} Further, sleep disruptions among individuals with PTSD are increasingly believed to negatively affect the ability to recover from PTSD,¹³ and quality sleep is viewed as a critical component to facilitate emotional processing of traumatic events.¹⁴ While effective first line treatments for PTSD such as cognitive behavior based psychotherapies and pharmacotherapies have been shown to improve sleep quality in several studies, the vast majority of PTSD treatment studies do not report sleep outcome measures. This is concerning due to a recent investigation which reported up to 50% of patients in PTSD remission will continue to experience sleep disturbance long-term.¹⁵ A growing number of studies examining supplemental sleep directed interventions to improve sleep quality among veterans with PTSD are emerging in the literature emphasizing the need for additional evidence based therapies to treat PTSD related sleep disturbance. The purpose of this research will be to

conduct a small scale feasibility study to examine whether the use of a three week auricular acupuncture regimen improves quality of sleep for OEF/OIF veterans diagnosed with PTSD and self-reported sleep disturbance.

Congressional Mandate to Study PTSD

PTSD among OEF/OIF veterans has become a national priority as numerous investigations and government reports have informed the public, clinicians, researchers, and legislators the significance of the emerging problem of PTSD in the current generation of veterans.^{16, 17} This has resulted in important legislation such as the Dignified Treatment of Wounded Warriors Act of 2007 which funds an extensive range of services for all wounded warriors, provides for improved training of health care professionals, medical care case managers, service member advocates (section 108), and PTSD research (section 115).¹⁸ Notably, since 2006 the National Defense Authorization Act has made various provisions for PTSD and mental health (*National Defense Authorization Act Fiscal Year 2007, 2008, 2009, 2010, and 2011 Act FY11*) and has further directed Defense Centers of Excellence to conduct research, evaluate, and disseminate evidenced based practices, as well as integrate knowledge into standards of treatment in the care of veterans with mental health conditions.¹⁹ Considerable resources and effort are being allocated to address PTSD among OEF/OIF veterans; however, PTSD is complex disorder, and the distressing symptoms that accompany it continue to warrant further investigation.

PTSD and Sleep Disturbance

Essential features of PTSD center around the development of characteristic symptoms or symptom clusters following an exposure to a traumatic event. These symptoms are arranged in four clusters which include: intrusion, avoidance, negative alterations in cognitions and mood, and alterations in arousal and reactivity.²⁰ According to the Diagnostic and Statistical Manual of Mental Disorders, sleep disruptions are frequently reported among those affected with PTSD, and sleep disturbance is both a specific intrusion symptom and altered arousal symptom listed in the DSM-V diagnostic criteria for PTSD.²⁰ PTSD sleep disturbances frequently include distressing dreams or nightmares (characteristic intrusion symptom), and difficulty falling asleep (characteristic alteration in arousal and reactivity symptom).^{20, 21} Previous research demonstrates that disturbed sleep after exposure to a traumatic event is a risk factor for the development of PTSD^{22, 23} however, the exact relationship of how sleep disturbances evolve and affects those individuals with PTSD is not fully understood. Debate exists whether sleep disturbance is a secondary symptom of PTSD, a residual symptoms that develops after PTSD treatment, or mediates PTSD symptoms.²⁴ Up until recent years, mental health care providers viewed sleep disturbance among individuals with PTSD as a secondary symptom of PTSD.²⁴ Therefore, treatment of PTSD symptoms including sleep disturbances, were targeted with evidenced based treatments for PTSD, and did not specifically target or monitor sleep disturbances.²⁴ However, as mentioned earlier, sleep disturbance frequently persists after successful treatment of PTSD leaving questions as to why sleep disturbance persists with resolution of other PTSD symptoms.^{15, 25} A second view of sleep disturbance among those affected with PTSD is that sleep disturbance develops into a separate disorder and should be treated with evidenced based treatments for insomnia. This approach to sleep disturbance is commonly utilized to treat

individuals with sleep disturbance after PTSD treatment, however, few studies (especially longitudinal studies) have evaluated the effectiveness of insomnia treatment strategies such as sleep hygiene education, stimulus control, and commonly prescribed sleep medications. A third view of sleep disturbance among those affected with PTSD sleep disturbance among those with PTSD is that sleep disturbance mediates PTSD symptoms²⁴ and the two entities may be intimately intertwined as targeted sleep directed interventions for sleep disturbance among individuals with PTSD frequently improves PTSD symptoms²⁶⁻²⁸ raising more questions as to the relationship between sleep and PTSD. This latter concept seems to be increasingly popular as more investigations focus on supplemental sleep directed interventions for those affected with PTSD.

Recently, pharmacotherapies used in treating PTSD related sleep disturbance such as prazosin have shown promising results to improve sleep parameters such as increased sleep quality,²⁹ increased sleep time,³⁰ and reduced nightmares.^{29, 30} However, medications can be accompanied by potential side effects, and many patients prefer non pharmacologic treatments for PTSD.³¹ Non pharmacologic interventions such as cognitive behavior therapies (CBT-I) have been reported to provide better long term improvement of sleep parameters for primary insomnia patients.³² Other non-pharmacologic interventions focused on relaxation, re-scripting, and mind body work have shown promising results to improve insomnia, particularly among those affected with PTSD.^{26, 28, 33, 34} Few investigations have focused on complementary and alternative therapies or techniques to examine the effects on PTSD related sleep disturbance. In particular, acupuncture has been reported to improve insomnia³⁵⁻³⁷ however, there is a paucity of studies investigating the use of acupuncture as a sleep directed intervention for PTSD among OEF/OIF veterans. In light of the current prevalence of PTSD, and its effects on sleep among OEF/OIF

veterans, investigating interventions to improve sleep quality in this population, is crucial to ameliorate immediate distress caused by sleep disturbances and avoid long term adverse health consequences associated with sleep disturbance.

Mechanism of Sleep Disturbance in PTSD

Rapid eye movement (REM) sleep is characterized by periods of rapid eye movements, low voltage EEG, low muscle tone, and dreams.³⁸ REM sleep regulation is not fully understood, but is believed to occur by neurons located in the brainstem.³⁸ Some researchers have proposed REM sleep as an alternating cycle between “REM-on” (cholinergic/glutamatergic neurons) and “REM-off” neurons (aminergic neurons).³⁹ This alternating cycle of REM sleep may be disrupted among individuals with PTSD due to an increased noradrenergic outflow, and in particular increased levels of norepinephrine (aminergic neurotransmitter).^{24, 40} This increased noradrenergic outflow is believed to innervate multiple structures in the brain including the hypothalamus, amygdala, prefrontal cortex, and other limbic structures via the locus coeruleus which may contribute to the hyperarousal and re-experiencing symptoms of PTSD and play a role in the disruption of the alternating REM cycles of cholinergic and aminergic neurons.^{24, 41, 42} REM sleep disturbances were proposed by Ross et al. over two decades ago to be the hallmark of PTSD, and central to its pathology.⁴³ Subsequently, numerous investigators examined objective measures (polysomnography and actigraphy) of sleep among subjects with PTSD. However, these studies have yielded inconsistent results. While some investigators have found significant differences in objective sleep parameters (i.e. decreased sleep onset, decreased sleep efficiency, decreased total sleep time, decreased slow wave sleep, and decreased rapid eye movement)

among PTSD subjects when compared to control groups;^{44, 45} other investigators have not found significant differences in objective sleep measures.⁴⁶⁻⁴⁸ A recent meta-analysis by Kobayashi et al. reviewed 20 studies utilizing polysomnography with PTSD subjects (including civilian & veteran PTSD) found that individuals with PTSD had increased stage 1 sleep, decreased slow wave sleep, and an increase in REM density as compared to individuals without PTSD.⁴⁹ Four moderating variables were also examined in this meta-analysis (age, gender, co-morbid depression, and substance abuse) and reported to contribute to sleep differences between PTSD subjects and controls.⁴⁹ For example, when compared to aged matched controls, younger PTSD subjects (<42.4 years) were found to have lower total sleep times, and older PTSD subjects had decreased slow wave sleep and increased REM sleep.⁴⁹ Male PTSD subjects were found to have shorter total sleep time, stage II sleep, increased sleep onset latency, and greater REM density.⁴⁹ The comorbid factor substance abuse was found to decrease REM sleep and have a longer REM latency than PTSD subjects with no substance abuse, and surprisingly, increased sleep disturbances were found among subjects with lower rates of co-morbid depression.⁴⁹ These moderating variables may provide an explanation as to why results among objectively measured sleep studies in PTSD populations vary.

Complementary and Alternative Medicine among Veterans

Complementary and alternative (CAM) medicine has experienced rapid growth and utilization in mainstream healthcare over the last several years. It is estimated that 37% of the America population utilizes some form of CAM within a 12 month period,⁵⁰ and an estimated \$33.9 billion out-of-pocket dollars are spent on CAM therapies in a 12 month period.⁵¹

Similarly, recent estimates of military populations have reported similar use rates of CAM therapies as the general population however; these therapies have only recently become available within Veterans Administration Healthcare facilities and Military Treatment facilities. In 2011, the Veterans Administration for Healthcare and the Veteran's Affairs Office of Research and Development reported on the need for CAM and PTSD research and revealed that 89% of VA facilities currently offer CAM therapies as compared to 84% in 2002.⁵² The VA reports that CAM therapies have been incorporated into VA hospitals to promote wellness and accommodate patient preference for CAM therapies⁵² and are in line with the VA/Department of Defense PTSD clinical treatment guidelines to offer referral for complementary and alternative modalities when available.⁵³

CAM practices have similarly increased within Military Treatment Facilities and are being offered to veterans and their families.⁵⁴⁻⁵⁶ In particular, the practice of acupuncture in Military Treatment Facilities has been well received among veterans, and has been used for a wide variety of health concerns such as: back pain, headaches, stress, sleep disturbance, anxiety, etc.^{55, 56} The use of acupuncture within military settings largely expanded due to the introduction of the auricular acupuncture protocol "battlefield acupuncture." This treatment was developed by Colonel Richard Niemtzow in 2008.⁵⁷ Colonel Niemtzow brought attention to the need for practical alternative techniques for pain relief and other physical complaints among deployed veterans and has educated military physicians, nurses, corpsmen, and medics in auricular acupuncture techniques.⁵⁷ Although the battlefield acupuncture protocol was designed to reduce pain among veterans in operational military settings, similar auricular acupuncture protocols exist for insomnia. Previous research has demonstrated that auricular acupuncture improves sleep measures; however, the results of these investigations are limited by poor methodological

designs and lack the use of objective outcome measures.⁵⁸⁻⁶⁰ The proposed study will attempt incorporate more rigorous study methods, objective sleep measures, and evaluate the feasibility of the study design.

Theoretical Perspective: Symptom Management Theory

The Symptom Management Theory (SMT) as described by Humphreys et al., (2008) will be used to inform the proposed study (figure 1).

Figure 1. Symptom Management Model. *Humphreys, J. et al., in Smith, M.J. and Liehr, P.R. (eds., 2008). Middle Range Theory for Nursing, Chapter 8. Theory of Symptom Management. New York: Springer Publishing Company.*

The Symptom Management Theory (SMT) is a middle range theory which three dimensions of symptom management are conceptualized and depicted in relationship to one another.⁶¹ The three concepts included in this theory include: symptom experience, symptom

management, and symptom outcomes, and are framed in the dimensions of nursing science: person, environment, and health and illness.⁶² Effective symptom management can only be attained through the careful consideration of each of the symptom dimensions.⁶¹ The SMT is based on five assumptions which include:

(1) the gold standard for understanding and studying symptoms is the perception of the individual experiencing the symptom and the individual's report of the experience; (2) the symptom need not be experienced by an individual in order for the symptom management model to be applied since the individual can be at risk for symptom development from the impact of a context variable such as a work hazard and intervention strategies can be initiated before the symptom is experienced by the individual; (3) nonverbal patients such as infants or post stroke aphasic individuals may experience symptoms where the interpretation by a parent or caregiver is accepted as accurate for intervention purposes since all troublesome symptoms need to be managed; (4) the target of management strategy can be the level of the individual, group, family, or work environment; (5) symptom management is a dynamic process in that it is modified by individual outcomes and the influences of the three nursing domains of person, health/illness, and environment.⁶¹

The first concept of symptom experience includes three inter related subdivisions which include simultaneous perception of symptoms, evaluation of symptoms, and response to symptoms by the individual.⁶² Symptom experience may include one symptom, or clusters of symptoms experienced by the individual.⁶³ As noted in the assumptions, it is essential to include the individuals report or perception of symptoms in the symptom experienced concept. The second concept of this model are symptom strategies which aim to avert, delay, or minimize

symptoms⁶² and should aim to reduce frequency, severity, and distress associated with symptoms.⁶⁴ The last concept of the theory is symptom outcomes. Symptoms outcomes are to be clear and measurable following a symptom management strategy and can include change in symptom frequency, intensity, or level of distress. It is thought that by improving symptoms, functional status of an individual can be improved. Bidirectional arrows indicate simultaneous interaction between concepts within the model.⁶²

The proposed study will focus primarily on the sleep disturbance symptom of veterans with PTSD, and use an auricular acupuncture regimen as a supplemental symptom management strategy to examine if this strategy is effective to improve quality of sleep in this population. Sleep disturbance symptoms will be evaluated based on self-reported measures on the Pittsburgh Sleep Quality Index (PSQI) as well as objective measures by actigraphy in conjunction with sleep diaries (symptom experience domain). The use of demographic information (represented at “person” in the nursing domain of the model) will also be examined in this sample of veterans. Additionally, subjective sleep disturbance symptoms as reported on the PSQI, and objective measures of sleep disturbance (actigraphy in conjunction with sleep diaries) will be examined prior to and after the intervention between the intervention and control group as outcome measures. Secondly, PTSD symptoms and depressive symptoms experienced by subjects will be evaluated based on self-reported measures on the PTSD Checklist Military Version (PCL-M) and the Patient Health Questionnaire 9 (PHQ-9) at baseline, week one, two, three, four, and five. These symptoms have been included in this investigation as they are likely closely associated with sleep disturbance. While the environment and health and illness domains are very important domains of this model and this population of subjects, they will not be included in this study for feasibility reasons.

Figure 2. Symptom Management Model adapted for the current study “Acupuncture for Sleep Disturbance in OEF/OIF veterans with Post Traumatic Stress Disorder (PTSD).”

Research Purpose

The purpose of this research will be to conduct a small scale feasibility study to examine whether the use of an auricular acupuncture regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. This proposal seeks to answer the following general research question: “What effect does auricular acupuncture have on sleep quality among OEF/OIF veterans with PTSD and self-reported sleep disturbances?”

Research Question #1: Is the use of an auricular acupuncture regimen for veterans with PTSD and self-reported sleep disturbance acceptable and feasible?

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an auricular acupuncture intervention study utilizing a consort diagram to track subject disposition throughout the study period.

Hypothesis #1: Subjects who receive auricular acupuncture will view it as a more acceptable treatment for sleep disturbance than those who receive standard therapy alone.

Research Question #2: Is there a difference in objective and subjective sleep disturbances and sleep quality at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI and sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #2: Objective and subjective sleep disturbances and sleep quality will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Research Question #3: Is there a difference in PTSD symptoms and depressive symptoms at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #3: Compare PTSD symptoms and depressive symptoms at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #3: PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Research Question #4: Is there a difference in PTSD symptoms and depressive symptoms during the study period between OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy?

Aim#4: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9) weekly during

the study period (baseline, week one, two, three, four, five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

Hypothesis #4: PTSD symptoms and depressive symptoms will be improved during the study period among OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Chapter 2: REVIEW OF THE LITERATURE

Background

PTSD was first included in the *Diagnostic and Statistical Manual of Mental Disorders Third Edition (DSM-III)* as a formal diagnosis in 1980.⁶⁵ Prior to that time, PTSD existed but was referred to as an assortment of names such as “shell shock”⁶⁶ or “traumatic neurosis”⁶⁷ to describe the symptoms that are currently utilized as diagnostic criteria for PTSD. The current *Diagnostic and Statistical Manual of Mental Disorders* is now in its fifth edition (DSM-V) and has made several revisions to the original criteria of PTSD.²⁰ PTSD is no longer classified as an anxiety disorder, but classified under a new class of disorders termed “trauma and stressor related traumas.”

Currently, a diagnosis of PTSD is made when characteristic symptom clusters are present for at least one month after exposure to a traumatic event. Eight specific criteria are utilized in order for a diagnosis of PTSD to be made. The first criterion is comprised of exposure to actual or threatened death, serious injury, or sexual violence or experiencing repeated traumatic events.²⁰ Traumatic exposure elements are specifically defined as: 1) a direct experience with a traumatic event, 2) witnessing in person traumatic events happening to others, 3) learning traumatic events have happened to close family members or friends, 4) experiencing repeated traumatic events.²⁰ The second criterion is the presence of at least one intrusion symptom related to the traumatic event which can include: 1) recurrent involuntary and intrusive memories, 2) recurrent distressing dreams, 3) dissociative reactions such as flashbacks, 4) intense or prolonged psychological distress, 5) marked physiological reactions to internal or external cues that symbolize a traumatic event.²⁰ The third criterion is at least one avoidance symptom to include:

1) efforts to avoid distressing memories thoughts or feelings about a traumatic event or 2) efforts to avoid external reminders that result in distressing memories of a traumatic event.²⁰ The fourth criterion is negative alterations in cognitions and mood associated with the traumatic event. This may occur in the following ways: 1) impaired memory of traumatic events, 2) persistent negative self-beliefs or expectations, 3) persistent distorted cognitions about the cause of the traumatic event, 4) persistent negative emotional state, 5) diminished interest in activities, 6) feelings of detachment from others and 7) inability to experience positive emotions.²⁰ The fifth criterion is at least two symptoms of marked alteration in arousal and reactivity associated with the traumatic event to include: 1) irritable behavior, 2) reckless or self destructive behavior, 3) hyper vigilance, 4) exaggerated startle response 5) impaired concentration, 6) sleep disturbance.²⁰ The sixth criterion is the duration of the symptoms must be present for at least one month. The seventh criterion is the symptoms must cause significant social, occupational, or other significant impairment.²⁰ The eight criterion is the symptoms must not be the result of the physiological effects of any substance.²⁰

PTSD and Sleep Disturbance Among Veterans

Post Traumatic Stress Disorder (PTSD) is common among veterans returning from Operation Iraqi Freedom and Operation Enduring Freedom and disturbed sleep is the most frequently reported symptom of PTSD among OEF/OIF veterans.⁶⁸ This finding is concerning because sleep disturbances frequently co-occur with a range of psychological problems,^{69, 70} and military members who self report the shortest duration of sleep hours were among those currently or previously deployed, and also reported symptoms of PTSD as well as other

psychological problems at follow-up assessment.⁶⁹ Research findings among Vietnam Veterans are consistent with these findings, and have shown that combat veterans commonly experience sleep disturbances,⁷¹ and sleep disturbances frequently occur prior to the onset of PTSD.^{22, 23, 72} Additionally, previous research has shown a consistent relationship between self-reported sleep disturbance, and PTSD symptoms, in which more severe sleep disturbances (self-reported by individuals with PTSD) have been associated with increased PTSD symptoms.²¹ Together these findings suggest that sleep disturbances are not only highly prevalent among veterans, but may be linked to the development and maintenance of PTSD.⁷³ Further, sleep disruptions among individuals with PTSD are believed to impair the ability to recover from PTSD,⁷⁴ and quality sleep is viewed as an important factor to facilitate emotional processing of traumatic events.⁷⁵ Thus, advancing research and clinical care for veterans with PTSD and sleep disturbance have the potential to have a cascading positive impact on healing and recovery from PTSD. Veterans affected with PTSD and sleep disturbance create complex health problems, but for the purposes of this dissertation, the overall focus will be on the use of auricular acupuncture for sleep disturbance among individuals with PTSD.

Auricular Acupuncture History

The history of auricular acupuncture can be divided according to two major perspectives: 1) ancient Chinese medicine (prior to the 20th century until the 1950's), and 2) contemporary auricular acupuncture (beginning in the 1950's).⁷⁶ The practice of ancient auricular acupuncture is referenced in the "Yellow Emperor's Classics of Internal Medicine," one of the oldest Chinese medical texts. Ancient auricular acupuncture was based in traditional Chinese medicine theory

and utilized ear acupoints which were believed to be connected to meridians. This use of ear acupoints relied on the meridian system of acupuncture and was primarily used to treat pain conditions.⁷⁷ Although the Chinese have documented the practice of auricular acupuncture dating back to the Chou period (first millennium BCE),⁷⁸ evidence of auricular acupuncture has been found in historical documents from Egypt, Greece, and Rome leaving an unclear origin of the practice of auricular acupuncture.⁷⁹ However, historically the Chinese people have widely practiced acupuncture as it has been a major modality treatment within Traditional Chinese Medicine.

In contrast, contemporary uses of auricular acupuncture are not dependent on the meridian system to function.⁷⁹ Rather, auricular acupuncture is viewed as micro-system that can affect the entire body.⁷⁹ This micro-system, maps all anatomic portions of the ear to specific parts of the body and internal organs. While this micro-system is independent of the meridian system, contemporary auricular acupuncturists contend that auricular acupuncture also influences the balance of yin and yang forces, regulates *qi* and blood and body fluids.⁷⁹

The auricular acupuncture micro-system was originally described by a French physician, Dr. Paul Nogier in the 1950's.⁸⁰ Dr. Paul Nogier's auricular acupuncture mapping was further investigated by Chinese researchers within the medical unit of the Chinese Nanking Army. The auricular acupuncture micro-system was used on thousands of patients, and substantiated Nogier's conceptualization of the somatotopic representation to the auricle.^{79, 81}

Since this early research was done on the auricular acupuncture micro-system, auricular acupuncture has been practiced worldwide and the nomenclatures of auricular acupuncture points have been standardized.⁸² Current auricular acupuncture practices consist of a variety of techniques to stimulate auricular acupoints. These techniques include: manual pressure, ear

tacks, needles, ear “seeds,” magnets, and electrically or laser stimulated needles placed to auricular acupoints. These techniques are utilized to treat a wide variety of health conditions.

Auricular Acupuncture Mechanisms of Action

The mechanisms of action of auricular acupuncture are not yet fully understood, however, several mechanisms are prevalent in current auricular acupuncture literature. The first mechanism of action for auricular acupuncture is based on recent evidence which indicates that effects of acupuncture occur through the central nervous system.⁸³ Images from both functional magnetic resonance imaging and positive emission tomography scans demonstrate a broad neuromatrix response involving limbic and limbic-related brain structures (amygdala, hippocampus, hypothalamus, cingulate cortex, prefrontal and insular cortices, basal ganglia, and cerebellum) after the placement of acupuncture needles.⁸³⁻⁸⁹ Many of the structures affected by acupuncture are also implicated in the pathophysiology of PTSD,⁹⁰ leading some researchers to speculate that acupuncture may be beneficial to improve PTSD symptoms.⁹¹ To date, only one pilot study has examined and reported improvements in PTSD symptoms after an acupuncture regimen,⁹¹ however, no sleep measures were reported in this investigation.

A second mechanism of action for auricular acupuncture is also based on previous research which has demonstrated that acupuncture increases endogenous opioid levels (enkephalins, endorphins, and dynorphins), and this finding has been supported in previous human⁹²⁻⁹⁴ and animal studies.^{95,96} These findings have largely supported the use of acupuncture as a pain intervention, and acupuncture is widely practiced for this purpose.⁹⁷ These findings relate to the proposed study in that the opioidergic system is also theorized to have a somnogenic

effect,^{98, 99} and may interact with melatonin to promote sleep.¹⁰⁰ Few studies have examined mechanisms of acupuncture in relation to sleep, and these findings and theories are presented here as a possible physiologic basis of how acupuncture may affect sleep.

A final mechanism of how auricular acupuncture may work is through the stimulation of nerves which innervate the external auricle. The external auricle is innervated by both spinal and cranial nerves. This innervation can vary among individuals, and can also present with overlapping distributions of innervations. However, most often the lobe is innervated by the greater auricular nerve (originating from the cervical plexus, C2 & C3), the helix, scaphoid fossa, superior crus, are innervated by the lesser occipital nerve (originating from the cervical plexus (C2 & C3), the spine of the helix, triangular fossa, tragus, and inferior crus are innervated by the auricular temporal nerve (originating from the trigeminal nerve, cranial nerve V), and the conchae and external auditory meatus are innervated by the auricular branch of the vagus nerve (cranial nerve X).¹⁰¹ This regional distribution of nerves to the ear provides a pathway for both parasympathetic (via the vagus nerve), and sympathetic nerve fibers (via the trigeminal nerve) to be stimulated.¹⁰¹

Although there is a paucity of evidence to demonstrate auricular acupuncture activates the sympathetic nervous system, several investigations have demonstrated that auricular acupuncture can activate the parasympathetic nervous system.^{102, 103} The ability of auricular acupuncture to influence the parasympathetic nervous system is believed to be a result of auricular acupuncture needles that are placed in the conchae of the ear where the auricular branch of the vagus nerve provides innervation.¹⁰³ As a result, the vagus nerve, which has a high distribution of parasympathetic activity, may exert its effect on autonomic regulation.

Activation of the parasympathetic nervous system among veterans with PTSD is particularly relevant, given that there is a known overactive sympathetic nervous system in this population.¹⁰⁴ Therefore, the use of auricular acupuncture may activate the parasympathetic nervous system and improve the imbalance of autonomic activity among individuals affected with PTSD.

The physiologic mechanisms described above provide some possible mechanisms of action that may produce improved sleep among veterans with PTSD. However, although there are some studies which support the above mechanisms of action, there remains a need to further investigate acupuncture mechanisms of action.

Previous Research Utilizing Auricular Acupuncture as a Sleep Directed Intervention

Acupuncture has been reported to improve insomnia in numerous research studies.³⁵⁻³⁷ However, of nine systematic reviews for acupuncture as an intervention for insomnia, only one review reported a positive effect,¹⁰⁵ and the remaining eight reported acupuncture may be beneficial, but evidence is limited or insufficient.^{58, 106-112} All nine reviews cited a need for improved methodological quality for future studies utilizing acupuncture as a sleep intervention, with recommendations including: randomization of subjects, use of appropriate control groups, use of objective sleep measures, and utilizing double blind research designs.^{58, 105-112} Further, a variety of acupuncture protocols and techniques (acupressure, magnetic pearls, electroacupuncture, ear seeds, etc.) make comparisons across studies difficult.^{110, 115} Recently, more randomized control trials for acupuncture and insomnia are being conducted, showing

improvement in sleep measures;^{114, 115} however, acupuncture as an intervention for insomnia warrants further investigation with rigorous study methodologies.

Military Nursing Relevance

The problem of sleep disturbance among military veterans has been well documented, particularly among those with post traumatic stress disorder (PTSD).⁶⁸ Therefore, military providers, and in particular military nurses are in a unique position to provide effective interventions to improve sleep among our current generation of veterans. Non pharmacologic interventions for sleep are desirable, as they avoid the need for long term medications, and the potential side effects associated with them. Additionally, many non-pharmacologic interventions can be implemented by a variety of military providers. Although auricular acupuncture has been traditionally performed by licensed Acupuncturists, Complementary and Alternative Medicine (CAM) experts within the US military have advocated for military providers to be allowed to practice auricular acupuncture to promote its availability to veterans in operational settings (verbal communication, CAPT Anita Hickey, 8/15/11). With appropriate training, auricular acupuncture can easily be performed in austere conditions, and the ear of wounded military personnel is usually easily assessable. Therefore, auricular acupuncture is viewed as a practical way to provide needed care to veterans. Although the most widely used auricular acupuncture protocol utilized in military settings is the “battlefield” protocol, similar auricular acupuncture protocols exist to improve sleep. Therefore, this study utilized an insomnia specific protocol developed by an internationally known expert on auricular acupuncture to examine the effects on sleep quality using objective and subjective sleep measures.

The results of this study have the potential to impact care offered to veterans by providing some evidence as to the efficacy of complementary techniques such as auricular acupuncture, and may promote further scientific inquiry of complementary and alternative therapies in this patient population.

Chapter 3: METHODOLOGY

This chapter will begin with a presentation of the research design followed by a discussion of the instruments, data collection methods, data analysis, and protection of human subjects.

Research Design

A controlled feasibility study was chosen for this investigation to test the study design, and examine acceptability of auricular acupuncture, and examine limited efficacy data of an auricular acupuncture regimen for sleep disturbance in a vulnerable population of OEF/OIF veterans.

Secondarily, PTSD symptoms and depression levels between groups were compared before and after a series of auricular acupuncture treatments, and bi-weekly during the study period.

Specific aims included:

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an auricular acupuncture intervention study by utilizing a consort diagram to track subject disposition throughout the study period.

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI and sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who received auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy.

Aim #3: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9) at baseline and at five weeks in OEF/OIF veterans with PTSD who received auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy.

Aim #4: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9 scores) every two weeks during the study period (at baseline, week three, and week five) between OEF/OIF veterans who received auricular acupuncture as compared to those that receive standard PTSD therapy.

Sample

This study included 30 active duty male Marine Corps, Army, Air Force, or Navy personnel participating in the Overcoming Adversity & Stress Injury Support (OASIS) Residential PTSD Program. Female subjects were excluded from this study due to the infrequent admission of females treated at the OASIS clinic. To participate in the OASIS Program, patients are diagnosed with PTSD by a board certified psychiatrist or licensed psychologist utilizing the DSM-IV PTSD criteria. For subjects who participated in the study, PTSD diagnosis and medical history was reviewed by a staff Psychiatrist at the OASIS clinic and communicated to the Primary Investigator to ensure subjects met inclusion criteria for the study. The following list was utilized for subject inclusion and exclusion criteria.

Subject inclusion criteria:

1. Age 18-50

2. Male gender
3. Combat veteran of Operation Iraqi Freedom or Operation Enduring Freedom enrolled in the OASIS Program-Excellence in Warrior Restoration (10 week PTSD multi-modal residency program).
4. Co-occurring disorders including depression, anxiety, or treated substance abuse or dependence problems were permitted.
5. Self reported sleep disturbance started during or after deployment (no history of insomnia prior to deployment) with duration of greater than one month (determined by demographic screening).
6. Prospective enrollees had to be available for five weeks. If prospective enrollee were expected to deploy within the next five weeks, the individual were ineligible to participate in the study.

Subject Exclusion Criteria:

1. Axis I mental disorders (those that are normally incompatible with active military service), such as psychotic disorders or bipolar type I, were not eligible.
2. History of moderate or severe traumatic brain injury (by verification of medical history with OASIS staff psychiatrist).
3. Current use of CPAP or BiPAP or known history of sleep apnea (subjects were screened with STOP Bang Questionnaire).
4. Significant comorbid disorders (including heart, liver, lung disease-were verified by medical Record with OASIS staff prior to enrollment).
5. Diagnosis of insomnia prior to deployment.
6. Concurrent enrollment in any other treatment program, research study, or counseling that involved cognitive-behavioral treatment, group therapy, or any other treatment that involves

systematic disclosure of troubling deployment-related memories. Subjects could continue current pharmacological treatment, marital counseling, or any supportive therapy.

7. No concurrent use of acupuncture treatments were allowed during participation of study.

8. On Coumadin, heparin, or lovenox, or any history of coagulation disorders.

9. Essential tremors

10. The use of sleep medications did not exclude subjects from the study. Medications were tracked during the study period due to the severe and complex nature of this patient population.

Setting

The setting for this research was at the OASIS Clinic in San Diego, CA. The OASIS Clinic treats active duty veterans with PTSD utilizing a multimodal (group cognitive processing therapy, individual processing therapy, music therapy, art therapy, meditation, spirituality, volunteerism, family support, exercise, education on sleep hygiene, medications, anger management, etc), intensive ten week residency program.

Subject Recruitment

Subjects were recruited by research presentation briefs by the Primary Investigator. The primary investigator wore civilian clothes during the initial research presentation for potential subjects, and at all subsequent visits to the OASIS clinic to avoid/minimize perception of coercion. Additionally, after research presentations by the Primary Investigator, any interested potential subjects were informed that further study details and informed consent would be performed in another location at the clinic for three hours after the presentation. Potential

subjects were informed that informed consent for the study could occur at any time during the first week of treatment at the OASIS Clinic to minimize perception of coercion to participate in the study. Prior to enrollment in the study, the diagnosis of PTSD and medical history was verified by the Primary Investigator with the OASIS staff.

Informed Consent

This study was conducted in compliance with Title 45 Part 46 of the Code of Federal Regulations (CFR) pertaining to informed consent. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continuing throughout the individual's study participation. For subjects meeting the proposed study criteria, written informed consent was obtained after having been informed about the nature and purpose of the study, participation conditions, risks, and potential benefits. Subjects signed the informed consent document prior to any procedures being initiated for the study and had sufficient opportunity to discuss the study, as well as process the information presented in the consent process prior to agreeing to participate. Additionally, subjects were asked to sign a procedural consent for the acupuncture intervention. The procedural consent was explained to subjects, and placed in their medical record at the OASIS Clinic. Subjects could withdraw consent at any time throughout the course of the study. A copy of the informed consent documents (research consent and procedure consent) will be given to the participants and an additional copy will be placed in the subject's medical record. The rights and welfare of the subjects were protected by emphasizing to subjects that the quality of their medical care would not be adversely affected if they decline to participate in this study. All subjects were expected to continue with all aspects of

the OASIS program, and were instructed on this item. Further, subjects were instructed not to take additional complementary or alternative therapies during the study period (this information was described in the informational package). Subjects were provided a written informational package containing study information, a copy of the written consent, contact information for CDR Heather King (Overall Primary Investigator), Dr. Ronald Elesh (Local Primary Investigator), CDR Paul Sargent (Associate Investigator, Staff Psychiatrist), LCDR Kenneth Richter (Research Monitor, Division Officer OASIS Clinic), and emergency mental health resources (all available 24 hours per day). The informed consent form from the Naval Medical Center San Diego Clinical Investigation Department was used for this study because all subjects were recruited and all activities took place at the OASIS Clinic which administratively is attached to NMCSO.

Data Collection Procedures

After the consent process was complete, subjects were assigned a subject number. Subjects were then randomly assigned through a computer generated random list to one of two conditions: auricular acupuncture group (intervention group) or waitlist group (control). For all instruments administered to subjects, personal identifiers were not used. Subject numbers were placed on instruments administered to subjects. Additionally, personal identifiers were removed from all instruments obtained from the OASIS clinic database, and replaced with the appropriate subject number. All data was stored on a designated laptop for the proposed study and data was backed up on two separate storage devices. All storage devices remained at the OASIS Clinic in a locked cabinet in a locked office.

The OASIS clinic maintained a database of instruments administered to patients to monitor clinical progress (for this study we accessed PSQI, PHQ, and PCL scores as described below). Initially, subjects were administered a demographic questionnaire and the STOP Bang Questionnaire. Subjects scoring greater than three on the STOP Bang Questionnaire were excluded from further participation in the study. For subjects who scored three or less on the STOP Bang Questionnaire, baseline PSQI, PHQ, and PCL scores were collected from the OASIS Clinic database (the PSQI is administered on admission to the OASIS clinic, and the PHQ and PCL were administered on admission as well every two weeks by the OASIS clinic to monitor clinical progress). Subjects were then given directions on the use of the actigraphy watch and the sleep diary. All subjects wore actigraphy watches and recorded sleep information in a sleep diary for seven consecutive days. A button on the actigraphy watch was pushed when subjects retired for the evening, and was pushed again upon awakening for the day. At the end of the first data collection period for actigraphy monitoring/sleep diary, subjects were asked to return the actigraphy watch and completed sleep diary. Actigraphy data was downloaded to a password protected computer available only to study personnel.

Subjects in the intervention group were then scheduled for three weekly auricular acupuncture treatments for three weeks. The insomnia auricular acupuncture protocol was used on subjects and included the following acupuncture points: shen men, point zero, brain, thalamus point, pineal gland, master cerebral, insomnia points 1 & 2, kidney, heart, occiput, and forehead (figure 3).⁷⁹ This auricular acupuncture protocol was selected based on expert consultation with CAPT Anita Hickey (the leading Acupuncturist in the Navy and expert consultant to numerous Department of Defense, National Institutes of Health, and Veteran Affairs Committees regarding the use of acupuncture among military veterans) and because the identified insomnia auricular

acupuncture protocol was developed by an internationally known auricular acupuncture expert (Dr. Terry Oleson). Although many auricular acupuncturists utilize an electrical point finder for point selection, a standardized protocol with the identified insomnia acupoints was used on all subjects in order to minimize variation across treatments.

FIGURE 3. Insomnia Auricular Acupuncture Protocol with identified acupuncture points (○) represents raised regions of the auricle, (●) represents deep regions of the auricle, and (■) represents hidden regions of the auricle. (Oleson, T. (2003). *Auriculotherapy Manual: Chinese and Western Systems of Ear Acupuncture*. London: Churchill Livingstone. Used with permission from Elsevier Copyright Clearance Center and Dr. Terry Oleson.

Subjects receiving the auricular acupuncture were treated in a quiet private room lying on a padded exercise mat. The external ear cartilage of both ears was cleaned with an isopropyl alcohol swab. A clean insertion technique was used with stainless sterile steel SEIRIN D Type acupuncture needles (0.20 mm diameter, 15mm in length) on each of the identified acupuncture points to bilateral ears for a total of 30 minutes at each acupuncture treatment. All acupuncture

treatments were administered by the Principle Investigator who possessed supplemental privileges to perform auricular acupuncture, and had two years of clinical experience in auricular acupuncture prior to the start of the study). One acupuncture provider was chosen to minimize treatment variation.

Subjects were closely monitored for any adverse events. No subjects experience adverse events related to the acupuncture intervention during this study. However, appropriate patient care was immediately available to any subject who may have experienced an adverse event, and would have been documented in the subject log book. Further, a plan was in place to report any significant adverse events will be immediately reported to the Overall Primary Investigator, Local Primary Investigator, Medical Monitor, Division Officer of the OASIS Clinic, and the Investigational Review Board at Naval Medical Center San Diego.

During the study period, bi-monthly PCL and PHQ scores were collected from the OASIS clinic (baseline, week three, and week five) on all subjects. At the conclusion of the fourth week, after subjects had completed three weeks of auricular acupuncture treatment or three weeks of standard therapy, all subjects and subjects were asked to complete the PSQI. Subjects were also asked to complete a likert question regarding the acceptability of auricular acupuncture for sleep disturbance. During the fifth week, all subjects were asked again to wear actigraphy watches and record sleep information in a sleep diary for seven consecutive days. After the collection of sleep data from actigraphy/sleep diaries, the waitlist/control group was offered the same auricular acupuncture insomnia regimen as the intervention group received. After subjects received the auricular acupuncture treatment a one item feedback question was given to subjects to report any feedback on the study or feedback about the auricular acupuncture intervention.

Sham Acupuncture

Sham acupuncture was used in the proposed study for several reasons. Sham acupuncture does promote blinding of study subjects, an important consideration for good methodological design, however, sham acupuncture practices vary widely across studies. Some investigators define “sham acupuncture” as placing acupuncture needles in an area close to but not in acupuncture points, while others insert sham acupuncture needles at differing depths of placement at acupuncture points (i.e. not achieving a deqi). Additionally, sham acupuncture (when used with acupuncture needles inserted to non acupuncture points), has been shown to have an effect leading some researchers to speculate that non-acupoints may be physiologically active, and may produce effects similar to identified acupuncture points.¹¹⁶ Lastly, since the proposed study was a small scale feasibility study in a vulnerable population of OEF/OIF veterans, the acceptability of a sham acupuncture group was unknown and speculated to be a deterrent to participation in the study.

Instrumentation

Demographic Questionnaire

A short self-administered questionnaire was administered to subjects which included: age, race/ethnicity, education, marital status, branch of service, rank, military occupational specialty (MOS), length of service, deployment history, current medications, duration of PTSD diagnosis, duration of treatment for PTSD, current medications, health problems including (sleep apnea and chronic pain), duration of sleep disturbance, and history of use of complementary and alternative therapies. The demographic data was obtained primarily to examine group characteristics.

The STOP Bang Questionnaire

The STOP Bang questionnaire is a self administered eight item dichotomized yes/no questionnaire, represented by the mnemonic STOP Bang (Snoring, Tiredness, Observed breathing cessation, Pressure-related to the presence or treatment of high blood pressure, Body Mass Index, Age, Neck circumference, and Gender).¹¹⁷ The STOP Bang questionnaire was designed to screen preoperative patients for obstructive sleep apnea (OSA), and originally consisted of four questions related to snoring, daytime tiredness, observed breathing cessation, and the presence or treatment of high blood pressure.¹¹⁷ Four additional questions were added to this instrument related to body mass index, age, neck circumference and gender which improved sensitivity from 65.6%, 74.3%, and 79.5% with apnea-hypopnea index values of >5, >15, and >30, to 83.6%, 92.9%, and 100% for respective apnea hypoxia index values.¹¹⁷ A score of three or more out of a possible eight indicates a high risk of the subject having obstructive sleep apnea (OSA).¹¹⁷ As the cumulative score on the STOP Bang Questionnaire increases, the probability of more severe sleep apnea is likely.¹¹⁸ Further, a recent study among subjects in a Heart Health Study reported that STOP Bang questionnaire scores of three or greater corresponded to moderate-to-severe sleep disordered breathing in 88.6% of subjects and 92.5% of subjects with severe sleep disordered breathing.¹¹⁹ This study also reported the STOP Bang questionnaire to have the highest sensitivity (87%) for detecting sleep disordered breathing among four commonly used screening tools.¹¹⁹ Specificities for the STOP Bang questionnaire are reported at 56.4, 43.0, and 37.0 for apnea hypoxia index values of >5, >15, and >30,¹¹⁷ and the test retest reliability of the STOP questionnaire (four question version of this instrument) has been reported at 96.4%.¹¹⁷ Although this instrument is relatively new, and was designed to screen surgical patients for OSA, the STOP Bang scoring model has also recently been validated in an Asian

population with reported sensitivities of 84.7%, 91.1%, and 95.4% and specificities of 52.6%, 40.4%, and 35.0% for corresponding apnea hypoxia indexes of >5, >15, and >30 respectively.¹²⁰ For this study, the STOP Bang questionnaire was used to screen subjects for the presence of OSA. A score of greater than three excluded subjects from participating in the study. The STOP Bang questionnaire was chosen to screen subjects for OSA due to its excellent psychometric properties, ease of completing and scoring, and brevity of administration.

The Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) is a nineteen item self administered questionnaire which assesses sleep quality and sleep disturbance over a one month period in clinical population.¹²¹ The PSQI has been used for more than twenty years, translated into 56 languages, used in a wide variety of populations and provides important information about sleep quality.¹²²⁻¹²⁶ A combination of Likert scale items and open ended response items are utilized. Five additional items are available to be completed by a bed partner or roommate, but are not used to calculate scores. Seven component scores are generated from the 19 items and are weighted on a 0-3 scale, and are then summed to produce a total score (range 0-21) with higher scores indicating decreased sleep quality.¹²¹ Scores greater than five are suggestive of significant sleep disturbance.¹²¹ The components included within the PSQI include: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction.¹²¹ These seven components of sleep quality are routinely assessed in clinical interviews for individuals with sleep/wake complaints.¹²¹ For the seven component scores on the PQSI, an overall reliability coefficient of 0.77 to 0.83 (Cronbach's α) has been

reported.^{121, 124, 127} Individual items on the PSQI have a reliability coefficient of 0.83 (Cronbach's α) and the sensitivity and specificity of the PSQI have been reported at 89.6% and 86.5% respectively.¹²¹ The Pearson's correlation coefficient for test retest reliability of the PSQI has been reported at 0.85 to 0.87 and has been shown to be stable over time.^{121, 128} The use of the PSQI for the current study will be used to examine sleep quality scores between groups. The PSQI is administered to subjects during the first week of admission to the OASIS Clinic, and these scores will be utilized as baseline PSQI scores. At the end of the fourth week (after one week of sleep data collected and intervention group has received last acupuncture session), the PSQI was administered by the Principle Investigator to the subjects. The PSQI was chosen for this study because it is a psychometrically sound instrument that captures important information regarding sleep disturbances which can impact sleep quality. Additionally, the PSQI is easy to administer, and can be completed by subjects in less than five minutes. Permission to use this instrument was obtained from the University of Pittsburgh the publisher of this instrument and is available free of charge.

The PTSD Checklist Military Version

The PTSD Checklist-Military Version (PCL-M) is a self report instrument designed to assess the symptoms of PTSD in which 17 items correspond to the DSM-IV's PTSD criteria.¹²⁹ Items one through five correspond to re-experiencing symptoms, items five and six correspond to avoidance symptoms, items eight through twelve correspond to numbing symptoms, and items thirteen through seventeen correspond to hyperarousal symptoms. The PCL-M is administered in a questionnaire format to individuals in which they are asked to endorse the level of distress with

each symptom over the last 30 days. Each item is scored on a five point likert scale with 1 = “not at all” to 5 = “extremely.” A total symptom severity score is obtained (range 17-85), with scores greater than 50 indicating a high likelihood of PTSD.¹²⁹ Although the PCL-M is not a diagnostic tool, it is highly correlated with the Clinician Administered PTSD Scale (CAPS) (0.929),¹³⁰ and has been used as a screening tool for PTSD,⁶⁸ as well as an instrument to measure patient progress during PTSD treatment.^{131, 132} The PCL-M is a psychometrically sound instrument demonstrating good temporal stability and reported internal consistency of 0.94-0.98 (Cronbach’s α).^{130, 133} Additionally, the test retest reliability of the PCL-M is reported at 0.88 to 0.96.^{129, 130} The use of the PCL-M for the current study was used to examine PTSD symptoms between groups. The PCL-M was an appropriate instrument for this study in that it is specific to military populations, is highly correlated with the CAPS, and reduces subject burden (the PCL-M is administered to subjects every two weeks by the OASIS Clinic to monitor clinical progress during treatment). PCL-M scores during the first week of admission to the OASIS Clinic were utilized as baseline PCL-M score for subjects. At the end of the third week and fifth week PCL-M scores were collected for all subjects enrolled in the study. Permission to use this instrument was granted from the National Center for PTSD, the publisher of the instrument and is available free of charge.

The Brief Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) is a nine item depression scale used widely by clinicians and researchers to examine depression.^{134, 135} This nine item self report questionnaire is derived from the depression module of the Patient Health Questionnaire (PHQ),¹³⁶ and each of the nine items on the PHQ-9 corresponds to the diagnostic criteria of

DSM-IV for depressive disorders.¹³⁷ The PHQ-9 is administered to individuals in which they are asked to endorse the level of distress with each symptom over the last two weeks. Each item is scored on a four point likert scale with 0 = “not at all,” 1= “several days,” 2= “more than half the days,” and 3 = “nearly every day.” The PHQ-9 can be used as a diagnostic tool, as well as a measure of severity of depression.¹³⁴ When used as a diagnostic tool for depression, major depression is diagnosed when five or more of the depressive items are reported to occur more than half of the days in the last two weeks, and one of the symptoms is depressed mood or anhedonia.¹³⁴ Other types of depression are diagnosed when more than two symptoms are reported to occur more than half of the days in the last two weeks, and one of the symptoms is depressed mood or anhedonia.¹³⁴ One item on the PHQ-9 states “thoughts that you would be better off dead or hurting yourself in some way.” When reported by an individual, this item is diagnostic of depression regardless of the time interval.¹³⁴ When used as a measure of severity of depression, a total symptoms severity score is obtained (range 0-27), with scores greater than ten indicating a high likelihood of depression.¹³⁸ The following scoring system is utilized to categorize severity of depression scores on the PHQ-9: 0-4 minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression.¹³⁴ The PHQ-9 is a psychometrically sound instrument demonstrating a reported internal consistency of 0.86-0.89 (Cronbach’s α).¹³⁴ Additionally, the test retest reliability of the PHQ-9 has been reported at 0.84.¹³⁴ The use of the PHQ-9 for the current study was used to examine PHQ-9 severity scores between groups. The PHQ-9 was administered to subjects every two weeks at the OASIS Clinic, and the first PHQ-9 score administered to patients was utilized as baseline PHQ-9 scores for subjects. Every two weeks PHQ-9 scores (baseline, week three, and week five) were collected to examine changes in scores over time between groups. The last

PHQ-9 score at week five was used to examine change scores from baseline between groups. This instrument was chosen for this study due to its excellent psychometric properties and to reduce subject burden (this instrument is administered every two weeks by the OASIS Clinic). Permission to use this instrument was obtained from the Pfizer, Inc. the publisher of this instrument and is available free of charge.

Sleep Diary

The Consensus Sleep Diary (CSD) was used to examine sleep latency times, total sleep times, sleep efficiency, and number of awakenings as reported by subjects as well as compare self-reported sleep times to actigraphy data.¹³⁹ The CSD is a brief nine item tool with the first eight items providing data on daytime napping, time subject goes to bed, time subject attempts to fall asleep, duration of time to fall asleep, frequency and duration of nighttime awakenings, duration of sleep, time of awakening, and quality of sleep. The ninth item is a blank comment section allowing subjects to record any information related to their sleep. Sleep diaries have been regarded as a gold standard for subjective sleep assessment,¹³⁹ and are viewed by sleep experts as a useful methodology for prospective self-monitoring of sleep for individuals with insomnia.¹⁴⁰ Further, sleep diaries have been validated against actigraphy, and have shown good correlations with objective sleep measures.¹⁴¹ Although the CSD is a new sleep diary, it was designed by leading sleep experts in an effort to create a standardized sleep diary for clinicians and researchers.¹³⁹ The CSD is based on sleep diaries previously used in sleep research, and has both a “core” CSD version (which allows for a standard set of sleep measures to be recorded), and an expanded version which allows for more sleep related data to be collected from subjects.¹³⁹

During this study, subjects were instructed to record daily prospective sleep data each morning to include all nine data items on the “core” CSD (daytime napping, bed time, time attempted sleep, duration of time to sleep, nighttime awakenings, total sleep time, time of awakening, sleep quality and comment section) for seven days. In the ninth item (comment section), four data items were requested from subjects: number of caffeinated drinks consumed during the previous day, presence of nightmares during the night, sleep medication taken the previous day, pain episodes that caused awakening. Subjects were provided with the CSD recommended standardized instructions, and a sample entry to facilitate appropriate data entry on the CSD. Subjects were asked to record this data for one week at the beginning of the study, and again at the end of the fourth week. This sleep diary was appropriate for this study in that it is brief (one page), easy to use, and allows for the collection of sleep onset latency times, total sleep times, sleep efficiency, and number of awakenings as reported by subjects. Additionally, this diary allows for subjects to record valuable information that will not be captured by objective measures of sleep (nightmares, caffeine consumption, etc.). Permission to use this sleep diary was obtained from Dr. Colleen Carney primary author of this sleep diary.

Actigraphy

Actigraphs are electronic devices which record movement using accelerometers (movement detectors) which sample movement several times per second. Activity/inactivity data is estimated in epochs (one minute for actigraphy) in which activity is associated with wakeful periods and inactivity is associated with sleep periods. Information is stored within the actigraphy device, and can be downloaded to a computer (with device specific software) which

will translate raw activity scores into sleep-wake scores based on computerized algorithms.¹⁴² These small portable devices resemble the appearance of a digital watch, and are worn most typically on the subject's non dominant wrist. Actigraphy has been shown previously to be a reliable and valid tool to estimate sleep parameters in healthy individuals across age groups¹⁴³⁻¹⁴⁸ and in more recent years has been validated in populations with comorbid conditions such as lung cancer, insomnia, osteoporosis, and obstructive sleep apnea.¹⁴⁹⁻¹⁵² Additionally, the American Academy of Sleep Medicine (AASM) has supported the use of actigraphy as a research tool¹⁵³ and as an appropriate tool in the evaluation of circadian rhythm disorders, insomnia, hypersomnia, and obstructive sleep apnea.¹⁵⁴

Although polysomnography is the gold standard for sleep/wake identification, actigraphy has been used as an alternative to polysomnography because of its convenience and low cost. Actigraphy also captures data in a more familiar sleep environment of the individual whereas, polysomnography most commonly measures sleep data in a laboratory setting. According to a recent systematic review, overall agreement rates between polysomnography and activity range from 72.1% to 96.5%.¹⁵⁵ Additionally, actigraphy has consistently demonstrates high sensitivity (approximately 89%) in numerous studies,¹⁵⁶⁻¹⁵⁸ but low specificity (approximately 36-66%) has been reported due to inability to detect wakeful periods (actigraphy reports subject asleep, but subject awake lying still in bed).^{156, 159, 160} As a result, actigraphy data tends to overestimate total sleep time, sleep efficiency, and underestimate sleep onset latency times.¹⁶⁰ Low specificity is also believed to be due to differences in actigraphy devices, differences in scoring algorithms, and specific populations.^{157, 158, 160} Although there are limitations to actigraphy data, studies comparing sleep diaries and actigraphy data have found good correlation between some sleep parameters such as total sleep time¹⁶¹ and the validity of actigraphy data is increased when

supplemented with sleep diaries.¹⁶² Additionally, reliability of actigraphy is also increased when used with sleep diaries for a minimum of seven days.¹⁶³ Current recommendations by the Standards of Practice Committee of the American Academy of Sleep Medicine state collecting sleep pattern data among individuals with insomnia is an indicated method to characterized circadian rhythm patterns or sleep disturbances and can be used in conjunction with subjective data (such as a sleep diary).^{140, 154} For this reason, actigraphy in conjunction with sleep diary information were used in the proposed study to examine sleep latency times, total sleep times, sleep efficiency, and number of awakenings. A frequently used actigraph in clinical research is the Motionlogger Watch (Ambulatory Monitoring, Inc.). The Motionlogger Watch is an FDA approved device that has been utilized in numerous investigations,¹⁶⁴ and recently has demonstrated higher sensitivity, specificity, overall agreement with polysomnography, and discriminability index calculations when compared to another commonly used actigraph.¹⁵⁶ For this study, the Motionlogger Watch (actigraph manufactured by Ambulatory Monitoring, Inc.) model CXat. #27.00 was used to collect objective sleep data on subjects (sleep onset latency, total sleep times, sleep efficiency, and number of awakenings). Subjects were instructed to wear the actigraph on the non dominant wrist for duration of one week at the beginning of the study and again at the end of the fourth week.

Feedback Questionnaire

A 1-5 point Likert scale created by the investigators addressed the acceptability of acupuncture as a treatment for sleep disturbance. Additionally, a one item open ended question

was administered to subjects after they had received the auricular acupuncture treatments (both intervention and control group). This question was used to evaluate any additional benefits subjects reported as a result of receiving the acupuncture intervention and feedback to aid in planning future studies with this population of veterans.

Table I.

Definition of Sleep Measures

Sleep Onset Latency (SOL)	Time elapsed from intent to fall asleep until sleep onset
Total Sleep Time (TST)	Total amount of time sleeping
Sleep Efficiency (SE)	$\frac{\text{Total amount of night time sleep}}{\text{Total time in bed}}$
Number of Awakenings (NOA)	Number of times one is awoken during nighttime sleep
Wake After Sleep Onset (WASO)	Total time awake after first episode of sleep

Table II.**Instrumentation for Study**

Instrument	Reliability and Validity	References
Actigraphy	A reliable and valid tool to estimate sleep parameters in healthy individuals across age groups, and has been validated in populations with comorbid conditions. The American Academy of Sleep Medicine (AASM) has supported the use of actigraphy as a research tool. Validity of actigraphy data is increased when supplemented with sleep diaries. Actigraphy has consistently demonstrated high sensitivity (approximately 89%) in numerous studies, but low specificity (approximately 36-66%) due to inability to detect wakeful periods. Overall agreement rates between polysomnography and activity range from 72.1% to 96.5%.	143-149 153 162 156-158 155
Consensus Sleep Diary	Result of the collaboration of leading sleep experts at the Pittsburg Assessment Conference to facilitate comparisons across studies.	139
PCL-M	Highly correlated with the Clinician Administered PTSD Scale (CAPS) (0.929), and a reported internal consistency of 0.94-0.98 (Cronbach's alpha). Additionally, the test retest reliability of the PCL-M is reported at 0.88 to .96.	129, 130, 133
PHQ-9	The PHQ-9 is a psychometrically sound instrument demonstrating a reported internal consistency of 0.86-0.89 (Cronbach's α) Additionally, the test retest reliability of the PHQ-9 has been reported at 0.84.	134
PSQI	For the seven component scores on the PQSI, an overall reliability coefficient of 0.77 to 0.83 (Cronbach's α) has been reported. Individual items on the PSQI have a reliability coefficient of 0.83 (Cronbach's α), and the sensitivity and specificity of the PSQI have been reported at 89.6% and 86.5% respectively. Pearson's correlation coefficient for test retest reliability	121, 124, 127, 128

	of the PSQI has been reported at 0.85 to 0.87 and has been shown to be stable over time.	
STOP BANG	Obstructive apnea screening instrument with reported sensitivity values of 83.6%, 92.9%, and 100% for apnea-hypopnea index values of >5, >15, and >30. Specificities for the STOP-BANG questionnaire are reported at 56.4, 43.0, and 37.0 for apnea hypoxia index values of >5, >15, and >30 (Chung et al., 2008), and the test retest reliability (four question version of this instrument) has been reported at 96.4% (Chung et al., 2008).	117
Feedback Questionnaire	A 1-5 point Likert scale created by the investigators will address the acceptability of acupuncture as a treatment for sleep disturbance. Additionally, a one item open ended question for study feedback is included.	Unpublished instrument.

Statistical Analysis

A small scale feasibility study was designed to collect preliminary data for this population of subjects. Therefore, a power analysis was not conducted for this study. The investigators of this study planned to sample 30 subjects, 15 assigned randomly to each group. An original plan to successful enroll 24-26 subjects (accounting for a 10-20% attrition rate) was proposed to adequately demonstrate feasibility of the proposed intervention, and study design in this population. Prior to conducting all statistical tests on data obtained, the investigators ensured that assumptions of described statistical tests were met. In addition, data was screened and outliers were identified and corrective action (deletion, adjustment, or retention) was taken depending on the source of the deviation. All statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) version 21.0 for Windows (SPSS Inc., Chicago, Illinois, USA). A *p* value of < .05 was considered statistically significant for all

statistical tests. Demographic and frequency data were analyzed using the t test, Fisher's exact test, likelihood ratio, and Wilcoxon ranked sum test.

Hypothesis #1: Subjects who receive auricular acupuncture will view it as a more acceptable treatment for sleep disturbance than those who receive standard therapy alone.

- 1.) Acceptability of the intervention and overall study design was evaluated by using a consort diagram to track subject disposition (number of potential subjects contacted, number of eligible subjects, number of subjects withdrawn prior to randomization, number of subjects randomized, number of subject attrition in each group, and number of subjects completing the study) throughout the study period to evaluate this aim. Also, acceptability of acupuncture as a treatment for sleep disturbance was compared between groups utilizing a 1-5 point Likert scale. Subject acceptability scores were analyzed using the Mann Whitney U test. One question allowed for subjects to write open ended feedback about the study. Information gathered from this question will be used to guide future studies.

Hypothesis #2: Objective and subjective sleep quality will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Objective data: Actigraphy data was scored to obtain sleep measures (using proprietary Motionlogger® Analysis Software, ACTION4 program). A two x two repeated measures analysis of variance was conducted to determine the effect of group (acupuncture or waitlist/control) at two time intervals (baseline and week 5) on differences in sleep times (sleep

onset latency, total sleep times, sleep efficiency, and number of awakenings). Mean scores were calculated for each sleep measure for individual subjects, and then used to calculate group means for the treatment and control groups.

Subjective data:

1.) Sleep diary data was analyzed in a similar manner with a two by two repeated measures analysis of variance conducted to determine the effect of group (acupuncture or waitlist/control) at two time intervals (baseline and week 5) on differences in sleep times (sleep onset latency, total sleep times, sleep efficiency, and number of awakenings). Mean scores were calculated for each sleep measure for individual subjects, and then used to calculate group means for the treatment and control group.

2.) PSQI data was analyzed with a two by two repeated measures analysis of variance conducted to investigate differences in scores between groups at baseline and at five weeks.

Hypothesis #3: PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

1.) A two by two repeated measures analysis of variance was conducted to determine the effect of group (acupuncture or waitlist/control) at two time intervals (baseline & week 5) on PTSD symptoms and depressive symptoms.

Hypothesis #4: PTSD symptoms and depressive symptoms was improved during the study period among OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

1.) A two by three repeated measures analysis of variance was conducted to determine the effect of group (acupuncture or waitlist/control) at three time intervals (baseline, week 3, and week 5) on PTSD symptoms and depressive symptoms.

Protection of Human Subjects

This proposal was reviewed by the Institutional Review Boards at the University of San Diego, the Naval Medical Center San Diego, and the Uniformed Services University of the Health Sciences. Potential subjects were asked to participate in the study during their first week of treatment for PTSD at the OASIS clinic. Participation in this study was be voluntary, and patient care was not affected if patients decided not to participate in the study.

Protection of Patient Privacy

Patient confidentiality was maintained through the assignment of subject identification numbers. These numbers were used in keeping of all research records. The key linking subject identification numbers to identifying information were kept in a locked cabinet in a locked office separate from other study data at the OASIS Clinic. All hard copy research materials remained at the OASIS clinic. Hard copy documents did not contain HIPAA identifiers. All electronic data generated from subjects will be managed with all current security provisions (password protected computer in a locked office). Every effort was made to protect patient privacy however; subjects were informed during the consent process about the limits of confidentiality.

Study Limitations

Veterans with PTSD are a vulnerable population at risk for depression,¹⁶ alcohol abuse,⁵ suicide,¹⁶⁵ and often do not complete PTSD treatment (P.D. Sargent, personal contact, 1/2/2011). Therefore, it may be challenging to recruit subjects, or continue the study to completion. Yet, disturbed sleep is a common complaint in this population, and recruitment of subjects may not be problematic. Reasons for attrition will be monitored during the study to evaluate the acceptability of the intervention and overall feasibility of the study design. Further, since this study is designed as a feasibility study to collect preliminary data on sleep measures (and a power analysis was not conducted), it is likely not powered to effectively study the effectiveness of the intervention. Further, the investigators realize that sleep disturbance is complex, and can be affected by numerous factors that are beyond the scope of this feasibility study. The design of this study attempted to minimize subject burden and study duration, while at the same time capturing enough valuable data to examine acceptability of auricular acupuncture in this population, and feasibility of this study design to decide if a larger investigation would be warranted in the future. Although the challenges of studying OEF/OIF veterans can be difficult, it emphasizes the critical need for novel therapies to improve health care.

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Chapter 4: MANUSCRIPTS

Manuscript I

UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Sciences

Tri-Service Nursing Research Program Graduate Award HT9404-12-1-TS15 (N12-P15)
Acupuncture for Disturbed Sleep in Veterans with Post Traumatic Stress Disorder

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Abstract

Military nurses provide care to our military veterans throughout the continuum of care from forward deployed combat settings, enroute care, inpatient settings, and during rehabilitation. Throughout this continuum of care, the problem of sleep disturbance among military veterans has been well documented, particularly among those with post traumatic stress disorder (PTSD). Therefore, military nurses are in a unique position to provide effective interventions to improve sleep among our current generation of veterans. Non pharmacologic interventions for sleep are desirable, as they avoid the need for long term medications, and the potential side effects associated with them. Additionally, many non-pharmacologic interventions improve sleep quality among individuals with sleep disturbance, and can be implemented by military nurses.

Auricular acupuncture is a non-pharmacologic intervention that has been reported to improve sleep quality in numerous studies. Although auricular acupuncture has been traditionally performed by licensed Acupuncturists, Complementary and Alternative Medicine (CAM) experts within the US military have advocated for military nurses to be allowed to practice auricular acupuncture to promote its availability to veterans in operational settings. This has strongly been advocated for this with the “battlefield acupuncture” protocol. Although this auricular acupuncture protocol was designed to reduce pain among veterans in operational settings, similar auricular acupuncture protocols exist to improve sleep. With appropriate training, auricular acupuncture can easily be performed in austere conditions, and the ear of wounded military personnel is usually easily assessable. Therefore, auricular acupuncture is viewed as a practical way to provide needed care to veterans by military nurses.

As an intervention to improve sleep quality, auricular acupuncture has some evidence to support its use however, among nine systematic reviews of all forms of acupuncture for insomnia, one review reported a positive effect, and eight reviews report inconclusive data due to poor methodological quality of acupuncture studies. This emphasizes the need for rigorous studies to evaluate the effectiveness of auricular acupuncture as an intervention for improving sleep quality. The proposed study seeks to examine the feasibility and acceptability of a three week auricular acupuncture regimen for veterans with PTSD and self-reported sleep disturbance. Additionally, this study seeks to evaluate whether an auricular acupuncture protocol improves sleep quality, depressive symptoms, and PTSD symptoms among Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans with PTSD and self-reported sleep disturbances.

This investigation will produce relevant military scientific knowledge as to whether or not auricular acupuncture improves sleep quality among OEF/OIF veterans, and supports TSNRP's Research Priority of Force Health Protection. Results of this investigation could have a significant impact on treatments available to veterans, as well as expanding the clinical practice of military nurses.

Key words: sleep disturbance, insomnia, acupuncture, post traumatic stress disorder.

Research Plan

A. Specific Aims

Post Traumatic Stress Disorder (PTSD) has emerged as a significant problem among Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans,¹ and disturbed sleep is one of the most frequently reported symptoms among OEF/OIF veterans with PTSD.² PTSD itself is impairing, but the burden of this disorder is likely heightened when accompanied by sleep disturbances. Sleep disturbances have been associated with a 75-90% increased risk of co-morbid conditions,³ increased levels of depression and anxiety,⁴ daytime sleepiness and fatigue,⁵ reduced psychomotor performance,⁶ diminished work productivity,⁷ work absenteeism,⁸ increased health care utilization,⁹ and decreased quality of life.¹⁰ These consequences of disturbed sleep emphasize the critical need for additional evidence based therapies to treat PTSD related sleep disturbances among OEF/OIF veterans with PTSD.

Pharmacotherapies used in treating PTSD related sleep disturbance have shown promising results to improve quality of sleep.¹¹ However, medications can be accompanied by potential side effects, and many PTSD patients prefer non-pharmacologic treatments.¹² Increasingly, non-pharmacologic therapies are being investigated for sleep disturbance among PTSD patients.¹³⁻¹⁶ However, few investigations have examined the efficacy of Complementary and Alternative (CAM) therapies on sleep disturbances among patients with PTSD. CAM practices such as acupuncture are emerging in the Department of Defense.^{17, 18} Yet, there are a limited number of well designed methodologically sound studies utilizing objective outcome measures to investigate the use of CAM therapies.¹⁹⁻²¹

This study seeks to examine whether the use of an auricular acupuncture regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. Our

approach is to conduct a small scale feasibility study to test the acceptability and efficacy of an auricular acupuncture regimen for sleep disturbance among OEF/OIF veterans with PTSD.

Differences in objective and subjective sleep measures will be compared between groups before and after an auricular acupuncture intervention. Additionally, PTSD symptoms and depressive symptoms between groups will be compared before and after an auricular acupuncture intervention, and weekly during the study period.

Specific aims include:

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an auricular acupuncture intervention study by utilizing a consort diagram to track subject disposition throughout the study period.

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI, sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Aim #3: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Aim #4: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9 scores) weekly during the study period (baseline, weeks one, two, three, four, and five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

The proposed study is innovative in that it utilizes a sleep specific auricular acupuncture regimen to examine feasibility and efficacy on sleep quality among OEF/OIF veterans. The work of this study supports important scientific inquiry for improving sleep quality among veterans, and has incorporated rigorous research methods. Investigating novel treatments to improve sleep quality among veterans addresses TriService Nursing Research Program's priority of Force Health Protection by promoting scientific inquiry of the treatments offered to OEF/OIF veterans entrusted to our care.

Background

Among troops returning from OEF/OIF, PTSD has emerged as a significant health problem.¹ PTSD is defined by the development of characteristic symptoms including: re-experiencing, avoidance, and hyperarousal following an exposure to a traumatic event.²² The overall prevalence of PTSD following deployment in support of OEF/OIF appears to be approximately 15% or greater,²³ and sleep disturbances are the most frequently reported symptom of PTSD among OEF/OIF veterans returning from deployment.² These findings are of concern because sleep disturbances frequently co-occur with a range of psychological problems,^{24, 25} and analysis of millennium cohort study data indicates military members who report the shortest duration of sleep were among those currently or previously deployed, and also reported symptoms of PTSD, depression, anxiety, or panic at follow-up assessment.²⁴ Previous research among Vietnam Veterans are consistent with these findings, and have shown that the vast majority of combat veterans will experience sleep disturbances,²⁶ which frequently precede, and co-occur with psychological problems, particularly PTSD.²⁷⁻²⁹ Additionally, previous research has shown a consistent relationship between self-reported sleep disturbance and PTSD symptoms, in which

more severe sleep disturbances have been associated with increased PTSD symptoms.^{30,31}

Together, these findings suggest that sleep disturbances are not only highly prevalent among veterans, but are associated with psychological problems, and may be related to the development and maintenance of PTSD.^{31,32}

Disturbed sleep among individuals with PTSD frequently manifests itself as difficulty falling and staying asleep (insomnia), frequent awakenings, and nightmares.³⁰ These symptoms may be due in part to the elevated levels of norepinephrine found among individuals with PTSD,³³ which is believed to have an effect on multiple structures in the brain (hypothalamus, amygdala, prefrontal cortex, and limbic structures via the locus coeruleus),³⁴ as well as play a role in the disruption of alternating rapid eye movement cycles of cholinergic and aminergic neurons.³⁵ However, sleep disturbances among veterans with PTSD are complex, and not yet fully understood.

Previous research has demonstrated effective first line treatments for PTSD such as cognitively based psychotherapies have been shown to improve sleep quality;³⁶ however, the majority of PTSD treatment studies do not report sleep outcomes. Further, sleep disturbances among individuals with PTSD are complex, and remain challenging to treat during initial treatment of PTSD and long-term.³⁷ Some pharmacotherapies used in treating PTSD related sleep disturbances have shown promising results to improve sleep quality¹¹ and sleep time,³⁸ as well as reducing nightmares.^{11,38} However, medications can be accompanied by side effects, and many PTSD patients prefer non-pharmacologic treatments.¹² Increasingly, non-pharmacologic therapies are being investigated for sleep disturbance among PTSD patients. Some of these therapies include: exposure, relaxation, and rescripting therapy, group cognitive behavior therapy, mind/body bridging, and imagery rehearsal therapy which have shown promising

therapy, mind/body bridging, and imagery rehearsal therapy which have shown promising results.¹³⁻¹⁶ Few investigations have focused on CAM therapies to examine the effects on PTSD related sleep disturbance. CAM practices, such as acupuncture, are emerging in the Department of Defense and are being offered increasingly to military members at Military Treatment Facilities.^{17, 18, 39} Acupuncture in particular has been well received among veterans in some settings,¹⁸ and has been used for a wide variety of health concerns.^{18, 39} Yet, there are a limited number of well designed methodologically sound studies utilizing objective outcome measures to investigate the use of CAM therapies including acupuncture.¹⁹⁻²¹ Acupuncture has been reported to improve insomnia in a variety of populations;⁴⁰⁻⁴² however, to date there are no published studies investigating the use of acupuncture as a sleep directed intervention for PTSD among OEF/OIF veterans. In light of the current prevalence of PTSD, and its effects on sleep among OEF/OIF veterans, investigating interventions to improve sleep quality in this population are crucial to ameliorate immediate distress caused by disturbed sleep, and avoid long term adverse health consequences associated with it. The purpose of this research will be to conduct a small scale feasibility study to examine whether the use of an auricular acupuncture regimen improves quality of sleep for OEF/OIF veterans diagnosed with PTSD and self-reported sleep disturbance.

Acupuncture Description

Acupuncture is a technique in which specific body points are pierced with acupuncture needles. Meridian channels are vertical lines mapped on the body which represent lines of energy which allow circulation between specific acupuncture points.⁴³ According to traditional Chinese medicine, utilizing acupuncture needles in meridian channels at the appropriate location is believed to alter the flow of energy and restore balance to the body.⁴³ Historically, auricular

acupuncture in China documented all six yang meridians directly connected to the auricle;⁴³ however, modern auricular acupuncture is credited to Dr. Paul Nogier who originated the somatotopic correspondence of the auricle with an inverted fetus.⁴⁴ This system maps all portions of the ear to specific parts of the body and internal organs. Auricular acupuncture is believed to activate meridians, collaterals, regulate Qi (pronounced 'chee'), and help create a balance between Yin and Yang forces.⁴³ Auricular acupuncture has numerous protocols for specific health problems including a protocol specifically for insomnia.⁴³

Proposed Mechanisms of Action for Acupuncture

Although acupuncture has been practiced for over 2,000 years, the basic mechanisms underlying the effects of acupuncture are still not clearly understood. Increasing evidence indicates that effects of acupuncture are mediated through the central nervous system.⁴⁵ The effects of acupuncture on the brain have been investigated with functional magnetic resonance imaging and positive emission tomography, showing a broad neuromatrix response involving limbic and limbic-related brain structures (amygdala, hippocampus, hypothalamus, cingulate cortex, prefrontal and insular cortices, basal ganglia, and cerebellum).⁴⁵⁻⁵¹ Many of these structures affected by acupuncture are also implicated in the pathophysiology of PTSD,⁵² leading some researchers to speculate that acupuncture may be beneficial to improve PTSD symptoms.⁵³ To date, only one pilot study has examined and reported improvements in PTSD symptoms after an acupuncture regimen,⁵³ however, no sleep measures were reported in this investigation.

Previous research has demonstrated that acupuncture increases endogenous opioid levels (enkephalins, endorphins, and dynorphins), and this finding has been supported in previous human⁵⁴⁻⁵⁶ and animal studies.^{57, 58} These findings have largely supported the use of acupuncture

as a pain intervention, and acupuncture is widely practiced for this purpose.⁵⁹ These findings relate to the proposed study in that the opioidergic system is also theorized to have a somnogenic effect,^{60, 61} and may interact with melatonin to promote sleep.⁶² Very few studies have examined mechanisms of acupuncture in relation to sleep, and these findings and theories are presented here as possible physiologic basis of how acupuncture may affect sleep and PTSD symptoms.

Preliminary Studies: Acupuncture and Sleep

Acupuncture has been reported to improve insomnia in numerous research studies.⁴⁰⁻⁴² However, of nine systematic reviews for acupuncture as an intervention for insomnia, only one review reported a positive effect,⁶³ and the remaining eight reported acupuncture may be beneficial, but evidence is limited or insufficient.^{20, 64-70} All nine reviews cited a need for improved methodological quality for future studies utilizing acupuncture as a sleep intervention, with recommendations including: randomization of subjects, use of control groups, use of objective sleep measures, and utilizing double blind research designs.^{20, 63-70} Further, a variety of acupuncture protocols and techniques (magnetic pearls, electroacupuncture, ear seeds, etc.) make comparisons across studies difficult.^{68, 71} Recently, more randomized control trials for acupuncture and insomnia are being conducted, showing improvement in sleep measures;^{72, 73} however, acupuncture as an intervention for insomnia warrants further investigation with rigorous study methodologies. Currently, there are no published studies investigating the use of acupuncture as a sleep directed intervention for veterans with PTSD.

Symptom Management Theory

The Symptom Management Theory (SMT) will be used to inform the proposed study (Figure 1).⁷⁴ The SMT is a middle range theory derived from the Symptom Management Model in which three dimensions of symptom management are conceptualized and depicted in relationship to one another.⁷⁵ The three major concepts of this theory include: symptom experience, symptom management, and symptom outcomes, and are framed in the dimensions of nursing science: person, environment, and health and illness.⁷⁵ The first concept of this theory is symptom experience which has three inter-related subdivisions: perception of symptoms, evaluation of symptoms, and response to symptoms by the individual.⁷⁴ Symptom experience may include one or more symptoms,⁷⁶ and it is essential to include the individuals report or perception of symptoms experienced.⁷⁵ The second concept of this theory is symptom management strategies which ward off, delay, or minimize symptoms,⁷⁵ and aim to reduce frequency, severity, and distress associated with symptoms.⁷⁷ The third concept of this theory is symptom outcomes. Symptoms outcomes are to be clear and measurable following a symptom management strategy, and can include change in symptom frequency, intensity, or level of distress.⁷⁵ It is believed that by improving symptoms, one's functional status can be improved. Bidirectional arrows indicate simultaneous interaction between concepts within the SMT.⁷⁵

Figure 1. Symptom Management Model. *Humphreys, J. et al., in Smith, M.J. and Liehr, P.R. (eds., 2008). Middle Range Theory for Nursing, Chapter 8. Theory of Symptom Management. New York: Springer Publishing Company.*

As described earlier, PTSD is defined by the development of characteristic symptoms, or symptom clusters including: re-experiencing, avoidance, and hyperarousal following an exposure to a traumatic event. Commonly, sleep disturbance symptoms manifest themselves as and difficulty falling and staying asleep (hyperarousal), and nightmares (re-experiencing).³⁰ Sleep disturbance for the proposed study will be defined as having one or more of the following symptoms: sleep onset latency greater than 30 minutes, two or more awakenings per night, total sleep time less than six hours per night, or the presence of nightmares. Further sleep disturbance symptoms must have started during or after deployment (this information will be obtained during subject screening and will be documented on the demographic questionnaire).

We propose the use of an auricular acupuncture regimen as a supplemental symptom management strategy (symptom management domain) for sleep disturbance, and will examine if

this strategy is effective to improve sleep quality in veterans with PTSD and self-reported sleep disturbance (Figure 2). Sleep disturbance symptoms and sleep quality (symptom experience domain) will be measured by utilizing objective and subjective sleep measures, and also will be used as symptom outcome measures (symptom outcome domain). Secondly, PTSD symptoms and depressive symptoms will be measured by subjective measures, and used as outcome measures as well. While the person, environment, and health and illness domains are important domains of the SMT, and this population, they are beyond the scope of this project. Figure 2 illustrates how the symptom experience, symptom management strategies, and symptom outcome domains will be represented in the proposed study.

Figure 2. Symptom Management Model adapted for the proposed study.

Research Purpose

The purpose of this research will be to conduct a small scale feasibility study to examine whether the use of an auricular acupuncture regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. This proposal seeks to answer the following general research question: “What effect does auricular acupuncture have on sleep quality among OEF/OIF veterans with PTSD and self-reported sleep disturbances?”

Research Question #1: Is the use of an auricular acupuncture regimen for veterans with PTSD and self-reported sleep disturbance acceptable and feasible?

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an auricular acupuncture intervention study utilizing a consort diagram to track subject disposition throughout the study period.

Hypothesis #1: Subjects who receive auricular acupuncture will view it as a more acceptable treatment for sleep disturbance than those who receive standard therapy alone.

Research Question #2: Is there a difference in objective and subjective sleep disturbances and sleep quality at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI and sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #2: Objective and subjective sleep disturbances and sleep quality will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Research Question #3: Is there a difference in PTSD symptoms and depressive symptoms at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #3: Compare PTSD symptoms and depressive symptoms at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #3: PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Research Question #4: Is there a difference in PTSD symptoms and depressive symptoms during the study period between OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy?

Aim#4: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ-9) weekly during the study period (baseline, week one, two, three, four, five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

Hypothesis #4: PTSD symptoms and depressive symptoms will be improved during the study period among OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Research Design and Methods

A prospective, randomized, wait list controlled small scale feasibility study will examine sleep disturbances and sleep quality in a convenience sample of OEF/OIF veterans with PTSD. A feasibility study was chosen for this investigation to test the acceptability and efficacy of an auricular acupuncture regimen for sleep disturbance in a vulnerable population of veterans. Differences in objective and subjective sleep measures will be examined between groups before and after an auricular acupuncture intervention. Additionally, PTSD symptoms and depression symptoms between groups will be compared before and after an auricular acupuncture intervention, and weekly during the study period (Appendix I).

Sample

This study will include 30 active duty male military personnel participating in the Overcoming Adversity & Stress Injury Support (OASIS) Residential PTSD Program. Female subjects will be excluded due to the infrequent admission of females at the OASIS clinic. To participate in the OASIS Program, veterans are diagnosed with PTSD by a board certified psychiatrist or licensed psychologist utilizing the DSM-IV PTSD criteria. For potential interested subjects, PTSD diagnosis and medical history will be reviewed by the Primary Investigator (PI) with a staff Psychiatrist at the OASIS clinic to ensure subjects meet study inclusion criteria. Subject inclusion criteria: 1) age 18-50; 2) male gender; 3) combat veteran of OIF or OEF enrolled in the OASIS Program-Excellence in Warrior Restoration; 4) co-occurring disorders including depression, anxiety, or treated substance abuse or dependence problems are permitted; 5) self-reported sleep disturbance (defined for this study as having one or more of the following: sleep onset latency greater than 30 minutes, two or more awakenings per night, total sleep time less than six hours per night, and/ or the presence of nightmares. Sleep disturbances must have started during or after deployment and will be determined by demographic screening); 6) prospective enrollees must be available for five weeks. Subject Exclusion Criteria: 1) Axis I mental disorders (incompatible with active military service); 2) history of moderate or severe traumatic brain injury (verification of medical history with OASIS staff psychiatrist); 3) current use of CPAP/BiPAP or history of sleep apnea (subjects will be screened for obstructive sleep apnea (OSA) with a screening questionnaire); 4) significant comorbid disorders (heart, liver, lung disease, etc.) verified by medical record with OASIS staff ; 5) concurrent enrollment in any other treatment program, research study, or counseling that involves cognitive-behavioral treatment, group therapy, or any other treatment that involves systematic disclosure of troubling

deployment-related memories. Subjects can continue current pharmacological treatment, marital counseling, or any supportive therapy, 6) no concurrent use of acupuncture treatments during participation of study; 7) taking Coumadin, Heparin, or Lovenox, or any history of coagulation disorders; 8) essential tremors; 9) the use of sleep medications will not exclude subjects from the study if they have been on sleep medications for duration of four weeks. Subjects will be asked not to increase dosage or change sleep medications during the study. Newly prescribed sleep medications during the study will result in the subject being withdrawn from the study.

Setting

The setting for the proposed study will be the OASIS Clinic in San Diego, CA. This clinic provides care for active duty veterans with PTSD utilizing a multimodal approach (group cognitive processing therapy, music therapy, art therapy, meditation, spirituality, volunteerism, family support, exercise, sleep hygiene, anger management, etc.), during a ten week residency program.

Subject Recruitment

Potential subjects will be recruited by informational flyers located in admission OASIS Clinic paperwork, through flyers posted at the OASIS Clinic, and from research presentation briefs by the PI. Potential subjects may be referred by OASIS Staff, or through self-referral from flyers located in the OASIS Clinic (Appendix II). OASIS staff may contact the PI directly to meet potential subjects at the clinic, or individuals may self-refer and contact the PI directly by phone. Once contact is made, an appointment will be offered to evaluate if the individual meets study inclusion criteria. If the individual is willing to be evaluated for the study, the PI will set a

time for the initial evaluation, in which all aspects of the study will be explained. The PI will wear civilian clothes during the initial evaluation for potential subjects, and at all subsequent visits to the OASIS clinic to avoid/minimize perception of coercion. Additionally, a research presentation will be done during the first week of patient enrollment at the OASIS Clinic. At these presentations, the PI will wear civilian clothes to avoid/minimize perception of coercion. Additionally, after research presentations by the PI, any interested potential subjects will be informed that further study details and informed consent will be performed in another location at the clinic. Further, potential subjects will be informed that informed consent may occur at any time during the first week of treatment at the OASIS Clinic, to minimize perception of coercion to participate in the study.

Informed Consent

This study will be conducted in compliance with Title 45 Part 46 of the Code of Federal Regulations pertaining to informed consent. Informed consent is a process initiated prior to the individual agreeing to participate in the study, and continues throughout the individual's study participation. For subjects meeting the proposed study criteria, written informed consent will be obtained after having been informed about the nature and purpose of the study, participation conditions, risks, and potential benefits. Subjects will sign the informed consent document prior to any procedures being initiated for the study and will have sufficient opportunity to discuss the study, as well as process the information presented in the consent process prior to agreeing to participate. Subjects may withdraw consent at any time throughout the course of the study. A copy of the informed consent documents will be given to the participants and an additional copy will be placed in the subject's medical record. The rights and welfare of the subjects will be

protected by emphasizing that the quality of their medical care will not be adversely affected if they decline to participate in this study. Subjects will be expected to continue with all aspects of the OASIS program and will be instructed not to take additional complementary or alternative therapies during the study period. Subjects will be provided a package containing study information, a copy of the written consent, contact information for the PI, the Medical Monitor, and mental health resources (available 24 hours per day).

Data Collection Procedures

After the consent process is complete, subjects will be assigned a subject number. Subjects will be randomly assigned to one of two conditions: auricular acupuncture group or waitlist/control group. Initially, subjects will be administered a demographic questionnaire and an obstructive sleep apnea (OSA) screening questionnaire.⁷⁸ Subjects scoring three or greater on the OSA screening questionnaire will be excluded from further participation in the study. For subjects who score three or less on the OSA screening questionnaire, baseline Pittsburgh Sleep Quality Index (PSQI), Patient Health Questionnaire 9 (PHQ-9), and PTSD Checklist Military Version (PCL-M) scores will be collected from the OASIS Clinic instrument database (the PSQI is administered on admission to the OASIS clinic, and the PHQ-9 and PCL-M are administered on admission and weekly by the OASIS staff to monitor clinical progress). Subjects will then be given directions on the use of the actigraphy watch and the sleep diary. All subjects will wear actigraphy watches and record sleep data in a sleep diary for seven consecutive days. At the end of the first data collection period for actigraphy monitoring/sleep diary, subjects will return actigraph watches and complete sleep diaries. Actigraphy data will be downloaded to a password protected computer available only to study personnel.

Subjects in the intervention group will be scheduled for three weekly auricular acupuncture treatments for three weeks. The insomnia auricular acupuncture protocol⁴³ will be used on subjects and includes the following acupuncture points: shen men, point zero, brain, thalamus point, pineal gland, master cerebral, insomnia points 1 & 2, kidney, heart, occiput, and forehead (Figure 3). This protocol was selected based on expert consultation with CAPT Anita Hickey (leading Acupuncturist in the Navy, and integrative medicine consultant to numerous Department of Defense, National Institutes of Health, and Veteran Affairs Committees), and because this insomnia auricular acupuncture protocol was developed by Dr. Terry Oleson (an internationally known auricular acupuncture expert).

Figure 3. Insomnia Auricular Acupuncture Protocol with identified acupuncture points (O) represents raised regions of the auricle, (●) represents deep regions of the auricle, and (■) represents hidden regions of the auricle. (Oleson, T. (2003). *Auriculotherapy Manual: Chinese and Western Systems of Ear Acupuncture*. London: Churchill Livingstone. Used with permission from Elsevier Copyright Clearance Center and Dr. Terry Oleson.

Subjects receiving the auricular acupuncture will be treated sitting in a quiet private room. External ear cartilage of bilateral ears will be cleaned with an isopropyl alcohol swab. A clean insertion technique will be used with stainless sterile steel SEIRIN D Type acupuncture needles (0.20 mm diameter, 15mm in length) on each of the identified acupuncture points to bilateral ears for a total of 30 minutes at each treatment. The acupuncture will be administered by a board

certified psychiatrist (LCDR Paul Sargent) who has supplemental privileges to perform acupuncture. As a contingent plan, in case of deployment or military related non availability issues, for the identified military acupuncture provider, the PI will provide the acupuncture intervention if needed (she has supplemental privileges to perform auricular acupuncture). Subjects will be closely monitored for adverse events. Appropriate care will be provided to any subject experiencing an adverse event, and any significant adverse events will be immediately reported to the Overall PI, Local PI, Medical Monitor, Division Officer of the OASIS Clinic, and the Investigational Review Board at Naval Medical Center San Diego. During the study period, PCL-M and PHQ-9 scores will be collected from the OASIS clinic database at six time points (baseline, week one, two, three, four, and five) on all subjects. At the conclusion of the fourth week, after subjects have completed three weeks of auricular acupuncture treatment or three weeks of standard therapy, all subjects will be asked to complete the PSQI and a feedback questionnaire. During the fifth week, all subjects will be asked again to wear the actigraphy watches and record sleep information in a sleep diary for seven consecutive days. After the collection of sleep data from actigraphy/sleep diaries, the waitlist/control group will be offered the same auricular acupuncture insomnia regimen as the intervention group received.

Sham Acupuncture

Sham acupuncture will not be used in the proposed study for several reasons. Sham acupuncture does promote blinding of subjects, an important consideration for good methodological design; however, sham acupuncture practices vary widely across studies. Some investigators define sham acupuncture as placing acupuncture needles in an area close to but not in acupuncture points, while others insert sham acupuncture needles at differing depths of

placement at acupuncture points. Additionally, sham acupuncture has been shown to have an effect,^{73, 79} leading to speculation that non-acupoints may be physiologically active and may produce effects similar to identified acupuncture points.⁷⁹ Lastly, since the proposed study is in a vulnerable population of veterans, the acceptability of a sham group was unknown, and speculated to be a deterrent to participation in the study.

Safety of Acupuncture

The safety of acupuncture has been reported in several large prospective investigations in Germany, the United Kingdom, and China.⁸⁰⁻⁸⁴ These investigations report the incidence of mild adverse events of acupuncture ranging from 3.76% to 15%.^{80, 82-84} Commonly reported adverse events include pain from acupuncture needles (range of 0%-5.4%), bleeding (range of 0.4% to 31%) or hematoma (range of 1.7%-8.11%).^{80, 82-84} Serious adverse events such as pneumothorax, nerve damage, or infection rarely occur.⁸⁰ Two surveys from the United Kingdom reported no adverse events when acupuncture is performed by physicians⁸⁵ or professional practitioners.⁸³ These studies indicate that acupuncture is generally a safe technique.

Demographic Questionnaire

A short self-administered questionnaire (see Appendix) will be administered to subjects which includes: age, race/ethnicity, education, marital status, branch of service, rank, military occupational specialty (MOS), length of service, deployment history, current medications, duration of PTSD diagnosis, duration of treatment for PTSD, current medications, health problems including (sleep apnea and chronic pain), and duration of sleep disturbance. Demographic data will be obtained primarily to examine group characteristics.

The STOP-Bang Questionnaire

The STOP-Bang questionnaire (see Appendix) is a self-administered eight item dichotomized yes/no questionnaire, represented by the mnemonic STOP-Bang (Snoring, Tiredness, Observed breathing cessation, Pressure-related to the presence or treatment of high blood pressure, Body Mass Index, Age, Neck circumference, and Gender).⁷⁸ The STOP-Bang questionnaire was designed to screen preoperative patients for OSA, and originally consisted of four questions related to snoring, daytime tiredness, observed breathing cessation, and the presence or treatment of high blood pressure.⁸⁶ Four additional questions were added to this instrument related to body mass index, age, neck circumference and gender which improved sensitivity from 65.6%, 74.3%, and 79.5% with apnea-hypopnea index values of >5, >15, and >30, to 83.6%, 92.9%, and 100% for respective apnea hypoxia index values.⁸⁶ A score of three or more out of a possible eight indicates a high risk of the subject having obstructive sleep apnea (OSA).⁸⁶ As the cumulative score on the STOP-Bang Questionnaire increases, the probability of more severe sleep apnea is likely.⁸⁷ Specificities for the STOP-Bang questionnaire are reported at 56.4, 43.0, and 37.0 for apnea hypoxia index values of >5, >15, and >30 respectively,⁷⁸ and the test retest reliability of the STOP questionnaire (four question version of this instrument) has been reported at 96.4%.⁷⁸ Although the STOP-Bang questionnaire is relatively new, it has excellent psychometric properties, is brief, and easy to complete. For the proposed study, the STOP-Bang questionnaire will be used to screen subjects for the presence of OSA.

The Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) (see Appendix) is a 19-item self-administered

questionnaire which assesses sleep quality and sleep disturbance over a one month period in clinical populations.⁸⁸ The PSQI has been used in a variety of populations,⁸⁹⁻⁹³ and provides important information about sleep quality. Both Likert scale items and open-ended response items are utilized. Five additional items are completed by a bed partner or roommate, but are not used to calculate scores. Seven component scores are generated from the 19 items and are weighted on a 0-3 scale, and are then summed to produce a total score (range 0-21) with higher scores indicating decreased sleep quality.⁸⁸ A scores of five or greater demonstrates a high specificity and sensitivity for insomnia.⁹⁴ Components within the PSQI include: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction⁹⁵ The seven component scores on the PQSI have an overall reliability coefficient of 0.77 to 0.83 (Cronbach's α).^{91, 95, 96} Individual items on the PSQI have a reliability coefficient of 0.83 (Cronbach's α), and the sensitivity and specificity of the PSQI have been reported at 89.6% and 86.5% respectively.⁸⁸ A correlation coefficient for test retest reliability of the PSQI has been reported at 0.85 to 0.87.^{88, 94} The PSQI for the current study will be used to examine scores between groups at baseline and at five weeks. The PSQI was chosen for this study because it measures important dimensions of sleep quality, has excellent psychometric properties, and minimizes subject burden (PSQI scores obtained from OASIS database).

The PTSD Checklist Military Version

The PTSD Checklist-Military Version (PCL-M) is a self-report questionnaire designed to assess the symptoms of PTSD in which 17 items correspond to the DSM-IV's PTSD criteria (see Appendix).⁹⁷ Items one through five correspond to re-experiencing symptoms, items five and six correspond to avoidance symptoms, items eight through twelve correspond to numbing symptoms, and items thirteen through seventeen correspond to hyperarousal symptoms. Individuals are asked to endorse the level of distress with each symptom over the last 30 days. Items are scored on a five point likert scale with 1 = "not at all" to 5 = "extremely." A total symptom severity score is obtained (range 17-85), with scores greater than 50 indicating a high likelihood of PTSD.⁹⁷ The PCL-M is highly correlated with the Clinician Administered PTSD Scale (CAPS) (0.929),⁹⁸ has been used as a screening tool for PTSD,² and is used to measure clinical progress during PTSD treatment.^{99, 100} The PCL-M is a psychometrically sound instrument with a reported internal consistency of 0.94-0.98 (Cronbach's α).^{98, 101} Additionally, the test retest reliability of the PCL-M is reported at 0.88 to .96.^{97, 98} The use of the PCL-M for the current study will be used to examine PTSD symptoms between groups. The PCL-M was chosen for this study because it is specific to military populations, has excellent psychometric properties, and minimizes subject burden (PCL-M scores obtained from OASIS database).

The Brief Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) is a nine item self-report questionnaire used to examine depression severity^{102, 103} (see Appendix). Individuals are asked to endorse the level of distress with each symptom on the PHQ-9 in the last two weeks. A four point likert scale with 0 = "not at all," 1 = "several days," 2 = "more than half the days," and 3 = "nearly every day" is

used. A total symptom severity score is obtained (range 0-27). Scores greater than ten indicate a high likelihood of depression.¹⁰⁴ Severity of depression is scored as follows: 0-4 minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression.¹⁰² The PHQ-9 has a reported internal consistency of 0.86-0.89 (Cronbach's α).¹⁰² The test retest reliability of the PHQ-9 has been reported at 0.84.¹⁰² The use of the PHQ-9 for the current study will be used to examine PHQ-9 scores between groups at baseline and five weeks. Also weekly PHQ-9 scores will be examined between groups. The PHQ-9 was chosen for this study due to its psychometric properties and it minimizes subject burden (PHQ-9 scores obtained from OASIS database).

Sleep Diary

The Consensus Sleep Diary (CSD) (see Appendix) is a nine item tool which provides data on daytime napping, bedtime, time attempted to fall asleep, sleep onset latency (SOL), number of awakenings (NOA), wake after sleep onset (WASO), total sleep time (TST), time of awakening, sleep efficiency (SE), and sleep quality.¹⁰⁵ A comment section allows subjects to record any item related to their sleep. Sleep diaries have been regarded as a gold standard for subjective sleep assessment,¹⁰⁵ and are viewed by sleep experts as a useful methodology for prospective self-monitoring of sleep for individuals with insomnia.⁹⁵ Sleep diaries have been validated against actigraphy, and have shown good correlations with objective sleep measures.¹⁰⁶ Although the CSD is a new sleep diary, it was designed by leading sleep experts in an effort to create a standardized sleep diary for clinicians and researchers.¹⁰⁵ The CSD has both a "core" CSD version (standard set of sleep data), and an expanded version.¹⁰⁵ For the proposed study, subjects will be instructed to record sleep data each morning on the "core" CSD for seven days. In the

comment section, four data items will be requested from subjects: number of caffeinated drinks, presence of nightmares, sleep medication taken, and pain episodes causing awakening. Subjects will be provided with the CSD standardized instructions, and a sample entry to facilitate appropriate data entry on the CSD. Subjects will be asked to record this data for one week at the beginning of the study, and again at the end of the study. The CDS will be used for the proposed study because of its brevity, ease of use, and allows for collection of the desired sleep measures: SOL, TST, SE, WASO, NOA.

Actigraphy

Actigraphs are electronic devices which record movement by sampling an individual's movement several times per second. Activity/inactivity data is estimated in which activity is associated with wakeful periods, and inactivity is associated with sleep periods. Actigraphy is a reliable and valid tool to estimate sleep parameters in healthy individuals across age groups,¹⁰⁷⁻¹¹² and has been validated in populations with comorbid conditions.¹¹³

Although polysomnography (PSG) is the gold standard for sleep/wake identification, actigraphy has been used as an alternative to PSG because of its convenience and low cost. Actigraphy also captures data in a more familiar sleep environment of individuals whereas, PSG commonly measures sleep data in a laboratory setting. According to a recent systematic review, overall agreement rates between PSG and actigraphy range from 72.1% to 96.5%.¹¹⁴ Actigraphy has consistently demonstrated high sensitivity (approximately 89%),^{115, 116} but low specificity (approximately 36-66%), due to inability to detect wakeful periods.^{115, 117} As a result, actigraphy data tends to overestimate total sleep time, sleep efficiency, and underestimate sleep onset latency times.¹¹⁷ Low specificity is also due to differences in actigraphy devices, scoring

algorithms, and specific populations.¹¹⁶⁻¹¹⁸ Although actigraphy has limitations, studies comparing sleep diaries and actigraphy data have found good correlation of some sleep measures such as total sleep time,¹¹⁹ and sleep diaries are recommended for use with actigraphs to identify artifacts, verify sleep measures, and support data analysis.¹¹¹ Additionally, reliability of actigraphy is also increased when used with sleep diaries for a minimum of seven days.¹²⁰ Recommendations by the American Academy of Sleep Medicine state collecting sleep pattern data among individuals with insomnia is an indicated method to characterize sleep disturbances and can be used in conjunction with subjective data.^{95, 121} For this reason, actigraphy (Appendix IX) in conjunction with sleep diary information will be used in the proposed study to obtain SOL, TST, SE, NOA, and WASO.

Table I.

Definition of Sleep Measures	
Sleep Onset Latency (SOL)	Time elapsed from intent to fall asleep until sleep onset
Total Sleep Time (TST)	Total amount of time sleeping
Sleep Efficiency (SE)	$\frac{\text{Total amount of night time sleep}}{\text{Total time in bed}}$
Number of Awakenings (NOA)	Number of times one is awoken during nighttime sleep
Wake After Sleep Onset (WASO)	Time spent awake after sleep onset

Feedback Questionnaire

A 1-5 point Likert scale created by the investigators will address the acceptability of acupuncture as a treatment for sleep disturbance (see Appendix). Additionally, a three item open

ended questions for study feedback are included. These questions will be used to evaluate the acceptability of the acupuncture intervention, and evaluate feedback for feasibility of study design and planning of future studies with this population of veterans.

Table II.

Instrumentation for Study

Instrument	Reliability and Validity	References
Actigraphy	Actigraphy has demonstrated high sensitivity 89% in numerous studies, but low specificity 36-66, due to inability to detect wakeful periods. Overall agreement rates between PSG and actigraphy ranges from 72.1% to 96.5%.	95, 107-110, 112, 114, 117, 121, 122
Consensus Sleep Diary	Created by leading sleep experts at to facilitate comparisons across studies.	105
PCL-M	Correlated to the Clinician Administered PTSD Scale (0.929), internal consistency of 0.94-0.98(Cronbach's α). Test retest reliability is 0.88 to .96.	97, 98, 101
PHQ-9	Internal consistency of 0.86-0.89 (Cronbach's α). Test retest reliability is reported at 0.84.	102
PSQI	Overall reliability coefficient of 0.77-0.83 (Cronbach's α) is reported. Individual items have a reliability coefficient of 0.83. Sensitivity & specificity is 89.6% and 86.5%. Test retest reliability is reported at 0.85 to 0.87.	88, 91, 94
STOP-Bang Questionnaire	OSA screening instrument with sensitivity values of 83.6%, 92.9%, and 100% for apnea-hypopnea index (AHI) values of >5, >15, and >30. Specificities are 56.4, 43.0, and 37.0 for AHI values of >5, >15, and >30 Test retest reliability is reported at 96.4%.	78
Feedback Questionnaire	A 1-5 point Likert scale to address acceptability of acupuncture for sleep disturbance.	Unpublished instrument.

Statistical Analysis

A small scale feasibility study was designed to collect preliminary data for this population of subjects. Therefore, a power analysis was not conducted. We plan to sample 30 subjects, 15

assigned randomly to each group. We believe successful enrollment of 24-26 subjects (with 10-20% attrition), will demonstrate feasibility of the intervention and study design in this population. Prior to conducting statistical tests, data will be examined to ensure assumptions of described statistical tests are met. Data will be screened, outliers will be identified, and corrective action (deletion, adjustment, or retention) will be taken depending on the source of the deviation. Statistical analyses will be performed with the most current version of the Statistical Package for the Social Sciences. A p value of $< .05$ will be considered statistically significant. Demographic and frequency data will be analyzed using the Chi-square test.

Hypothesis #1: Subjects who receive auricular acupuncture will view it as a more acceptable treatment for sleep disturbance than those who receive standard therapy alone.

-Acceptability of the intervention and overall study design will be evaluated by using a consort diagram to track subject disposition throughout the study period. Acceptability of acupuncture as a treatment for sleep disturbance will be compared between groups utilizing a 1-5 point Likert scale. Subject acceptability scores will be analyzed by the Mann Whitney U test. One question will allow for subjects to write open-ended feedback about the study. Information gathered from this question will be used to guide future studies.

Hypothesis #2: Objective and subjective sleep disturbances and sleep quality will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

-**Objective data:** Actigraphy data will be scored to obtain sleep measures using Motionlogger® Analysis Software. Mean scores will be calculated for each sleep measure of individual subjects, and used to calculate group means for groups. A two-way multivariate analysis of variance will

be conducted to determine the effect of group (intervention or control) at two time intervals (baseline and week 5) on differences in sleep measures (SOL, TST, SE, NOA, and WASO).

Subjective data:

-Sleep diary data will be analyzed with a two-way multivariate analysis of variance conducted to determine the effect of group (intervention or control) at two time intervals (baseline and week 5) on differences in sleep measures (SOL, TST, SE, NOA, and WASO). Similar to actigraphy data, mean scores will be calculated for each sleep measure for individual subjects, and then used to calculate group means. Pearson correlation coefficients will examine the relationship between objective (actigraphy) and subjective (sleep diary) sleep measures.

-PSQI data will be analyzed with a two-way analysis of variance conducted to investigate differences in scores between groups at baseline and at five weeks.

Hypothesis #3: PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

-A two-way multivariate analysis of variance will be conducted to determine the effect of group (intervention or control) at two time intervals (baseline & week 5) on PTSD symptoms and depressive symptoms.

Hypothesis #4: PTSD symptoms and depressive symptoms will be improved during the study period among OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

-A two-way multivariate analysis of variance will be conducted to determine the effect of group (intervention or control) at six time intervals (baseline, week one, two, three, four, and five) on PTSD symptoms and depressive symptoms.

Study Limitations

Veterans with PTSD are a vulnerable population at risk for depression,¹²³ alcohol abuse,¹²⁴ suicide.¹²⁵ and often do not complete PTSD treatment (P.D. Sargent, personal contact, 1/2/2011). Therefore, it may be challenging to recruit subjects, or continue the study to completion. Yet, disturbed sleep is a common complaint in this population, and recruitment of subjects may not be problematic. Reasons for attrition will be monitored during the study to evaluate the acceptability of the intervention and overall feasibility of the study design. Further, since this study is designed as a feasibility study to collect preliminary data on sleep measures (and a power analysis was not conducted), it is likely not powered to effectively study the effectiveness of the intervention. Further, the investigators realize that sleep disturbance is complex, and can be affected by numerous factors that are beyond the scope of this feasibility study. The design of this study attempted to minimize subject burden and study duration, while at the same time capturing enough valuable data to examine acceptability of auricular acupuncture in this population, and feasibility of this study design to decide if a larger investigation would be warranted in the future. Although the challenges of studying OEF/OIF veterans can be difficult, it emphasizes the critical need for novel therapies to improve health care.

Dissemination Plan

At the completion of the study, at least one manuscript will be submitted to a peer-reviewed journal, and a national military conference will be attended to disseminate the study findings.

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Manuscript II

UNIVERSITY OF SAN DIEGO

Hahn School of Nursing and Health Sciences

Auricular Acupuncture: A Brief Introduction for Military Providers

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Abstract

Injured veterans returning from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) often require long-term medical management for a variety of complex physical and mental health conditions. These conditions can be challenging to treat with conventional Western medicine practices alone. Recently, complementary and alternative medicine (CAM) practices have been utilized within military settings, and have been well received by veterans. Auricular acupuncture is a practice that has provided veterans with a new approach to manage symptoms associated with a wide range of health conditions. This treatment has become an attractive treatment option due to its low cost, portability, minimal side effect profile, and ease of use in clinical and operational settings. Although formally trained Oriental medicine practitioners have historically performed these treatments, military healthcare providers are now receiving education and training to administer these treatments. This education and training allows military healthcare providers to expand their knowledge of acupuncture, and provide this treatment to veterans across the continuum of care. The purpose of this article is to provide a fundamental description of auricular acupuncture, and increase awareness of this treatment and its relevance to military settings.

Keywords: acupuncture, history of acupuncture, complementary and alternative medicine.

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Manuscript III

UNIVERSITY OF SAN DIEGO

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**Auricular Acupuncture for Sleep Disturbance in Veterans with Post Traumatic Stress Disorder:
A Feasibility Study**

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Abstract

Post Traumatic Stress Disorder (PTSD) has emerged as a significant problem among Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans. Disturbed sleep is one of the most frequently reported symptoms among OEF/OIF veterans with PTSD. PTSD itself is impairing, but the burden of this disorder is likely heightened when accompanied by sleep disturbances. Sleep disturbances have been associated with a 75-90% increased risk of comorbid conditions, increased levels of depression and anxiety, daytime sleepiness and fatigue, reduced psychomotor performance, diminished work productivity, and decreased quality of life. These consequences of disturbed sleep emphasize the critical need for additional evidence based therapies to treat PTSD related sleep disturbances among OEF/OIF veterans with PTSD.

Increasingly, non-pharmacologic therapies are being investigated for sleep disturbance among PTSD patients. However, few investigations have examined the efficacy of Complementary and Alternative (CAM) therapies on sleep disturbances among veterans with PTSD. CAM practices are emerging in the Department of Defense, yet, there are a limited number of well designed methodologically sound studies to investigate CAM therapies.

The overall purpose of this study was to conduct a small scale feasibility study to examine whether the use of an auricular acupuncture regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. Our approach was to conduct a small scale feasibility study to test the acceptability of an auricular acupuncture regimen for sleep disturbance, examine feasibility of study design, and test efficacy of an auricular acupuncture regimen for sleep disturbance among OEF/OIF veterans with PTSD.

Keywords: auricular acupuncture, OEF.OIF veterans, PTSD, sleep disturbance

Introduction

Among troops returning from Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF), Post Traumatic Stress Disorder (PTSD) has emerged as a significant health problem.¹ PTSD is defined by the development of characteristic symptoms which include: intrusion, avoidance, negative alterations in cognition/mood, and alterations in arousal and reactivity following exposure to a traumatic event.² The overall prevalence of PTSD following deployment in support of OEF/OIF appears to be approximately between 9-24%,³ and sleep disturbances are the most frequently reported symptom of PTSD among OEF/OIF veterans returning from deployment.⁴ Disturbed sleep among individuals with PTSD frequently manifests itself as difficulty falling and staying asleep (insomnia), frequent awakenings, and nightmares.⁵

These findings are of concern because sleep disturbances frequently co-occur with a range of psychological problems,^{6, 7} and analysis of millennium cohort study data indicates military members who report the shortest duration of sleep were among those currently or previously deployed, and also reported symptoms of PTSD, depression, anxiety, or panic at follow-up assessment.⁶ Previous research among Vietnam Veterans are consistent with these findings, and have shown that the vast majority of combat veterans will experience sleep disturbances,⁸ which frequently precede, and co-occur with psychological problems, particularly PTSD.⁹⁻¹¹

Additionally, previous research has shown a consistent relationship between self reported sleep disturbance and PTSD symptoms, in which more severe sleep disturbances have been associated with increased PTSD symptoms.^{5, 12} Further, sleep disruptions among individuals with PTSD are increasingly believed to negatively affect the ability to recover from PTSD,¹³ and quality sleep is viewed as a critical component to facilitate emotional processing of traumatic events.¹⁴ Thus, advancing research and clinical care for veterans with PTSD and sleep

disturbance has the potential to have a cascading positive impact on healing and recovery from PTSD.

First line PTSD treatments such as cognitive therapies have been shown to improve sleep quality among individuals with PTSD,¹⁵ however, disturbed sleep among individuals with PTSD can persist long-term even after successful PTSD treatment.¹⁶ These findings have prompted numerous investigations to examine the use of supplemental sleep strategies in addition to standard PTSD therapy to evaluate their effectiveness. Many of these supplemental sleep strategies utilize pharmacotherapies and have improved sleep quality among individuals with PTSD.^{17, 18} However, medications can be accompanied by side effects, and many PTSD patients prefer non-pharmacologic treatments.¹⁹

Increasingly, non-pharmacologic therapies are being investigated for sleep disturbance among individuals with PTSD; although, few of these investigations have examined the use auricular acupuncture (AA) to improve sleep among veterans with PTSD.

AA is a minimally invasive treatment in which specific points on the ear are pierced with acupuncture needles specifically designed to be placed in the external auricle. Contemporary AA is based on the work of Dr. Paul Nogier who originated the somatotopic correspondence of the auricle with an inverted fetus.²⁰ This system maps all portions of the ear to specific parts of the body and internal organs. Acupuncture needles placed at specific locations on the ear are believed to directly affect the corresponding part of the body. AA has numerous protocols for specific health problems including a protocol specifically for insomnia.²¹

While few studies have examined a mechanism for how AA may promote sleep, previous research has demonstrated that acupuncture increases endogenous opioid levels²²⁻²⁴ and melatonin levels.²⁵ The opioidergic system is theorized to have a somnogenic effect,^{26, 27} and

may interact with melatonin to promote sleep.²⁵ These findings provide a possible physiologic basis of how acupuncture may affect sleep, and provide a reasonable foundation to conduct this study.

Previous investigations have reported that AA treatments have improved sleep measures in several populations with insomnia,^{28, 29} however, of nine recent systematic reviews for acupuncture as an intervention for insomnia, only one review reported a positive effect,³⁰ and the remaining eight reported acupuncture may be beneficial, but evidence is limited or insufficient.³¹⁻³⁵ All nine reviews cited a need for improved methodological quality for future studies utilizing acupuncture as a sleep intervention, with recommendations including: randomization of subjects, use of control groups, use of objective sleep measures, and utilizing double blind research designs.³⁰⁻³⁸ Further, a variety of acupuncture protocols and techniques (magnetic pearls, electroacupuncture, ear seeds, etc.) make comparisons across studies difficult.^{36, 39} Recently, more randomized control trials for acupuncture and insomnia are being conducted, showing improvement in sleep measures;^{40, 41} however, acupuncture as an intervention for insomnia warrants further investigation with rigorous study methodologies.

Although it is unknown if the use of AA will improve sleep disturbances among OEF/OIF veterans with PTSD, investigating non-pharmacologic interventions such as AA to improve sleep disturbances and improve sleep quality are critically needed to avoid the adverse health consequences of disturbed sleep.

Purpose

Given the complexity of veterans with PTSD and sleep disturbances, the purposes of this study were 1) examine the feasibility and acceptability of an AA insomnia regimen among OIF/OEF veterans with PTSD, 2) measure the effect of an AA insomnia regimen on a) objective sleep times by wrist actigraphy, b) subjective sleep times by sleep diary, and c) sleep quality ratings utilizing the Pittsburgh Sleep Quality Index , and 3) measure the effect of an AA insomnia regimen on PTSD symptoms and depressive symptoms. Given these purposes, the hypothesis of this investigation were: 1) subjects who receive AA will view it as a more acceptable treatment for sleep disturbance than those who receive standard PTSD therapy alone, hypothesis 2) objective and subjective sleep times and sleep quality will be improved in OEF/OIF veterans with PTSD who receive AA as compared to those that receive standard PTSD therapy alone, and 3) PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive AA as compared to those that receive standard PTSD therapy alone.

Methods

Study Design

A controlled feasibility study was designed to examine sleep quality in a convenience sample of OEF/OIF veterans with PTSD and self-reported sleep disturbances. Two groups were included: an experimental group which received nine AA treatments according to a standardized AA insomnia protocol, and a control group.

Study Site and Subjects

Subjects consisted of active duty military personnel participating in a 10-week residential PTSD treatment program for combat related PTSD. This study was conducted at a military

facility located in the Southern California region. PTSD diagnosis was confirmed by a board certified psychiatrist or licensed psychologist utilizing the DSM-IV PTSD criteria for all subjects. Recruitment of subjects occurred during orientation sessions for patients enrolled at this facility. Study inclusion criteria included: 1) 18-50 year old male veterans of OIF or OEF diagnosed with PTSD and self reported sleep disturbance. For purposes of this study, sleep disturbance was defined as having one or more of the following self-reported symptoms: sleep onset latency greater than 30 minutes, two or more awakenings per night, total sleep time less than six hours per night, or the presence of nightmares which started after a deployment. Study exclusion criteria included: 1) significant co-morbid conditions (heart disease, lung disease, etc.), 2) history of moderate or severe traumatic brain injury, 3) known sleep apnea history or other sleep disorder, 4) scoring greater than 3 on the STOP-Bang questionnaire 5) essential tremors. All subjects participated in a multi-modal treatment program for PTSD which included: individual and group cognitive processing therapy for PTSD, educational PTSD classes, anger management classes, exercise programs, and community involvement. Additionally, all subjects received four hours of psychoeducational sleep didactic in a group setting during the first three weeks of PTSD treatment.

Subjects resided in military berthing with two to four roommates per unit.

The use of sleep medications did not exclude subjects from the study, however subjects were asked not to increase dosage or change sleep medications during the study. Sleep medications were tracked during the study, and did not result in disenrollment from the study, but were examined in the statistical analysis.

Prior to enrollment in this study, all aspects of subject participation were explained to potential subjects. All subjects that enrolled in this study received written informed consent.

This study was approved by the Naval Medical Center San Diego Investigational Review Board, University of San Diego Investigational Review Board, and the Uniformed Services University of the Health Sciences University Investigational Review Board.

Data Collection Procedures

Subjects completed a demographic questionnaire and the STOP-Bang Questionnaire (an obstructive sleep apnea (OSA) screening instrument).⁴² Subjects scoring greater than three on the STOP-Bang questionnaire were excluded from further participation in the study. For subjects who scored three or less on the STOP-Bang questionnaire, a baseline Pittsburgh Sleep Quality Index (PSQI) score was completed. Subjects were then given instructions on the use of actigraphy watches and a sleep diary. Subjects wore actigraphy watches and recorded sleep information in a sleep diary for seven consecutive days.

After seven days of sleep data collection, subjects were randomly assigned by a computer generated list to one of two conditions: an AA intervention group or control group. Subjects in the AA intervention group were scheduled for a total of nine AA treatments (three weekly AA treatments for three weeks between 4:00-7:00 pm). Subjects in the control group received the same standard multi-modal therapy for PTSD as the AA intervention group. During the fourth week after the AA intervention group completed all acupuncture treatments; all subjects completed the PSQI, and were instructed to wear actigraphy watches and record sleep information in a sleep diary for seven consecutive days. At the completion of the second sleep data collection period, the control group was offered the AA insomnia treatment.

Intervention Group

An AA insomnia protocol following Dr. Nogier's ear reflex theory as described by Dr. Oleson was used on subjects in the intervention group and included the following acupuncture

points: shen men, point zero, brain, thalamus point, pineal gland, master cerebral, insomnia points 1 & 2, kidney, heart, occiput, and forehead.²¹ Acupoint selection was based on review of previous AA insomnia studies, and expert opinion. Although acupuncturists in many clinical settings utilize an electrical point finder to identify active acupoints and individualize treatments, this study utilized a standardized protocol using the identified insomnia acupoints. Standardized acupuncture protocols are preferred when conducting research in order to minimize variation across treatments, and contribute to the reproducibility and generalizability of research findings.³⁴

For subjects receiving the AA, each acupoint was identified and the external ear cartilage of each ear was cleaned with isopropyl alcohol. A clean insertion technique was used with stainless sterile steel acupuncture needles (0.20 mm diameter, 15mm in length, D type needles, SEIRIN Corporation,[®] Shizuoka, Japan) on each of the identified acupuncture points bilaterally. Treatments lasted for a total of 30 minutes per treatment. Needles were inserted to a depth of 2-3 millimeters at each acupoint. All acupuncture treatments were performed on subjects in a supine position in a quiet treatment room. AA treatments were performed by the same privileged military acupuncture provider, who had two years of clinical experience (over 1,500 treatments) providing AA.

Control Group

The group randomized to the control group did not receive any acupuncture treatments during the study period. However, the control group continued to receive the same multimodal treatment for PTSD as the AA intervention group.

Measures

Demographic Questionnaire

A brief self-administered questionnaire was given to subjects to obtain demographic information which included: age, race, ethnicity, education, marital status, branch of service, rank, occupation, length of service, deployment history, current medications, medical problems, presence of chronic pain, presence of nightmares, duration of sleep problems, and duration of PTSD diagnosis. This demographic questionnaire was created by the investigators, and therefore, reliability and validity have not been established for this instrument.

Acupuncture Acceptability and Feasibility

A five point Likert scale question created by the investigators addressed the acceptability of acupuncture as a treatment for sleep disturbance. Subjects were asked to rate their view of the acceptability of auricular acupuncture as a treatment for sleep disturbance with responses ranging from: 1 = “completely disagree that acupuncture is an acceptable treatment for sleep disturbance”, 2 = “disagree that acupuncture is an acceptable treatment for sleep disturbance”, 3 = “undecided if acupuncture is an acceptable treatment for sleep disturbance”, 4 = “agree that acupuncture is an acceptable treatment for sleep disturbance”, and 5 = “completely agree that acupuncture is an acceptable treatment for sleep disturbance.”

Several factors were examined to determine study feasibility. These factors included: study completion rate, study attrition rate, number of AA treatments completed, and adherence to using actigraphs and sleep diaries. Adherence rates were calculated by examining how many scorable nights of actigraphy and sleep diary data were available for each subject and then group means were calculated. Unscorable nights were defined as nights in which the actigraph was not worn

or nights in which the event button was not pushed and sleep diary data was not available to estimate the time a subject attempted to fall asleep.

Sleep Diary

The Consensus Sleep Diary (CSD) was used to collect subjective sleep data during the first and last week of the study. The CSD is a nine item instrument which provides data on daytime napping, bedtime, time attempted to fall asleep, sleep onset latency (SOL), number of awakenings (NOA), wake after sleep onset (WASO), total sleep time (TST), time of awakening, sleep efficiency (SE), and sleep quality.⁴³ Sleep diaries have been regarded as a gold standard for subjective sleep assessment,⁴³ and are viewed by sleep experts as a useful methodology for prospective self-monitoring of sleep for individuals with insomnia.⁴⁴ Further, sleep diaries have been validated against actigraphy, and have shown good correlations with objective sleep measures.⁴⁵

Actigraphy

The Motionlogger Watch, (Ambulatory Monitoring, Inc., Ardsley, NY) was used to collect objective sleep data for this investigation. The Motionlogger Watch has demonstrated high sensitivity (92-96%), high specificity (66-69%), and high accuracy (89%), when compared to polysomnography.^{46, 47} Actigraphs were initialized to use zero crossing and proportional integrating measure modes simultaneously to collect sleep data in one minute epochs. Actigraph data was analyzed using Action W-2 version 2.7.1 software (AMI, Ardsley, NY) and the Cole-Kripke algorithm was used to identify each epoch as sleep or wake.

Both the actigraphy data with event-marked points and sleep diary data were used to calculate sleep measures which included: SOL, TST, SE, WASO, and NOA. All actigraphy data and sleep diary data was reviewed by a sleep expert to ensure sleep data was correctly recorded.

The STOP-Bang Questionnaire

The STOP-Bang questionnaire was used to screen subjects at risk for OSA. The STOP-Bang questionnaire is a self administered eight item dichotomized yes/no questionnaire, represented by the mnemonic STOP-Bang (Snororing, Tiredness, Observed breathing cessation, Pressure-related to the presence or treatment of high blood pressure, Body Mass Index, Age, Neck circumference, and Gender).⁴² A score of three or more indicates a higher risk of the subject having OSA.⁴⁸ As the cumulative score on the STOP-Bang Questionnaire increases, the probability of more severe OSA increases.⁴⁹ The test retest reliability of the STOP questionnaire (four question version) has been reported at 96.4%.⁴²

The Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) is a 19-item self administered questionnaire which assesses sleep quality and sleep disturbance over a one month period in clinical populations.⁵⁰ Both Likert scale items and open-ended response items are utilized. Seven component scores are generated from the 19 items and are weighted on a 0-3 scale, and are then summed to produce a total score (range 0-21) with higher scores indicating decreased sleep quality.⁵⁰ A score of five or greater demonstrates a high specificity and sensitivity for insomnia.⁵¹ Components within the PSQI include: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction.⁴⁴ The seven

component scores on the PQSI have an overall reliability coefficient of 0.77 to 0.83 (Cronbach's α).^{44, 52, 53} Individual items on the PSQI have a reliability coefficient of 0.83 (Cronbach's α), and the sensitivity and specificity of the PSQI have been reported at 89.6% and 86.5% respectively.⁵⁰ A correlation coefficient for test retest reliability of the PSQI has been reported at 0.85 to 0.87.⁵⁰ ⁵¹ The PSQI for the current study was used to examine scores between groups at baseline and at five weeks.

The PTSD Checklist Military Version

The PTSD Checklist-Military Version (PCL-M) is a self-report instrument designed to assess the symptoms of PTSD in which 17 items correspond to the DSM-IV's PTSD criteria.⁵⁴ Items one through five correspond to re-experiencing symptoms, items five and six correspond to avoidance symptoms, items eight through twelve correspond to numbing symptoms, and items thirteen through seventeen correspond to hyper arousal symptoms. The PCL-M is administered in a questionnaire format to individuals in which they are asked to endorse the level of distress with each symptom over the last 30 days. Each item is scored on a five point likert scale with 1 = "not at all" to 5 = "extremely." A total symptom severity score is obtained (range 17-85), with scores greater than 50 indicating a high likelihood of PTSD.⁵⁴ The PCL-M is a psychometrically sound instrument demonstrating good temporal stability and reported internal consistency of 0.94-0.98 (Cronbach's α).^{55, 56} Additionally, the test retest reliability of the PCL-M is reported at 0.88 to 0.96.^{54, 56} The use of the PCL-M for the current study was used to examine PTSD symptoms between groups.

The Brief Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9) is a nine item depression scale used widely by clinicians and researchers to examine depression.^{57, 58} This nine item self-report questionnaire is derived from the depression module of the Patient Health Questionnaire (PHQ),⁵⁹ and each of the nine items on the PHQ-9 corresponds to the diagnostic criteria of DSM-IV for depressive disorders.⁶⁰ The PHQ-9 is administered to individuals in which they are asked to endorse the level of distress with each symptom over the last two weeks. Each item is scored on a four point likert scale with 0 = “not at all,” 1= “several days,” 2= “more than half the days,” and 3 = “nearly every day.” When used as a measure of severity of depression, a total symptoms severity score is obtained (range 0-27), with scores greater than ten indicating a high likelihood of depression.⁶¹ The following scoring system is utilized to categorize severity of depression scores on the PHQ-9: 0-4 minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression.⁵⁷ The PHQ-9 is a psychometrically sound instrument demonstrating a reported internal consistency of 0.86-0.89 (Cronbach’s α).⁵⁷ Additionally, the test retest reliability of the PHQ-9 has been reported at 0.84.⁵⁷ The use of the PHQ-9 for the current study was used to examine PHQ-9 severity scores between groups.

Statistical Methods

Demographic continuous variables were assessed for normal distribution utilizing the Shapiro-Wilk test. Demographic continuous variables were analyzed by *t* test for normally distributed data and by the Wilcoxon Rank Sum test for non-normally distributed data. Categorical variables were analyzed by the Fisher’s Exact Test or Likelihood Ratio as appropriate. Subject acceptability scores on the Likert scale for acceptability of acupuncture as a treatment for sleep disturbance were analyzed by the Mann Whitney U test.

Outcomes sleep data for both actigraphy and sleep diary data was defined as the change from baseline sleep times (actigraphy and sleep diary data) to week five sleep times. Sleep times examined included: SOL, NOA, WASO, TST, SE. Mean scores based on seven nights of actigraphy data and sleep diary data were calculated for each individual subject, and then used to calculate group means for the intervention group and the control group. A 2 x 2 repeated measures ANOVA was performed on sleep time means to compare the AA intervention group and the control group to determine if there were statistical differences between the groups.

Sleep quality data as measured by the PSQI were analyzed with a 2 x 2 repeated measures ANOVA conducted to investigate differences in global scores at baseline and at five weeks. PSQI component scores were analyzed by the Wilcoxon rank sum-test.

PTSD and depression symptoms as measured by the PCL and PHQ were analyzed with a 2 x 2 repeated measures ANOVA to investigation differences in scores at baseline and at five weeks. Further, a 2 x 2 repeated measures ANOVA was conducted to investigation differences in PCL and PHQ scores at baseline, week three, and week five.

A test with a p value < .05 was considered statistically significant. Statistical analysis was performed using SPSS (version 21, SPSS, Inc., Chicago, IL).

Sample Size

Since this study primarily evaluated the feasibility of this study design in a population of veterans with PTSD and sleep disturbances, a power analysis was not conducted.

RESULTS

Demographic Data

Demographic characteristics between the two groups were similar (Table I). The mean age of all subjects was 33 (SD $\pm$ 7.2), and 90% of subjects were enlisted. Fifty percent of subjects in the study were active duty Marines, 40% active duty Navy personnel, and 10% Army personnel. The mean duration of PTSD symptoms among all subjects was 5.44 years (SD $\pm$ 5.1), while the mean duration of PTSD treatment time was 2.4 years (SD $\pm$ 3.1). The mean duration of sleep problems was 4.77 years (SD $\pm$ 3.5), and duration of PTSD symptoms and duration of sleep disturbances were highly correlated with an r of .94 (p < .00).

TABLE I. Demographic Characteristics of the Sample

<u>Baseline Characteristics</u>	<u>AA Group</u> ($n = 12$)	<u>Control Group</u> ($n = 8$)	<u>p-Value</u>
Age (years) (Mean, SD)	33.3 $\pm$ 6.1	32.75 $\pm$ 9.2	.885 ^a
Marital Status			.158 ^b
Single/Divorced (n , %)	6 (50)	1 (0)	
Married (n , %)	6 (50)	7 (100)	
Race			.066 ^c
Caucasian, non-Hispanic (n , %)	4 (33.3)	5 (62.5)	
Black, non-Hispanic (n , %)	1 (8.3)	0 (0)	
Hispanic (n , %)	6 (50)	1 (2.5)	
Pacific Islander (n , %)	0 (0)	2 (25)	
Asian (n , %)	1 (8.3)	1 (2.5)	
Education Level			.411 ^c
High School (n , %)	6 (50)	4 (50)	
Some College, No Degree (n , %)	5 (41.7)	3 (37.5)	
Bachelor's Degree (n , %)	0 (0)	1 (12.5)	
Master's Degree (n , %)	1 (8.33)	0 (0)	
<u>Military Characteristics</u>			.495 ^b
Enlisted (n , %)	10 (83.3)	8 (100)	
Officer (n , %)	2 (16.7)	0 (0)	
Branch of Service			.097 ^c
Army (n , %)	1 (8.3)	1 (12.5)	
Marines (n , %)	4 (33.3)	6 (75)	
Navy (n , %)	7 (58.8)	1 (12.5)	
<u>Clinical Characteristics</u>			
Duration of PTSD (Mean, SD)	4.8 $\pm$ 3.5	6.5 $\pm$ 6.8	.464 ^a
Duration of PTSD Treatment (Mean, SD)	3.0 $\pm$ 3.3	1.6 $\pm$ 2.7	.126 ^d
Duration of Sleep Problems (Mean, SD)	5.1 $\pm$ 3.9	3.9 $\pm$ 2.5	.522 ^a

^a t Test, ^bFisher's Exact Test, ^cLikelihood Ratio, ^dWilcoxon Rank Sum Test

Purpose 1a. Study feasibility

The original criterion set to determine the feasibility of implementing this study was the successful enrollment and retention of 24-26 subjects. A total of 30 subjects consented to participate in this study. The attrition rate among subjects in the intervention group was 20% ($n = 3$) and the attrition rate among the control group was 43% ($n = 6$). Overall, a 33% attrition rate occurred during this study ($n = 10$). The high attrition rate was largely attributed to incomplete treatment of the residential PTSD program ($n = 7$). One subject was disenrolled due to a high score on the STOP Bang questionnaire (indicating a high likelihood of the presence of obstructive sleep apnea) ($n = 1$), while two other subjects from the treatment group voluntarily withdrew from the study ($n = 2$). These later two subjects who voluntarily withdrew from the study endorsed the following reasons for their decision not to continue with the study: one subject cited feeling overwhelmed with the requirements of the study in addition to the PTSD residential treatment program, and the other subject endorsed uncomfortable feelings while receiving the AA treatment. A consort diagram is displayed in Figure 1.

FIGURE 1. Consort diagram.

Subjects readily participated and engaged in the AA treatments. The mean number of completed treatments in the intervention group was 8.42 ($SD \pm .996$) and the mean number of completed treatments in the control group was 8.4 ($SD \pm .99$). Seven of the subjects in the AA intervention group completed all treatments, three subjects completed eight treatments, two subjects completed seven treatments, and one subject completed six treatments. Reasons for missed treatments included forgetting treatment times and schedule conflicts.

During this study subjects were asked to wear actigraphs for seven nights at baseline and seven nights at week five (total of 14 nights). The mean number of scorable actigraphy nights for all subjects in the sample was 9.9 ($SD \pm 3.53$). Subjects in the intervention group had a mean of

9.33 (SD $\pm$ 4.2) scorable actigraphy nights, in comparison to subjects in the control group who had a mean of 10.75 (SD $\pm$ 2.3) scorable actigraphy nights. Scorable actigraphy nights did not demonstrate statistically significant differences ($p = .689$, $z = -.432$, $W_s=120.5$) between the intervention group (*Median* = 11.0, min score = 3, max score = 5) and control group (*Median* = 11.0, min score = 3 max score = 5).

Similarly, subjects were asked to record sleep information for seven nights at baseline and seven nights at week five (total of 14 nights). The mean number of nights all subjects in the sample recorded sleep information in the sleep diary was 11.9 (SD $\pm$ 2.9). Subjects in the intervention group recorded sleep diary information fewer nights ($\mu = 10.75$, SD $\pm$ 3.5) when compared to subjects in the control group ($\mu = 13.5$, SD $\pm$.76). No significant differences of sleep diary information were found ($p = .083$, $z = 1-.762$, $W_s=104.5$) between the intervention group (*Mdn* =12.5) and control group (*Mdn* = 14.0).

Purpose 1b. Acupuncture acceptability

Data from a one question five point likert scale demonstrated that among subjects in the AA intervention group (*Median* = 5) viewed the AA insomnia protocol as a more acceptable treatment for sleep disturbance than subjects in the control group (*Median* = 3) $U = 12.0$, $z = -2.99$, ($p = .004$). Subjects in the control group largely reported they were “undecided if acupuncture is an acceptable treatment for sleep disturbance” because the majority of subjects in this group had never received the AA insomnia protocol (Fig. 2).

FIGURE 2. Acceptability of AA as Treatment for Sleep Disturbance

Purpose 2a. Actigraphy Data

No significant differences in sleep measures by actigraphy were found between the AA intervention group and control group: SOL $p = .5$, WASO $p = .24$, NOA $p = .14$, SE $p = .36$, TST $p = .81$. In both the AA intervention group and the control group SOL, WASO, and NOA increased at week five, while SE and TST decreased, but these changes were not statistically significant between groups. Changes in sleep measures obtained by actigraphy at baseline and at week five between groups are shown in Table II.

Purpose 2b. Sleep Diary Data

No significant differences in sleep measures by sleep diary were found between the AA intervention group and control group: SOL $p = .55$, WASO $p = .82$, NOA $p = .67$, SE $p = .65$, TST $p = .78$ (Table II). WASO and SE increased in both groups, while TST and NOA decreased in both groups; however, these changes did not demonstrate statistically significant differences between groups. SOL decreased in the AA intervention group and increased in the control group, but this change between groups was also not significant.

TABLE II. Week Five Between-Group Analysis: Actigraphy and Sleep Diary Data

Sleep Measures by Actigraphy ^a	AA Group BSL(n=10)	AA Group Week 5	Control Group BSL (n=8)	Control Group Week 5	p - Value
SOL	47.6 ± 30.0	58.4 ± 43.9	40.2 ± 26.3	65.9 ± 40.5	.50
WASO	34.4 ± 14.3	41.1 ± 15.1	22.9 ± 13.3	49.8 ± 43.5	.24
SE %	92.4 ± 3.2	90.0 ± 4.3	94.3 ± 3.0	88.5 ± 9.1	.361
NOA	15.6 ± 4.4	16.5 ± 5.6	11.0 ± 4.2	16.6 ± 6.6	.14
TST	462 ± 49.0	417.6 ± 68.2	413.3 ± 77.5	394.5 ± 82.5	.81
Sleep Measures by Sleep Diary					
SOL ^b	68.2 ± 47.5	36.0 ± 26.6	88.8 ± 37.3	89.3 ± 134	.56
WASO ^c	55.6 ± 46.2	72.7 ± 80.5	49.7 ± 51.1	85.9 ± 166.2	.82
SE % ^b	58.5 ± 46.2	73.3 ± 16.7	62.2 ± 17.5	70.7 ± 30.4	.65
NOA ^d	3.2 ± .88	2.1 ± 1.2	2.7 ± 1.8	2.1 ± 1.8	.67
TST ^e	344.5 ± 118.3	74.3 ± 15.5	325.7 ± 113.4	73.6 ± 28.8	.78
Results are presented as $\mu \pm$ SD. SOL refers to sleep onset latency (min.), WASO, wake after sleep onset (min.), SE%, sleep efficiency, NOA, number of awakenings longer than 5 minutes, TST, total sleep time (min.). ^a Missing actigraphy data for two subjects in the intervention group, ^b missing sleep diary data for seven subjects in the intervention group and two subjects in the control group, ^c missing sleep diary data for six subjects in the intervention group and two subjects in the control group, ^d missing data from seven subjects in the intervention group and one subject in the control group, ^e missing sleep diary data for five subjects in the intervention group and one subject in the control group.					

Purpose 2c: Sleep quality measures

At week five, differences in sleep quality as measured by the PSQI were not significant between groups ($p = .082$), however, this value was trending toward statistical significance, and would likely be resolved with a powered study (Table III, Fig. 3). PSQI component scores were not statistically significant between the AA intervention group and control group with the exception of the sleep quality component ($p = .003$), and the daytime dysfunction component ($p = .004$) (Fig. 4, Fig. 5 respectively). Post hoc analysis of the sleep quality component demonstrated a decrease in group mean of .75 for the intervention group, while the control group demonstrated no change in group mean score ($p = .057$). Post hoc analysis of the daytime dysfunction component demonstrated a decrease in group mean of .75 for the intervention group, while the control group demonstrated an increase in mean score of .37 ($p = .005$). The partial eta squared value was .38 demonstrating a moderate effect for the interaction of time and group assignment.

TABLE III. Pittsburg Sleep Quality Index Mean Scores at Week Five

	AA Group	Mean Difference	Control Group	Mean Difference	<i>p</i> Value
PSQI Global	14.0 ± 3.4	-3.3	16.25 ± 2.8	-1.25	.08
Sleep Quality	1.8 ± .75	-0.7	2.4 ± .52	.02	.003*
Sleep Latency	2.2 ± .84	-0.7	2.6 ± .52	-0.4	.29
Sleep Duration	1.4 ± .80	-0.9	2.3 ± .70	-0.7	.23
Sleep Efficiency	1.9 ± .90	-0.4	2.0 ± 1.2	-0.6	.75
Sleep Disturbances	2.1 ± .67	-0.3	2.0 ± .93	0	.31
Sleep Medication	3.0 ± .00	0.5	2.6 ± 1.1	0.1	.52
Daytime Dysfunction	1.6 ± .67	-0.7	2.3 ± .74	0.3	.004*
Results are presented as $\mu \pm SD$. Mean difference is the mean change in score within each group from Week 1 to Week 5. PSQI (range 0-21), component scores (range 0-3), higher scores indicate decreased sleep quality. *significant result					

FIGURE 3. PSQI Global Scores Between Groups

FIGURE 4. PSQI Component Sleep Quality Interaction

FIGURE 5. PSQI Component Daytime Dysfunction Interaction

Purpose 3: PTSD symptoms and depression symptoms

At week five, differences in PTSD and depression symptoms as measured by the PCL and PHQ were not significantly different between groups ($p = .85$, $p = .28$, respectively) (Fig. 6 and Fig. 7 respectively). Similarly, differences in PTSD and depression symptoms were not significantly different between groups at three time points: baseline, week three, and week 5 ($p = .94$, $p = .48$ respectively) (Fig. 8 and Fig. 9 respectively).

FIGURE 6. PCL Group Means at Week Five

A higher score on PCL reflects worse PTSD symptoms.

FIGURE 7. PHQ Group Means at Week Five

A higher score on PHQ reflects worse depression symptoms.

FIGURE 8. PCL Group Means at Three Time Points

FIGURE 9. PHQ Group Means at Three Time Points

Safety

A total of five adverse events occurred during the study period. These adverse events included: one subject fell, two subjects became intoxicated, one subject injured his wrist while attempting to dissolve a fight, and one subject had suicidal ideation. All adverse events occurred in subjects in the control group with the exception of the subject who fell. This subject had received an AA treatment two days prior to his fall. All adverse events were reviewed by a Medical Monitor and were deemed unrelated to the AA treatment. No adverse events directly related to the AA intervention were noted during the study period.

Discussion

The purpose of this feasibility study was to examine the feasibility and acceptability of an AA treatment for insomnia, and examine limited efficacy of an AA insomnia treatment for active duty veterans with PTSD. The acceptability of using an AA treatment for insomnia among subjects in this investigation was high, as subjects readily volunteered to participate in this study and receive the AA treatments. Many of the subjects participating in this study were curious about the auricular acupuncture intervention as this treatment is not available at many small military bases. Additionally, many of the subjects participating in this study commented on their interest in receiving non pharmacologic treatment options to improve their sleep and continued to receive AA treatments after the study was completed.

Overall this study design was feasible; however, the high attrition rate from the residential PTSD program at the study site, and subsequent attrition from the study, was the most challenging aspects of this investigation. Previous interventional investigations among veterans

with PTSD have experienced similar rates of attrition,^{62, 63} and this finding highlights the complex and vulnerable nature of veterans with PTSD. Subjects in this study were frequently affected not only by severe PTSD, but also depression, chronic pain, daytime fatigue, memory deficits, anxiety, in addition to sleep disturbances. The frequent presence of symptoms related to these co-morbidities among veterans with PTSD have been well documented in other investigations^{64, 65} and have recently been referred to as the Trauma Spectrum Response (TSR).⁶⁶ Many of the TSR symptoms can be overlapping, thus, designing interventional sleep studies among veterans with PTSD can present challenging circumstances. Despite the high attrition rate experienced in this study, the investigators believe this study demonstrated a reasonable enrollment and retention rate for the implementation of the study design among active duty veterans with PTSD receiving treatment in a residential treatment program.

Another challenge experienced during this study was adherence to the data collection methods of actigraphy and sleep diary data which was different between groups. Although this difference was not statistically significant for either scorable actigraphy nights or recorded sleep diary nights, the differences noted between group assignments were relevant to feasibility and study design. The differences noted in sleep data collection methods between groups is speculated to be a result of the control group desiring the AA treatment, and therefore ensuring completeness of the requirements to obtain the AA treatment.

Differences in completion of the sleep diary were most apparent between the assigned groups. The intervention group completed the CSD less often at the five week period and this was speculated to be a result of the intervention group already receiving the AA treatment. Since there was a difference in adherence rates for both CSD completion and scorable actigraphy nights between the AA intervention group and the control group, the use of incentives may

improve the adherence to data collection measures thereby improving the available data to analyze.

Our findings on the use of an AA insomnia regimen for insomnia demonstrated that a three week AA insomnia intervention did not have a significant effect on the sleep measures we examined. The majority of sleep measures by actigraphy and CSD actually worsened, however, this is believed to be related to the concurrent cognitive processing therapy subjects were participating in at the residential program.

An interesting finding of this study was the significant difference between the AA intervention group and control group for the PSQI components sleep quality and daytime dysfunction. These two components of the PSQI influenced the global PSQI score trending towards significance, and suggest that an improvement in sleep quality and daytime dysfunction occurred as a result of receiving the AA intervention. Since the PSQI was administered to subjects at the closest time interval to the administration of AA intervention, there may be a short term effect on sleep may have existed, but was not captured by the other study instruments. Specifically, since sleep measures were examined the week after the AA intervention, there may have been short term improvements in sleep that were not captured by the timing of data collection in this study. Future investigations may benefit from collecting sleep measurement data closer to the timing of the AA interventions.

Another consideration of timing of implementing the AA intervention in this population may be to employ the AA intervention later in the residential PTSD program. This may demonstrate greater improvements in sleep at a time PTSD symptoms and sleep disturbances tend to return to baseline values. Alternatively, a longer AA intervention during the entire course of treatment at the residential site may have been beneficial.

Limitations

This study was limited by the small sample size, lack of sham acupuncture group, and control of sleep medications during the study. The use of a sham acupuncture group was omitted in this feasibility study as the investigators were primarily evaluating acceptability of the acupuncture and implementation of the study design. The use of sham acupuncture in research studies is controversial, and believed to have an effect. However, the use of a sham group provides a more effective scientific study design. Secondly, this study did not control or restrict the use of sleep medications. Controlling for sleep medications would have allowed more transparency in evaluating the acupuncture intervention. However, during this study subjects did not frequently change sleep medications or dosages during the study period, but frequently changed antidepressant medications. Further, because subjects in this study represent some of the most severe cases of PTSD on active duty, many subjects were taking numerous classes of medications all of which likely affect sleep. The investigators of this study decided not to limit medication changes, but to examine sleep medication usage over time. Additionally, limiting medication changes in this study was believed to self-select higher functioning veterans with PTSD, and limits the ability to conduct a study on this population which could benefit from non-pharmacologic options to improve sleep. Despite the limitation of this study, the preliminary results of this study are encouraging and warrant further investigation of AA treatments for insomnia among veterans with PTSD.

Conclusion

A number of important implications resulted from this feasibility study. Primarily, the AA intervention utilized in this study was extremely acceptable to veterans with PTSD in this sample. Given the importance of sleep and its implications in PTSD recovery, finding non

pharmacologic treatments that are acceptable to veterans with PTSD to enhance sleep quality are critically important.

AA treatments offer numerous benefits. AA treatments are inexpensive, portable, and are easily administered in a variety of settings. Further, AA treatments are rooted in traditional Chinese Medicine which emphasizes maintaining health by creating a balance of forces through self-adaptation and self-regulation techniques within one's own environment. These concepts are particularly relevant to veterans with PTSD and sleep disturbance. Treatments such as AA promote the use of non-pharmacologic methods to restore balance and promote healthy strategies to improve sleep. AA treatments avoid potential side effects associated with medications and may help address the complex nature of PTSD and sleep disturbance which can include a combination of physiologic, psychosocial, cognitive, and behavioral factors.

Although a growing numbers of small studies have demonstrated improved sleep with the use of AA interventions, these studies have been limited by small sample sizes, a variety of techniques (acupressure, acupuncture seeds, magnets, etc.), lack of objective sleep measures, and a lack of randomized control trials. Thus, there is a need for rigorous scientific studies exploring AA as an intervention to improve sleep in this population.

Future directions for utilizing AA interventions to investigate sleep disturbances among veterans with PTSD may need to more fully address the complex nature of this population. This might be accomplished by investigating AA treatments in conjunction with cognitively based sleep interventions. Additionally, future studies utilizing AA as an intervention for sleep may benefit from utilizing instruments which capture the short term effects of AA as well as investigate long term effects.

The investigators believe this study captured valuable preliminary data, which would warrant a larger study incorporating acupuncture as a supplemental adjunct to treat veterans with PTSD and disturbed sleep.

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Appendix A

Research Participant Consent Form

Title of Research Study: *Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Traumatic Stress Disorder.*

NAVAL MEDICAL CENTER

SAN DIEGO, CALIFORNIA 92134-5000

**CONSENT BY A *SUBJECT* FOR VOLUNTARY
PARTICIPATION IN A CLINICAL INVESTIGATION
(RESEARCH) STUDY**

1. You, _____, have been asked to voluntarily participate in a research project entitled, " Acupuncture for Sleep Disturbance in OEF/OIF veterans with Post Traumatic Stress Disorder (PTSD)" being conducted at the Overcoming Adversity, Stress and Injury Support (OASIS) Clinic, by medical researchers from the Naval Medical Center San Diego Department of Mental Health Department and the University of San Diego School of Nursing.

Inclusion or exclusion in this study will in no way impact your treatment at OASIS.

2. WHY IS THE STUDY BEING DONE?

The purpose of this research project is to: examine whether the use of ear acupuncture improves sleep quality for Operation Iraqi Freedom/Operation Enduring Freedom (OEF/OIF) veterans with PTSD and sleep disturbance. This study is being done because sleep disturbances frequently occur among veterans with PTSD, and these sleep disturbances can be challenging to treat. No studies have examined ear acupuncture, in addition to standard treatment for veterans with

PTSD to determine whether or not it improves sleep quality. This study will look at sleep quality, depression, and PTSD symptoms at the beginning of the study and at the end of the study to see if there are differences in the participants that receive ear acupuncture in addition to standard PTSD therapy or standard PTSD therapy alone.

3. HOW LONG WILL YOU BE PARTICIPATING IN THE STUDY?

This study will occur over a five week period during your treatment for PTSD at the OASIS Clinic. You are allowed to enroll in the study during the first week of treatment at the OASIS Clinic.

4. WHAT IS INVOLVED IN THE STUDY?

If you enroll in this study, you will be asked to complete two questionnaires (one with general information about you such as age, rank, how long you have had PTSD, etc. and a second questionnaire about your risk for having sleep apnea- a breathing disorder where you stop breathing at night). If you are not at risk for having sleep apnea, you will be allowed to participate in the study, if you are at risk for having sleep apnea you will not be allowed to continue in the study.

Information will be obtained from three of your baseline questionnaires at the OASIS Clinic (sleep questionnaire, PTSD questionnaire, & depression questionnaire). You will then be asked to wear a device which resembles a watch (which records your sleep information) and will be asked to record written sleep information in a sleep diary for one week. After this week, you will be randomly assigned by chance to receive ear acupuncture for three weeks (three times per week) or be assigned to a waitlist/control group. Neither your doctor, the researcher for this study, nor you will be able to choose the group to which you will be assigned. After this three week period has ended, you will be asked to complete a sleep questionnaire and a study feedback questionnaire. Additionally, you will be asked to wear the watch device and record written sleep information for one week. If you were randomized to the waitlist/control group, and desire to have the ear acupuncture intervention, this will be offered to you after the conclusion of the study (after second set of questionnaires completed, watch device worn and written sleep diary/log completed for the second week).

5. WHAT IS THE EXPERIMENTAL PART OF THE STUDY?

Specifically, the experimental part of this research project is the ear acupuncture treatment. Although acupuncture is currently used in clinical practice among OEF/OIF veterans with PTSD for a wide variety of symptoms, no studies have looked at the effect of acupuncture on sleep quality in veterans.

6. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 30 subjects are expected to participate in this study.

7. WHAT ARE THE RISKS OF THE STUDY?

The risks or discomforts which are possibly related to your participation in this study are as follows: potential loss of confidentiality, pain from acupuncture needles, bleeding from acupuncture needle insertion site, infection, nerve damage, or bruising after acupuncture needles have been removed. The safety of acupuncture has been reported in several large studies and the incidence of the most commonly reported adverse events are mild (pain, bleeding, or bruising) and occur between 3.76%-15% of the time. Serious adverse events occur less than 1% of the time (including infection and nerve damage). No deaths have been associated with acupuncture treatment.

8. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Your participation in this research project may not be of direct benefit to you personally, however, you may receive more frequent acupuncture treatment which may not be available to you without participation in this study. Further, acupuncture treatments will not be available to you as part of your standard care at the OASIS clinic after your participation in the study is completed. The results of this study may help us gain important knowledge about acupuncture and its effect on sleep quality in veterans with PTSD. If the ear acupuncture intervention is shown to have a positive effect on sleep measures, the results will be immediately disseminated to the NMCS D Mental Health Department and NMCS D Command Leadership to promote the availability of this intervention to other veterans who may benefit from it.

9. WHAT OTHER OPTIONS ARE THERE?

The alternate procedure(s) or course of treatment, should you decide not to participate in this research study, has been explained to you as follows:

You may discuss medication/treatment options available with your assigned doctor at the OASIS Clinic. You will continue to receive standard medical treatment, decided on by your mental health team at OASIS.

10. WILL I BE PAID TO PARTICIPATE?

You will not be financially compensated for your participation in this study.

11. WHAT IF I AM INJURED AS A RESULT OF PARTICIPATION IN THIS STUDY?

If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

12. WHAT ABOUT CONFIDENTIALITY?

In all publications and presentations resulting from this research study, information about you or your participation in this project will be kept in the strictest confidence and will not be released in any form identifiable to you personally. However, authorized personnel from the Navy Medical Department and from the Food and Drug Administration (FDA), where applicable, may have access to your research file in order to verify that your rights have been adequately protected.

PATIENT AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)

(In Keeping with the Health Insurance Portability and Accountability Protection Act)

What is Confidentiality of records all about?

The Naval Medical Center San Diego makes every effort to maintain the confidentiality of protected health information we obtain about you. However, we cannot absolutely guarantee confidentiality because other people may need to see your information in the course of this research study. Most people and organizations will protect the privacy of your information, but may not be required to do so by the law. Also, if the results of this research study are presented at meetings or are published, your name will not be used.

What is HIPAA all about?

The Health Insurance Portability and Accountability Act (HIPAA) require that we get your permission to use protected health information about you that is either created by or used in connection with this research study. This permission is called an Authorization. The information we use includes information from your medical records, and name.

What will we do with this information?

Your protected health information will be collected and used during the course of the research study, to monitor your health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests, procedures, and commercial products.

Your research doctor will use this information to report the results of research to sponsors and federal agencies, like the Food and Drug Administration (FDA). The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

Who will we share your information with?

Your information may be shared with any of the following:

- The sponsor of the study, or its agents, such as data repositories

- Other medical centers, institutions, or research investigators outside of the Naval Medical Center San Diego, participating in this research study
- State and Federal agencies which have authority over the research, the Naval Medical Center San Diego or patients. Good examples are: the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institute of Health (NIH), the Office of Human Research Protections (OHRP), and the Department of Social Services (DSS) or other.
- This hospital or clinic.
- Accrediting agencies, such as JCAHO.
- A data safety monitoring board, if applicable
- Clinical staff who may not be involved directly in the research study, but who may become involved in your care, if it is possibly related to treatment

For this research study, the study investigator may share this authorization form and records which identify you to comply with regulatory requirements or for purposes related to this research to:

All documented Principal, Associate, and Sub-investigators, and the Medical Monitor.

What if you want to revoke or cancel away your Authorization?

If you decide to participate in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke your Authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

Revoking your Authorization only affects the use and disclosure (sharing) of information after your written request has been received. Federal law requires sending study information to the FDA for studies it regulates, like studies of drugs and devices. In a case like this, your information may need to be reported to them and cannot be removed from the research records once it is collected.

Do you have to sign this form?

You have the right to refuse to sign this Authorization form and not be a part of this study. You can also tell your study doctor you want to withdraw from the study at any time without revoking the Authorization to use your health information. By signing this research Authorization form, you authorize the use and/or disclosure of your protected health information described above.

This authorization expires 25 years from the date of signature.

13. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding this research study, you may contact CDR Heather King, NC, USN, Principal Investigator at (619) 788-6728.

If you have any questions about your rights as an individual while participating in a research study at the Naval Medical Center, San Diego, you may contact **CDR John Arnold, MC, USN, Chairman, Institutional Review Board at (619) 532-9927, or John D. Malone, M.D., Head, Clinical Investigation Department at (619) 532-6099.**

If you believe that you have been injured as a result of your participation in this research study, you may contact **CAPT Mary Ellen Moss, JAGC, USN, Naval Medical Center, San Diego, Legal Department, at (619) 532-6475.**

14. WHAT ARE MY RIGHTS AS A PARTICIPANT?

Your participation in this project is entirely voluntary and your decision not to participate will involve no penalty or loss of benefits to which you are entitled under applicable regulations. If you choose to participate, you are free to ask questions or to withdraw from the study at any time. If you should decide to withdraw from the research project, you will notify **CDR Heather King, NC, USN, at (619) 788-6728** to ensure your timely removal from the study. Your withdrawal will involve no prejudice to your future health care or any loss of rights or benefits to which you are otherwise entitled. Any new significant finding developed during the course of this study, which might affect your willingness to continue participation will be communicated to you.

California Experimental Subject's Bill of Rights

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- (i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

15. CAN I BE TERMINATED FROM THE STUDY?

The investigator may terminate your participation in this study for the following reasons: subject's failure to comply with study procedures, unacceptable side effects from the ear acupuncture treatment, the investigator's determination that ear acupuncture is ineffective or unsafe, subjects sleep medications/dosages are altered during the study period, or at the request of the OAISIS Clinic staff. In the event that sleep medications are changed, please contact the principle investigator CDR Heather King at (619) 788-6728.

16. SIGNATURE

You are making a decision whether or not to participate in the research project above. Your signature indicates that you have had this information presented to you, have had the opportunity to ask questions about the research and your participation, and agree to participate in the study.

**SIGNATURES AND DATE SIGNED:
IDENTIFICATION:**

PRINTED OR TYPED

Patient / Subject

(Date)

Name

Investigator/Researcher

(Date)Name / Grade or Rank

Appendix B

Demographic Questionnaire

Demographic Questionnaire

Subject ID# _____

Age: _____ Rank: _____

Branch of Service (circle one): Navy Army Air Force Other _____

Active Duty or Reserves (circle one)

Marital Status (circle one): Single Married Divorced Separated

Race/Ethnicity: _____

What is the highest level of education you have obtained (circle one):

High School Diploma Some College, No Degree Associates Degree

Bachelor's Degree Master's Degree Doctoral Degree

Occupation (specialty or MOS): _____ Length of Service (in years): _____

How many times have you deployed? _____

What location were you deployed to? _____

What medications do you currently take? _____

How long have you had PTSD? _____

How long have you received treatment for PTSD? _____

Do you have any other health problems? _____

Do you have chronic pain? _____

Do you have sleep apnea, use a CPAP or BiPAP machine? _____

How long have you had trouble sleeping? _____

How long does it take you to fall asleep? _____

How many times (on average) do you awaken at night? _____

Do you have nightmares? _____

How many hours do you sleep per night? _____

Appendix C

STOP Bang Questionnaire

Subject # _____ Date: _____

STOP BANG Questionnaire

INSTRUCTIONS:

Please answer the 8 questions below to help us assess for possible sleep apnea, a condition in which your breathing pauses or stops for periods of time while you sleep. Please circle yes or no for each question.

- Yes No 1. Snoring: Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?
- Yes No 2. Tiredness/fatigue: Do you often feel tired, fatigued, or sleepy during the daytime, even after a "good" night's sleep?
- Yes No 3. Observed apnea: Has anyone has ever observed you stop breathing during your sleep?
- Yes No 4. Pressure: Do you have or are you being treated for high blood pressure?
- Yes No 5. Body mass index: Do you weigh more for your height than is shown in the tables below?

Height	Weight (lb)	Height	Weight (lb)
4'10"	167	5'8"	230
4'11"	173	5'9"	237
5'	179	5'10"	243
5'1"	185	5'11"	250
5'2"	191	6'	258
5'3"	197	6'1"	265
5'4"	204	6'2"	272
5'5"	210	6'3"	279
5'6"	216	6'4"	287
5'7"	223	6'5"	295

Weights shown in the tables above correspond to a BMI of 35 for a given height.

- Yes No 6. Age: Are you older than 50 years?

Yes No 7. Neck size: Does your neck measure more than $15\frac{3}{4}$ inches (40 cm) around?

Yes No 8. Gender: Are you male?

Appendix D

Consensus Sleep Diary

Consensus Sleep Diary

☐ Baseline ☐ Week 5 Assessment

Subject #: _____ Date: _____

Today's date	MM/DD/YYYY							
1. What time did you get into bed?	HH:MM							
2. What time did you try to go to sleep?	HH:MM							
3. How long did it take you to fall asleep?	HH:MM							
4. How many times did you wake up, not counting your final awakening?	# times							
5. In total, how long did these awakenings last?	HH:MM							
6. What time was your final awakening?	HH:MM							
7. What time did you get out of bed for the day?	HH:MM							
8. How would you rate the quality of your sleep?	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good
9. Comments:								
a. # of caffeinated drinks	#							
b. did you have nightmares last night	Y/N							
c. sleep medication taken today	Medication							
d. any pain episodes that caused awakening	Y/N							
e. other comments	# times							

Cassey, C. R., Rogers, D. J., Ansel-Leland, R., Ellinger, J. D., Bryant, A. D., Linsmith, K. C., & Mohr, C. M. (2012). The consensus sleep diary: standardizing prospective sleep and awakening. *Sleep, 35*(2), 287-302. Used with permission.

Appendix E

Pittsburgh Sleep Quality Index

Subject # _____ Date: _____
☐ Baseline ☐ Week 5 Assessment

Pittsburg Sleep Quality Index (PSQI)

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night?
(This may be different than the number of hours you spent in bed.)

HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

- a) Cannot get to sleep within 30 minutes

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

- b) Wake up in the middle of the night or early morning

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

c) Have to get up to use the bathroom

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

d) Cannot breathe comfortably

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

e) Cough or snore loudly

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

f) Feel too cold

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

g) Feel too hot

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

h) Had bad dreams

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

i) Have pain

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

j) Other reason(s), please describe _____

How often during the past month have you had trouble sleeping because of this?

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or roommate?

No bed partner or room mate _____

Partner/roommate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a roommate or bed partner, ask him/her how often in the past month you have had...

a) Loud snoring

Not during the Less than Once or twice Three or more
past month _____ once a week _____ a week _____ times a week _____

b) Long pauses between breaths while asleep

Not during the Less than Once or twice Three or more
past month _____ once a week _____ a week _____ times a week _____

c) Legs twitching or jerking while you sleep

Not during the Less than Once or twice Three or more
past month _____ once a week _____ a week _____ times a week _____

d) Episodes of disorientation or confusion during sleep

Not during the Less than Once or twice Three or more
past month _____ once a week _____ a week _____ times a week _____

e) Other restlessness while you sleep; please
describe _____

Not during the Less than Once or twice Three or more
past month _____ once a week _____ a week _____ times a week _____

Buyse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989. Reprinted with permission.

Appendix F

Post Traumatic Stress Disorder Checklist Military Version

Instruction to patient: Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, put an "X" in the box to indicate how much you have been bothered by that problem *in the last month*.

No.	Response	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
1.	Repeated, disturbing <i>memories, thoughts, or images</i> of a stressful military experience from the past?					
2.	Repeated, disturbing <i>dreams</i> of a stressful military experience from the past?					
3.	Suddenly <i>acting or feeling</i> as if a stressful military experience <i>were happening</i> again (as if you were reliving it)?					
4.	Feeling <i>very upset</i> when <i>something</i> reminded you of a stressful military experience from the past?					
5.	Having <i>physical reactions</i> (e.g., heart pounding, trouble breathing, or sweating) when <i>something</i> reminded you of a stressful military experience from the past?					
6.	Avoid <i>thinking about</i> or <i>talking about</i> a stressful military experience from the past or avoid <i>having feelings</i> related to it?					
7.	Avoid <i>activities</i> or <i>situations</i> because they <i>remind you</i> of a stressful military experience from the past?					
8.	Trouble <i>remembering important parts</i> of a stressful military experience from the past?					
9.	Loss of <i>interest in things that you used to enjoy</i> ?					
10.	Feeling <i>distant</i> or <i>cut off</i> from other people?					
11.	Feeling <i>emotionally numb</i> or being unable to have loving feelings for those close to you?					
12.	Feeling as if your <i>future</i> will somehow be <i>cut short</i> ?					
13.	Trouble <i>falling</i> or <i>staying asleep</i> ?					

14.	Feeling <i>irritable</i> or having <i>angry outbursts</i> ?					
15.	Having <i>difficulty concentrating</i> ?					
16.	Being " <i>super alert</i> " or watchful on guard?					
17.	Feeling <i>jumpy</i> or easily startled?					

PCL-M for DSM-IV (11/1/94) Weathers, Litz, Huska, & Keane National Center for PTSD - Behavioral Science Division. Reprinted with permission.

Appendix G

Patient Health Questionnaire

Copyright restriction prohibits reproduction of this instrument.

Appendix H

Feedback Questionnaire

Subject ID# _____

We appreciate your participation in the study entitled “Acupuncture for Sleep Disturbance in OEF/OIF veterans with Post Traumatic Stress Disorder (PTSD).” We are interested in your opinion of acupuncture as a treatment for sleep disturbance and your feedback about this study.

Please circle the number below which most closely describes your view of acupuncture as an acceptable treatment for sleep disturbance:

1. Completely disagree that acupuncture is an acceptable treatment for sleep disturbance.
2. Disagree that acupuncture is an acceptable treatment for sleep disturbance.
3. Somewhat agree that acupuncture is an acceptable treatment for sleep disturbance.
4. Agree that acupuncture is an acceptable treatment for sleep disturbance.
5. Completely agree that acupuncture is an acceptable treatment for sleep disturbance.

Please write any comments or feedback in the space below regarding your participation in this study, and recommendations for future studies with acupuncture.

Clinical Investigation Department
Naval Medical Center, San Diego
34800 Bob Wilson Drive, Suite 5
San Diego, CA 92134-1005
Tel: 619-532-9416; FAX: 619-532-8137
Email: kelsey.preston@med.navy.mil

November 1, 2012

From: Head, Clinical Investigation Department (CID)
To: Heather King, BSN, MSN
Subj: **FINAL APPROVAL OF CLINICAL INVESTIGATION PROGRAM (CIP)
STUDY CIP #NMCSO.2012.0053, "Acupuncture for Sleep Disturbance in OEF/OIF
Veterans with Post Traumatic Stress Disorder (PTSD)"**
Ref: (a) NAVMEDCEN SDIEGOINST 6500.9A

1. The Institutional Review Board (IRB) has reviewed and recommended approval of the application that involves human research subjects, as reported in the September 19, 2012 IRB meeting minutes. This board reviewed all documents attached to the original submission. Naval Medical Center San Diego holds Office of Human Research Protections Federal Wide Assurance number FWA00002342 and DOD Navy Assurance number 40005.

2. IRB APPROVAL DATE: September 19, 2012
Type of Review: Full Committee Review

3. CLINICAL INVESTIGATION PROGRAM NUMBER (CIP#): NMCSO.2012.0053
This number is the clinical investigation program number and is required to be included with all correspondence, consent forms, and research data files.

4. ADVERSE EVENT (AE) REPORTING: All problems that could possibly effect subject safety must be reported to the IRB within five days; serious AEs must be reported within 24 hours. All deaths, whether or not they are directly related to study procedures, must be reported.

5. AMENDMENTS: Prior IRB approval is required before implementing any changes to the protocol, including investigator additions or deletions, edits to consent documents or any other modifications to the documentation contained in the original submission package.

6. EXPIRATION DATE: Your protocol will expire on September 18, 2013. If the project is to continue, it must be renewed *prior to the expiration date*.

7. COMMENT: The Research Administration Office will send you a *Continuing Review Report (CRR) approximately 60 days prior to the expiration of the study*. The IRB wishes to remind you that, according to the Department of Health and Human Services (DHHS) and NMCSO policy, the renewal of exempt research projects is the *investigator's* responsibility and a renewal application is required *at least* annually for all projects involving human subjects.

8. ARTICLES/ABSTRACTS/POSTERS: : If you wish to submit an item for publication or presentation, it must be submitted to the CID Medical Editing staff. The Lead Editor, Ms. Elisea Avalos can be reached at (619) 532-8134; she will assist in their preparation, will ensure proper acknowledgment of BUMED as sponsor, will obtain command approval and submit them to journals and publications.

9. QUESTIONS: Please contact the IRB Research Administration Division (RAD) if you have any questions:

Kelsey Preston at 619-532-9416

J.D. Malone, MD
Head, Clinical Investigation Department

John Arnold Comments - [379172-2] Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Trau...

10/2

Minor mode made as requested. Fully approvable meeting 32CFR219.111 CFA

Recommendation:	Approve
Last Updated:	10/02/2012 06:07 PM

☒ Mark my personal review as complete.
Completed Date: 10/02/2012 06:07 PM

Reviewer Documents:

There are no reviewer documents attached.

Submission Detail

Naval Medical Center San Diego (NMCSD) Institutional Review Board

[379172-2] Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Traumatic Stress Disorder (PT...

[Click to add Project Notes.](#)

Project Status as of: 11/01/2012 ▼

Reviewing Board: Naval Medical Center San Diego (NMCSD) ..

Project Status: Deferred - Modifications Required
 Project Risk Level: Minimal Risk

Project Expiration Date: 09/18/2013
 Initial Approval Date: 09/19/2012

Package Details

IRBNet ID 379172-2

Title Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post
 Traumatic Stress Disorder (PTSD)

OKelsey

Principal Investigator King, Heather, BSN, MSN

Lock Status Locked - Revisions Complete

| [Unlock](#) | [Lock](#) | [View History](#) |

Submission Details

Submission Date 09/06/2012

Submitted by Heather King

Submission Type Amendment/Modification ▼

Local Board Reference Number NMCSD.2012.0053-IR-CONV

Review Details:

Agenda	Review Type	Action	Effective Date	Expiration Date
09/19/2012 09:30 AM	FULL	Pending Review	09/19/2012	09/18/2013

Assign this submission to an additional Agenda date (existing Agenda assignments, review details and minutes are retained).

New and Revised Documents in this Package:

(Flag Documents for Review)

Document Type	Description	Last Modified
▼ Amendment/Modification	King_Modification Memorandum	09/06/2012 05:30 PM
▼ Consent Form	Consent Form	10/01/2012 02:11 PM
▼ Other	Acupuncture Certificate LCDR Sargent	09/05/2012 04:18 PM
▼ Other	Acupuncture Needles 510(k)	09/05/2012 04:18 PM
▼ Other	Acupuncture training CDR King	09/06/2012 03:47 PM
▼ Other	Modification Memorandum	10/01/2012 02:11 PM
▼ Other	Oral_Presentation Brief for Potential Participants	09/05/2012 04:31 PM
▼ Other	Subject Information Package	09/05/2012 04:32 PM
▼ Proposal	Proposal	10/01/2012 02:02 PM

There are no Training & Credentials records linked to this package.

| [Show Project Team Tracking](#) |

Submission Detail

Naval Medical Center San Diego (NMCS) Institutional Review Board

[379172-1] Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Traumatic Stress Disorder (PT...

[Click to add Project Notes.](#)

Project Status as of: 06/27/2012

[Show Project Status at the Time of Submission](#)Project Status:
Project Risk Level:Project Expiration Date:
Initial Approval Date:

Package Details

IRBNet ID 379172-1

Title Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post
Traumatic Stress Disorder (PTSD)

O Elisea

Principal Investigator King, Heather, BSN, MSN

Lock Status Locked[Unlock](#) | [Lock - Revisions Complete](#) | [View History](#)

Submission Details (Update)

Submission Date 06/19/2012

Submitted by Heather King

Submission Type New Project

Local Board Reference Number

Review Details:

Agenda	Review Type	Action	Effective Date	Expiration Date
Unassigned	Pending Review			

Assign this submission to an additional Agenda date (existing Agenda assignments, review details and minutes are retained).

New and Revised Documents in this Package:

(Flag Documents for Review)

Document Type	Description	Last Modified
▼ Advertisement	Subject Recruitment Flyer	06/08/2012 05:12 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:56 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:57 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:58 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:58 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:58 PM
▼ Conflict of Interest - Declaration	COI	06/13/2012 12:59 PM
▼ Consent Form	Subject Consent	06/08/2012 05:11 PM
▼ CV/Resume	King_CV	06/15/2012 02:45 PM
▼ CV/Resume	Richter_CV	06/15/2012 02:47 PM
▼ CV/Resume	Sargent_CV	06/15/2012 02:48 PM

TRISERVICE NURSING RESEARCH PROGRAM

Fostering Excellence in Military Nursing Science

TRISERVICE NURSING RESEARCH PROGRAM

Fostering Excellence in Military Nursing Science

3 December 2012

Kimberlee T. Eudy
Director, Office of Sponsored Programs
University of San Diego
5998 Alacala Park, Room 264
San Diego, CA 92110-2492
keudy@sandiego.edu

SUBJECT: TriService Nursing Research Program Grant HT9404-12-1-TS15 (N12-P15),
"Acupuncture for Disturbed Sleep in Veterans with Post Traumatic Stress Disorder,"
Principal Investigator: CDR Heather King

Dear Ms. Eudy:

The TriService Nursing Research Program (TSNRP) has received the human use documentation from the Institutional Review Boards of the Naval Medical Center San Diego and the University of San Diego indicating Initial Approval for the above referenced TSNRP study. The documentation has been reviewed and accepted by the Uniformed Services University of the Health Sciences Office of Scientific Management for Grants and Contracts. Enclosed please find a copy of the acceptance memorandum for your records. This is the **START LETTER** for the study.

If you have any questions, please contact Donna Gentry, Grants Manager, at 301-319-0589 or donna.gentry.ctr@usuhs.edu.

JOHN P. MAYE, CRNA, PhD, CAPT, NC, USN
Executive Director
TriService Nursing Research Program

Enclosures: As stated
cc: CDR Heather King
heatherking@sandiego.edu

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December 3, 2012

**MEMORANDUM FOR CDR HEATHER KING, NAVAL MEDICAL CENTER, SAN DIEGO, AND
TRISERVICE NURSING RESEARCH PROGRAM**

**SUBJECT: Acceptance of IRB Initial Review Approval of Naval Medical Center, San Diego IRB
of TSNRP (N12-P15) [#NMCS.D.2012.0053] for Human Subjects Research
Participation**

In accordance with Department of Defense Directive 3216.02 dated 8 November 2011, USU accepts the 1 November 2012 Initial Review Approval by the Naval Medical Center, San Diego (NMCS.D) Institutional Review Board (IRB) regarding the research protocol entitled *"Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Traumatic Stress Disorder (PTSD)"* under your direction. The documents for this action were received by this Office of Scientific Management for Grants and Contracts on 27 November 2012.

This study seeks to examine whether the use of an auricular acupuncture regimen improves sleep quality for Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF), veterans with Post Traumatic Stress Disorder (PTSD), and self-reported sleep disturbance. This will be a small scale study to test the acceptability and efficacy of the treatment. The study is expected to impact care offered to veterans by providing some evidence as to the efficacy of complementary techniques such as acupuncture. A total of 30 subjects will be recruited from the Overcoming Adversity & Stress Injury Support (OASIS) clinic at the NMCS.D.

You are required to submit amendments to this protocol, continuing reviews, adverse event reports, and other pertinent information relative to human research protections for this project to this office for review prior to changes being implemented. You are also required to submit human subjects' protection training certification every three years. There are two sites for this study: Naval Medical Center, San Diego and the University of San Diego.

If you any questions regarding this action, please call me at 301-295-8999 or contact me at charles.salter@usuhs.edu.

Charles A. Salter, Ph.D., S.D.
LTC (ret) U.S. Army
Scientific Director, Office of Scientific
Management for Grants and Contracts

cc: Executive Director, TSNRP (CAPT John P. Maye)
File

Learning to Care for Those in Harm's Way

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December 3, 2012

MEMORANDUM FOR CDR HEATHER KING, UNIVERSITY OF SAN DIEGO, AND
TRISERVICE NURSING RESEARCH PROGRAM

SUBJECT: Acceptance of University of San Diego IRB Initial Review Approval of TSNRP (N12-P15) [2012-11-054] for Human Subjects Research Participation

In accordance with Department of Defense Directive 3216.02 dated 8 November 2011, USU accepts the 21 November 2012 Initial Review Approval by the University of San Diego Institutional Review Board (IRB) regarding the research protocol entitled "*Acupuncture for Sleep Disturbance in OEF/OIF Veterans with Post Traumatic Stress Disorder (PTSD)*" under your direction. The documents for this action were received by the Office of Scientific Management for Grants and Contracts (OSM) on 27 November 2012.

This study seeks to examine whether the use of an auricular acupuncture regimen improves sleep quality for Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF), veterans with Post Traumatic Stress Disorder (PTSD), and self-reported sleep disturbance. This will be a small scale study to test the acceptability and efficacy of the treatment. The study is expected to impact care offered to veterans by providing some evidence as to the efficacy of complementary techniques such as acupuncture. A total of 30 subjects will be recruited from the Overcoming Adversity & Stress Injury Support (OASIS) clinic at the NMCSO.

You are required to submit amendments to this protocol, continuing reviews, adverse event reports, and other pertinent information relative to human research protections for this project to this office for review prior to changes being implemented. You are also required to submit human subjects' protection training certification every three years. There are two sites for this study: Naval Medical Center, San Diego and the University of San Diego.

If you any questions regarding this action, please call me at 301-295-8999 or contact me at charles.salter@usuhs.edu.

Charles A. Salter, Ph.D., S.D.
LTC (ret) U.S. Army
Scientific Director, Office of Scientific
Management for Grants and Contracts

cc: Executive Director, TSNRP (CAPT John P. Maye)

Learning to Care for Those in Harm's Way