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Examination of the Use of Accelerated Resolution Therapy (ART) in the Treatment of Symptoms of PTSD and Sleep Dysfunction in Veterans and Civilians

Marian Jevone Hardwick

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Examination of the Use of Accelerated Resolution Therapy (ART) in the Treatment of
Symptoms of PTSD and Sleep Dysfunction in Veterans and Civilians

by

Marian J. Hardwick

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
Department of Nursing
College of Nursing
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Abstract

Posttraumatic Stress Disorder (PTSD) is a prevalent anxiety disorder that is debilitating to both veterans and civilians following one or more traumatic events. Sleep disturbances are hallmark features of PTSD. Sleep disturbances and PTSD remain two significant PTSD-related issues that continue to plague veterans returning from active duty, thereby preventing full reintegration into society. The same problem exists for civilians. This research was conducted as a previously collected pilot study data and a secondary data analysis. The purpose of the study consisted of: 1) examining the impact of treatment with Accelerated Resolution Therapy (ART) on symptoms of PTSD and sleep disturbances; 2) examining the relationships and treatment response among both subjective and objective measures of sleep function; and 3) comparing the relationship between PTSD and sleep disturbances among military versus civilians, including the effects of treatment with ART.

The study represents one of only a few studies consisting of subjective measures of PTSD (PCL checklist) and sleep quality (Pittsburgh Quality Sleep Index (PSQI)), and objective measurement of sleep function by use of electroencephalography (EEG) testing and based on a 30-minute nap protocol. The aims of this study were to: 1) investigate the effects of ART on comorbid PTSD and sleep disturbances in U.S. veterans measured both subjectively (self-report) and objectively (sleep EEG data) from previously collected pilot study data; 2) assess the relationships between objective and subjective measures of sleep disturbances before and after treatment with ART for symptoms of PTSD in U.S. veterans from previously collected pilot

study data; and 3) compare self-report PTSD and sleep disturbances symptoms between civilians and veterans before and after treatment with ART using a secondary analysis from two previously conducted studies.

For Specific Aims 1 and 2, the methods consisted of previously collected pilot study data of 8 veterans who were treated with ART at the University of South Florida, College of Nursing. For Specific Aim 3, data were pooled from two completed studies of ART directed by Dr. Kevin Kip that included civilians ($n=75$) and veterans ($n=50$) who were treated for PTSD. Data analysis for Aim 1 included the use of paired t tests to compare PSQI score and each stage of sleep measured from qEEG (Delta, Theta, Alpha, Beta, Gamma) before and after treatment with ART. For Aim 2, Pearson correlation was used to assess the relationship between objective measurement of sleep disturbances and subjective sleep quality before and after ART. For Aim 3, multiple linear regression models were fit with PSQI (sleep) score as the dependent variable, PCL (PTSD) score as the primary independent variable, along with a main effect term for military status (civilian versus military) and an interaction term (military status * PCL score).

Results for aims 1 and 2 showed the mean age of the sample to be 37.6 years, 87.5% male, 87.5% White (non-Hispanic), 87.5% had experienced prior combat, 50% had experienced 5 or more traumatic memories that impacted their lives, and 87.5% had previous treatment for PTSD. Sample mean scores were above established screening criteria for PTSD (PCL-M = 63.7), sleep disturbance (PSQI = 14.5), and Center for Epidemiologic Studies Depression Scale (CES-D = 28.9). For Aim 1, after treatment with ART, the mean score on the PSQI dropped 4.88 points, mean score on the PCL-M dropped -30.13 points, thereby indicating significant reductions in sleep dysfunction and symptoms of PTSD. Mean Delta 1.5-3.5 Hz waves increased pre/post by 299.89 ($p=.032$), and Theta 4-6.5 Hz waves increased pre/post mean by 83.07

($p < 0.001$), both indicative of improved sleep quality. Results for Aim 2 showed statistically significant strong inverse correlations between PSQI and Theta 1.5-3.5 Hz waves ($r = -0.79$) and PSQI and Alpha 8-11 Hz waves ($r = -0.89$) at baseline. Post-ART, non-significant trends were observed for higher PSQI scores and higher Beta (conscious, alert) waves. For Aim 3, mean age of military participants ($n = 50$) was 41.9 years versus 40.4 years among civilians ($n = 75$, $p = .439$). For the military cohort, 18% were female compared to 80% among civilians ($p < 0.001$), with lower Hispanic ethnicity among military compared to civilian participants (12% vs. 27%, $p = 0.04$). In multiple regression analysis, change in PCL score was a strong predictor of change in PSQI score, regardless of military status PCL.

In summary, within the setting of PTSD, military participants tend to present with different traumatic exposures and worse sleep quality compared to civilian counterparts. In spite of these differences, the treatment protocol with ART demonstrated similar level of benefit (reduction in symptoms of PTSD and sleep disturbance) for both military and civilian personnel. Thus, nurses caring for individuals with PTSD, whether military or civilian, need to routinely assess sleep disturbances and initiate an open dialogue regarding these conditions. In return, nurses will be able to provide patients with resources to help them better understand and address these concerns, including after experiencing restless nights of sleep. Lastly, nurses should recognize the bi-directional temporal relationship between PTSD and sleep disturbances places. This places a premium on assessing these conditions collectively, rather than as discrete, independent clinical conditions.

Chapter One:

Background

Introduction

Posttraumatic stress disorder (PTSD) is a prevalent anxiety disorder that is debilitating to its victims following exposure to one or more traumatic events. According to the Diagnostic and Statistical Manual of Mental Disorders DSM-V (2013), sleep disturbances and nightmares are hallmark features of PTSD. There are four core characteristic symptoms following exposure to traumatic incidents that include intrusion and avoidance symptoms, negative modifications in cognitions and mood, and changes in arousal and reactivity (American-Psychiatric-Association, 2013). Comorbidity rates with respect to PTSD are often >80% and include sleep disturbances, depression, panic disorder, substance abuse, high somatic symptom severity, decreased role functioning, and an increased risk of suicide (Brady, Killeen, Brewerton, & Lucerini, 2000; Kessler, 2000; Oquendo, 2003; Kessler, Berglund, Delmer, Jin, Merikangas, Walters, 2005; Hoge, Terhakopian, Castro, & Messer, Engel, 2007; Krysinska & Lester, 2010). Of these comorbidities, sleep disturbances is very difficult to treat, and may be refractory to treatments that successfully resolve other PTSD symptoms (Spoomaker and Montgomery, 2008, Galovski, et al., 2009). In terms of severity, risk of suicide is elevated in both civilians and veterans who have experienced traumatic events such as natural disaster, violent crime, sexual assault, and critical illness (Krakow et al, 2000; Krakow et al., 2000; Krakow et al., 2001; Krakow et al., 2004; and Lamarche & Koninck, 2007).

Among the civilian population in the U.S., the lifetime and past year prevalence of PTSD have been estimated at 6.8% and 3.5%, respectively (Kessler et al., 2008). U.S. civilians experience trauma somewhat differently than military personnel with the most common sources of trauma being physically or sexually assaulted, being in an accident or fire, witnessing violent death or harm to a close family member or friend including physical or sexual assault, and witnessing a natural disaster (Kilpatrick et al., 2013). By way of comparison, the most prevalent forms of trauma experienced among Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans include: 1) having a friend killed or wounded, seeing dead or seriously injured noncombatants; 2) witnessing an accident resulting in death or serious injury, smelling decomposing bodies; 3) having an experience with an improvised explosive device (IED); 4) receiving an injury that does not require hospitalization, and among women, experiencing military sexual trauma (Tanielian & Jaycox, 2008; Maguen et al., 2012).

Sleep disturbances is a broad term that can include one or more different aspects of sleep problems including but not limited to insomnia, sleep-disordered breathing, trauma-related nightmares, and circadian rhythm sleep disorders. Sleep disturbances encompass disorders of initiating and maintaining sleep (insomnias), disorders of excessive somnolence, disorders of sleep-wake schedule, and dysfunctions associated with sleep, sleep stages, or partial arousals (Cormier, 1990). Evidence suggests that sleep disturbances *appear before the onset of PTSD*, and therefore sleep disturbances could be a risk factor in development of PTSD (Koren, Arnon, Lavie & Klein, 2002; Mellman et al., 2002; and Mellman et al., 2004). This evidence suggests that sleep disturbances is more than a secondary symptom of PTSD -- it seems to be a core feature (Spoormaker & Montgomery, 2008; and Lydiard & Hammer, 2009). Indeed, evidence shows that sleep disturbances are a frequent residual symptom after successful PTSD treatment, whereas

both sleep disturbances and severity of PTSD symptoms may be alleviated following treatments that focus only on sleep disorders (Jacobs-Rebhun , 2000; and Zayfert & DeViva, 2004). With respect to military PTSD, the most common types of sleep disturbances include trauma-related nightmares in addition to insomnia and inability to maintain sleep including waking up too early, and having non-restorative sleep.

Regarding the high prevalence of nightmares, there remains a lack of successful interventions that target trauma-related nightmares (Cook, *et al.*, 2010) despite evidence-based psychotherapy for PTSD at large. This assumption comes from the notion that there is no direct distinction between nightmares and other reoccurring phenomena (Cook, *et al.*, 2010). Thus, sleep disturbances and trauma-related nightmares remain two significant PTSD-related issues that continue to plague veterans returning from active duty, thereby preventing full re-integration into society.

Brief Historical Review of Etiology of PTSD.

In 1871, symptoms of PTSD started to be described for a certain group soldiers as tachycardia, anxiety, breathlessness, and hyper-arousal (Javidi, & Yadollahie, 2012).

After World War I, these symptoms were given a name known as *shell shock*. Presently, according to the Diagnostic and Statistical Manual V, by definition, an individual must be exposed to trauma or a very stressful event for their diagnosis to be considered PTSD (2013).

According to Wallace, *et al.* (2011) recurring nightmares related to service, avoiding sleep and frequent nocturnal checking of windows and doors within the home are all behaviors consistent with PTSD. Hyperarousal in the presence of PTSD is when one is in a state of psychological and physiological tension, and manifests as exaggeration of startled responses and sleep disturbances (Krakow, *et al.*, 2000).

Some important traumatic events which predispose to the development of PTSD include violent personal assault, being taken hostage or kidnapped, becoming a prisoner of war, torture, terrorist attacks, a range of war-related and combat exposures, or severe car accidents (Russel, 2011). Of personal assaults, sexual abuse is a leading cause of PTSD in both civilians and military personnel (Perrin et al., 2013). In addition, witnessing a crime, accident or war, as opposed to personal involvement, is also strongly associated with development of PTSD (Perrin et al., 2013). After a traumatic event, many individuals may develop acute symptoms (i.e. Acute Stress Disorder) including but not limited to severe anxiety, dissociative symptoms, dissociative amnesia, poor concentration, sleep disturbances, and de-realization (American Psychological Association, 2013). These symptoms may resolve but, on the other hand, they can also worsen in some individuals and progress to frank PTSD.

Comorbidity of Military PTSD and Sleep Disturbance.

Comorbidity is when two disorders occur in the same individual, simultaneously and the interactions between the illnesses affect the course of the disease as well its prognosis (National Institute on Drug Abuse, 2010). Recent research has reported that approximately 74% of military personnel with sleep disturbances and PTSD symptoms rated their sleep significantly worse in the deployed and post deployed environments, with 40% having a sleep efficiency of <85% (Peterson, Goodie, Satterfield & Brim, 2008). Collectively, this phenomenon represents a major health problem in terms of physical, mental and emotional functioning. Compared to the civilian population, sleep disturbances are significantly higher among combat veterans with mood disorders and symptoms of PTSD (Capaldi et al., 2011). Importantly, sleep disturbances have been linked to individuals with panic disorder (PD) and alcohol dependence (AD) (Lauterbach et al., 2011). Sleep disturbances and nightmares can be so distressing and severe that they can cause

somatic symptoms, health dysfunction, and poor work performance (Lauterbach et al., 2011). At times, individuals with PTSD give up, refuse, or are simply unable to sleep due the nature of their anxiety.

Sleep disturbances impact long-term chronicity of adverse health status. Having sleep complaints at one month can initiate post-trauma sleep conditions and significantly predict PTSD at twelve months (Koren et al., 2002). Untreated sleep symptoms can persist for years and intensify daytime PTSD symptoms and cause comorbid psychiatric problems and may be the reason for the poor clinical outcomes that occur with PTSD. These conditions may contribute to the poor clinical outcomes often observed in PTSD (Germaine et al., 2008).

Whereas sleep disturbance is commonly associated with PTSD, it is poorly understood in terms of etiology and which treatments work best (Nakamura, Lipschitz, Landward, Kuhn & West, 2011). First, there is considerable uncertainty as to the temporal relationship between PTSD and sleep disturbances (i.e. the “chicken or egg” phenomena). Based on quantitative EEG analysis, there have been discrepancies as to whether or not sleep disturbances serve as a platform for future development of PTSD, as opposed to the more conventional hypothesis that PTSD is a primary cause of future sleep disturbances. In reality, both directions of association are plausible and perhaps a major reason for which there exists consistent evidence of a strong association between PTSD and sleep quality. At the broadest level, new, evidence-based treatments are needed that address the major clinical dilemma of comorbid military PTSD and sleep disturbances. This challenge is the motivation for examination of Accelerated Resolution Therapy (ART) in this setting, and the basis for this dissertation.

The Hyperarousal Symptom of PTSD.

Hyperarousal is a core symptom of PTSD (American-Psychiatric-Association, 2013) and

often manifests as being easily startled, feeling tense or “on edge”, and having difficulty sleeping, and/or having angry outbursts. The information from traumatic events in the setting of PTSD is stored and processed in the brain to be adaptive (i.e. to be “on guard” for future similar circumstances), yet is also maladaptive in everyday life. This includes, but is not limited to an imbalance produced by insufficient control from the prefrontal cortex and parasympathetic nervous system (physiology) over excessive amygdala and sympathetic activity (Hammer 1999, Morris 2013, Semple 2000, Shin 2006, Zoldaz 2013).

Given this state of hyperarousal, there have been psychophysiological investigations into triggers of symptoms of PTSD. This includes the study of increased arousal from noise and light and physiological reactivity in persons suffering from PTSD. Increased reactivity to both trauma-related cues and unconditioned stimuli, such as loud noises, has been the topic of research for decades. Elevated levels of physiological arousal elicited by audiovisual and imaginal reminders of the original trauma have been reported in studies of combat veterans and traumatized civilians of both sexes (Blanchard et al., 1986; Pitman et al., 1987; Pitman et al., 1990; Shaley et al., 1992; Shaley et al., 1993). In addition, studies with individuals who have PTSD demonstrate greater sympathetic responses, such as increased heart rate to strong stimuli such as loud noises (Paige et al, 1990; Shaley et al., 1992; Shaley 1997; Orr et al., 1995; Orr et al., 1997). Recent psychophysiological studies of PTSD have started to focus on the physiological hyperactivity of patients to unconditioned stimuli, such as the exaggerated response toward loud noises. Exaggerated startle response, such as to loud noises or light, is a criterion for the diagnosis of PTSD as defined in the DSM V (American Psychiatric Association, 2013). In this realm, many individuals with PTSD who have been exposed during combat or military training to very loud battle noises or different assortment of lights are more likely to be startled post- deployment

(Shalev et al., 1998).

Conceptually, the traumatized person stays in a state of hyperarousal in an effort to protect themselves from real life events as well as nightmares that may continuously replay in the minds (Krakow, *et al.*, 2000). The resultant morbidity and mortality related to lack of sleep has been well documented and the manifestations of sleep disturbances concomitant to PTSD include obstructive sleep apnea (OSA), periodic leg movement disorder, sleep terrors, nocturnal anxiety attacks, and sleep avoidance (Germain, Hall, Krakow, Katherine Shear, & Buysse, 2005). Thus, with the ongoing burden and high prevalence of returning military veterans afflicted with PTSD, addressing their sleep disturbances is critical in improving quality of life, restoration of health, and psychological well-being (Ulmer, *et al.*, 2011).

Current PTSD Treatment Approaches.

First-line recommended treatment approaches for adults with trauma-related issues with PTSD vary substantially by setting (American Psychiatric Association, 2004; National Institute for Health and Clinical Excellence, 2005; Foa, Keane & Friedman, 2008; Forbes et al., 2010; Management of PTSD and ASR, 2010). Cognitive behavioral therapies (CBTs) are formally endorsed and frequently used in the treatment of PTSD among veterans. This includes the use of prolonged exposure (PE) therapy, cognitive processing therapy (CPT), and eye movement desensitization and reprocessing (EMDR) (Resick, Schnicke, 1992; Shapiro, 2001; Friedman, 2003; Ballenger et al., 2004; Foa, Hembree & Rothbaum, 2007; Resick et al., 2012). Whereas use of PE and CPT is promulgated as a preferred treatment modality in military and veteran treatment settings, in civilian settings, only 17% of licensed psychologists trained in exposure therapy reported using this modality to treat PTSD, in large part due to a reported 59% treatment dropout rate (Becker, Zayfert & Anderson, 2004). In a similar sobering manner, a recent review

of randomized controlled trials conducted primarily among civilians reported that approximately two-thirds of patients who receive PE therapy or CPT (i.e. standard-of-care), retain their diagnosis post-treatment (Steenkamp, 2015).

Accelerated Resolution Therapy (ART) is a new innovative, brief exposure-based therapy for PTSD that has been recently studied in both civilian and military populations (Kip et al., 2012; Kip et al., 2013). ART is delivered in just 1-5 treatment sessions over an approximate 2-week timeframe. The ART protocol does not require homework or skills practice, thereby reducing patient commitment time by more than 50% when compared to other treatments such as PE, CPT, and EMDR. Results from empirical data from both civilians and military personnel treated with ART were based on near-identical treatment and outcome assessment protocols resulting in appropriate comparison of clinical presentation and treatment response (Kip et al., 2012; Kip et al., 2013). These data provide the opportunity to examine relationships between symptoms of PTSD and sleep disturbances, before and after treatment with ART, and among both civilian and military adults.

Purpose of the Study.

The purpose of this study was to investigate, from a previously conducted pilot data study, and through a separate secondary data analysis, the impact of treatment with ART on symptoms of comorbid PTSD and sleep disturbances. This includes both subjective and objective measures of sleep disturbances. In addition, a secondary purpose was to examine the consistency versus discordance in sleep symptoms between civilians and veterans with PTSD, and whether ART appears to have a differential effect on these symptoms by military versus civilian status.

Aims.

The Specific Aims of this dissertation were as follows:

Aim # 1: Investigate the effects of ART on comorbid PTSD and sleep disturbances in U.S veterans measured both subjectively (self- report) and objectively (sleep EEG data), from previously collected pilot study data.

Hypothesis # 1: ART will be effective in improving both subjective and objective measures of sleep disturbances in U.S veterans.

Aim # 2: Assess the relationship between objective and subjective measures of sleep disturbances before and after treatment with ART for symptoms of PTSD in U.S veterans, from previously collected pilot study data.

Hypothesis # 2: There will be a strong association between objective and subjective measures of sleep disturbances in U.S. veterans before treatment with ART, after treatment with PTSD, and based on treatment-related change in PTSD symptoms.

Aim # 3: Compare self-report PTSD and sleep disturbance symptoms between civilians and veterans before and after treatment with ART using a secondary data analysis from two previously conducted studies.

Hypothesis # 3: Civilians and veterans will report similar self-report PTSD and sleep disturbances symptoms before and after treatment with ART.

Significance of the Study

Since the September 11, 2001 terrorist attacks on the World Trade Center, more than 2.6 million American military personnel had been deployed to Iraq, Afghanistan, or both (U.S. Department of Defense). Approximately 21% of the soldiers in Operation Iraqi Freedom/Operation Endurance Freedom (OIF/OEF), after service, will receive a diagnosis of

PTSD (Seal et al., 2010). Approximately 70 to 90% of veterans have difficulty initiating or maintaining sleep, and 70% of civilians who have PTSD have sleep disturbances (Mahe, Rego, & Asnis, 2006; DaViva, Zayfert & Mellman, 2004). Evidence suggests that about 50% achieve some level of PTSD remission yet continue to experience sleep disturbances symptoms (Zayfert, & DeViva, 2004; Belleville, Guay, & Marchand, 2009). Among many contributing factors, military duties and roles in both combat and noncombat environments have changed individual sleep cycles during deployment.

In the backdrop of comorbid PTSD and sleep disturbances, current evidence-based treatments for PTSD have highly variable results and substantial rates of drop out, and similarly, successful interventions for major types of sleep disturbances, including target trauma-related nightmares, remain a major challenge. Importantly, untreated sleep disturbances can persist for decades and exaggerate daytime PTSD symptoms and associated comorbid psychiatric problems (Germaine, *et al.*, 2008). Thus, examination of new therapies that may effectively treat military PTSD and sleep disturbances, in combination, is highly warranted.

Innovation of the Study.

The analyses carried out in this dissertation are innovative in several ways. First, this study represents one of only a few studies with both subjective and objective measurement of sleep function in veterans, and is the only study in which the influence of ART on symptoms of sleep dysfunction by use of electroencephalography (EEG) during a 30-minute nap is examined. Similarly, this is the only study to date in which symptoms of military PTSD and sleep disturbances are compared between civilian and veterans, including before and after treatment with ART. Finally, consistent with the ART protocol, this study examined whether comorbid symptoms of PTSD and sleep disturbances in veterans can be substantially reduced with ART in

just a few treatment sessions. This evidence would provide the rationale for larger-scale follow-up research, particularly given the lengthy PTSD treatment regimens currently endorsed by the VA and DoD.

Chapter Two:

Literature Review

Introduction

This chapter describes the conceptual framework and review of the relevant PTSD/sleep disturbances literature. This includes review of the epidemiology and etiology of military PTSD and sleep disturbances, risk factors for comorbid military PTSD and sleep disturbances, efficacy of current treatment approaches, and characteristics of the ART intervention proposed in the current study.

Conceptual Framework.

The Theory of Unpleasant Symptoms (TOUS) guides the basis for this dissertation. The TOUS has three major components: (i) influencing factors that affect the symptom experience; (ii) symptoms that the individual is experiencing; and (iii) consequences of the symptom experienced (Lenz et al., 1997). Within this realm, it is not well established as to why some individuals with traumatic experiences go on to develop PTSD, while others with similar experiences do not. However, as reviewed briefly above, many potential factors may predispose to the development of PTSD. Specifically, duration, intensity, quality, and timing of traumatic exposures are risk factors for future development of PTSD (Javidi, & Yadollahie, 2012; American Psychological Association, 2013).

Within the framework of the TOUS, a wide range of exposures and behavioral and environmental factors can influence the development and maintenance of PTSD (Figure 1). Once

present, PTSD is often associated with comorbidities including but not limited to symptoms of anxiety, depression, and substance abuse and dependence. With respect to military PTSD, the strength and consistency of potential risk factors varies considerably. Figure 1 depicts the “full” conceptual framework for the TOUS with respect to development of comorbid PTSD and sleep dysfunction. This “full” model is based on a review of the literature and includes the three major etiological components of: (1) Influencing Factors → (2) Symptom Experience → (3) Symptom Consequences. As depicted in the figure, there exist a large number of predisposing and military service factors that may contribute to the development of PTSD.

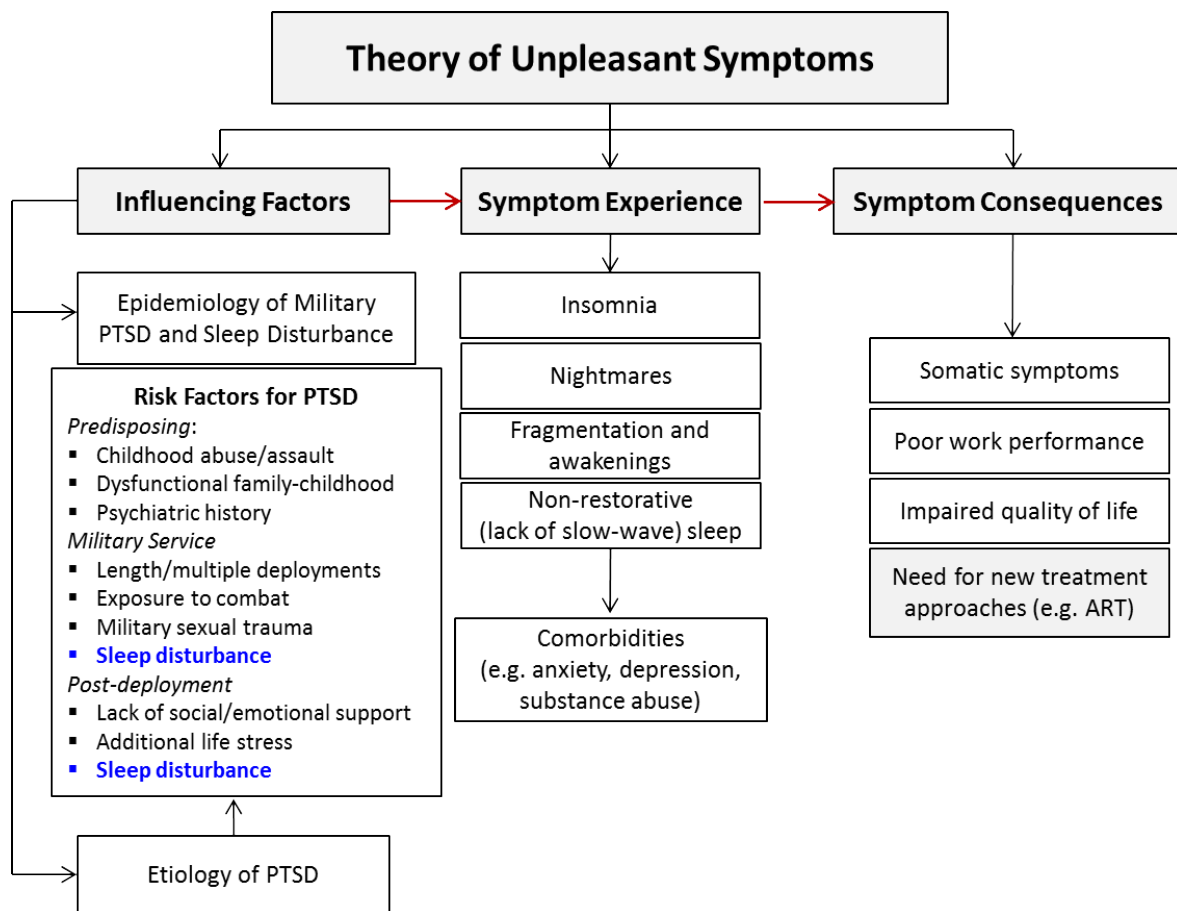


Figure 1. Full Conceptual Framework

For the purpose of this dissertation, a “pared down” model of the TOUS was used.

Specifically, as seen in Figure 2, this dissertation is limited to the two major etiological

components of: (1) Influencing Factors and (2) Symptom Experience, and also a reduced set of risk factors for PTSD. This approach is consistent with the three specific aims of this research, and also was selected based on the specific data variables available in the pilot study (specific aims 1 and 2) and secondary data analysis (specific aim 3).

With this approach, the risk factors for PTSD reviewed below include: (i) predisposing: prior psychiatric history; (ii) military service: length of deployment and multiple deployments, exposure to combat, military sexual trauma, sleep disturbance; and (iii) post-deployment: sleep disturbances.

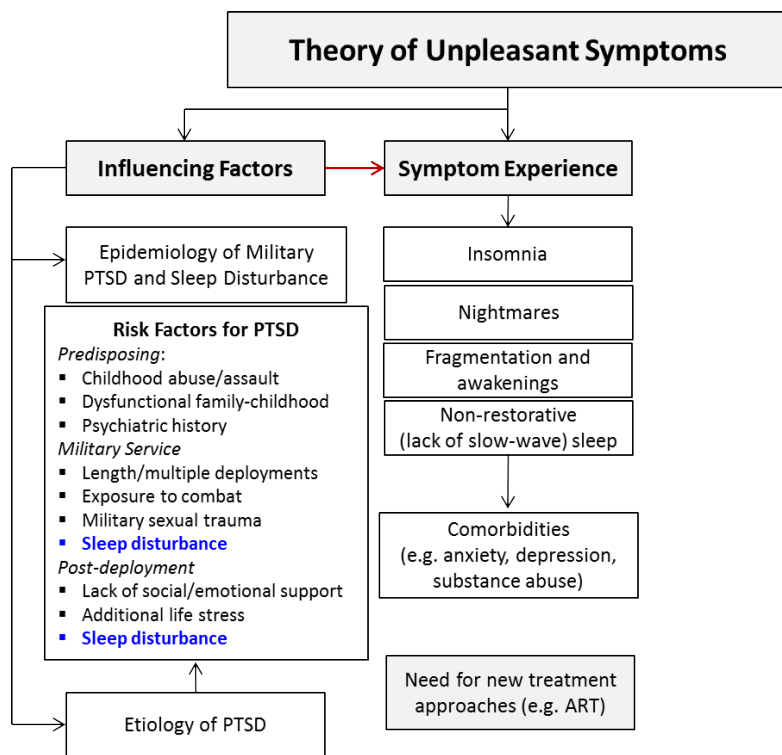


Figure 2. Pared Down Conceptual Model

Theory of Unpleasant Symptoms Component #1. Influencing Factors:

Predisposing Risk Factor for Development of PTSD.

Psychiatric History and Risk of Suicide. Prior psychiatric history can lead to increased risk of PTSD. The U.S. Army suicide rate doubled between the years of 2004–2005 and 2008–

2009 and reached an all-time high of 27.9/100,000 in 2012 (Schoenbaum M, Kessler RC, Gilman SE, et al, 2014). Given the demand and strong need, the Army created suicide prevention programs. Many of the responses from participants with mental disorders made a connection of suicide, and the prolonged military operations in Iraq and Afghanistan were the leading causes of high rates of mental health cases among these veterans. Evidence also showed that many soldiers are not seeking treatment for the mental issues due to stigmatization (Hoge CW, Castro CA, Messer SC, McGurk D, Cotting DI, Koffman RL, 2004; Held P, Owens GP, 2013; & Kim PY, Britt TW, Klocko RP, Riviere LA, Adler AB, 2011).

To address the major challenge of mental illness among veterans, beginning in 2006, the Department of Defense (DoD) authorized post-deployment screening in order to identify soldiers returning from deployment with behavioral health problems (Zinzow HM, Britt TW, Pury CL, Raymond MA, McFadden AC, Warner CH, Breitbach JE, Appenzeller GN, Yates V, Grieger T, Webster, 2007). However, with the more recent movement of identifying these veterans, the stigmatization and underreporting has decreased validation of studies in post-deployment screening. Moreover, the limited focus of these surveys has made it very difficult to estimate the actual extent and correlation of untreated mental disorders and causes (Hourani L, Bender R, Weimer B, Larson G, 2012). Jeon et al. (2014) conducted a study where lifetime suicide attempts (LSA) were significantly more frequent in persons with major depressive disorder (MDD) and who had experienced six types of traumas including military combat, witnessing a violent crime, rape or sexual assault, being badly beaten, being threatened by others, and learning of trauma experienced by others.

Capone (2013) conducted a study regarding other Axis I disorders. A total of 25 participants met criteria for current Major Depressive Disorder (MDD). Rates of other current

Axis I disorders in the Diagnostic and Statistical Manual of Mental Disorders-V (DSM-V) in this sample were relatively low. Four participants had diagnoses of Generalized Anxiety Disorder (GAD) and two had diagnoses of panic disorder. Nine participants endorsed symptoms consistent with current alcohol abuse, and an additional nine participants met criteria for current alcohol dependence. The authors stated being interested in history of Alcohol Use Disorder (AUD), since prior drinking and related impairment may be relevant to current relations between PTSD and alcohol use. As far as a lifetime AUD, 52 participants met criteria for alcohol abuse and 50 met criteria for alcohol dependence at some point during their lifetime.

Military Service Risk Factors for Development of PTSD. Military personnel often have risk factors for the development of PTSD. Elbogen et al. (2014) conducted a risk factor study and found significant relationships ($p < 0.05$) between financial instability, combat experience, alcohol misuse, violence or arrests anger, violence and developing PTSD. Phillips, Leardmann, Gumbs & Smith (2010) conducted a study on predisposing risk factors and discovered adverse childhood experiences, prior violence exposures, pay grade, number of deployments, number of close friends or relatives at follow-up, and race/ethnicity were significantly associated with PTSD. O'Toole, Marshall, Schureck & Dobson (1998) conducted a study about risk factors for military personnel where there was a significant finding that men with PTSD reported a greater incidence of assault or mugging. They were also more likely to have admitted to a pre-enlistment civilian criminal record; these were usually juvenile offences, as major crimes would have prohibited enlistment.

Length of Deployment and Multiple Deployments. The length of time and multiple deployments can play a role in the health of a soldier. Fear et al. (2010) conducted a study about the effects of multiple deployments in which overall, 4.0% of participants reported probable

PTSD, 19.7% reported a common mental disorder, and 13.0% reported alcohol misuse.

MacGregor, Han, Dougherty & Galarneau (2012) conducted a study that found that overall, 80% of those with two deployments were home for at least as long as the length of their first deployment. The rate of PTSD overall and other mental health disorders was 1.5% and 6.1%, respectively, with higher rates of PTSD among military personnel with two deployments compared to those with a single deployment (2.1% versus 1.2%) and, conversely, higher rates of other mental health disorders among those with a single deployment compared with two (6.3% versus 5.7%). A breakdown of the other mental health disorder category indicates substance abuse disorder as the most common subcategory, with higher rates among those with one deployment than among those with two (2.4% versus 1.7%). Similarly, mood disorders were slightly higher among those with a single deployment.

Exposure to Combat. There are several reactions soldiers can have from combat. Tracie Shea, Reddy, Tyrka & Sevin (2013) conducted a study that showed those with PTSD significantly differed from those without PTSD on multiple hypothesized risk variables with the exception of perceived preparation and training and unit support. Data on combat experiences were available for 219 participants. Of these, 59% reported receiving small arms fire, 57% having seen dead bodies, 56% with exposure to Intermittent Explosive Device explosions, 55% attacked or ambushed, 54% knowing someone injured or killed, 37% seeing dead or injured Americans, 33% clearing homes or buildings, 30% one or more casualties within their unit, 20% handling dead bodies, 15% being injured, 11% being responsible for the death of the enemy, and 1% being responsible for the death of a noncombatant (Tracie Shea, Reddy, Tyrka & Sevin, 2013).

Military Sexual Trauma. Military sexual trauma is most common among women in the military. It is also beginning to be more common in men in today's society. Decker, Rosenheck, Tsai, Hoff & Harpaz-Rotem (2013) conducted a study on participants who reported military sexual trauma (MST) and were more likely to be currently married and to endorse greater severity of PTSD and psychiatric symptoms. Homeless female veterans who reported or experienced MST significantly endorsed lower self-esteem, quality of life, and did not feel safe in their neighborhoods, and as victims in the past year. Kimerling (2007) conducted a study that reported the association of PTSD with MST to be almost three times stronger among women than among men. The link between MST and adjustment disorders was significantly stronger among men than among women. Alcohol disorders and anxiety disorders were more common among both men and women who reported MST, but the relation to MST was significantly stronger among women than among men. The relation of MST to bipolar disorders and schizophrenia or psychoses was strong among men and women, but significantly stronger among men. Women were more likely to show signs of dissociative, eating, and depressive disorders than men.

Post-Deployment Risk Factors for Development of PTSD.

Sleep Disturbance. Sleep disturbances have played a central role in predicting development of PTSD after exposure to trauma (Schoenfeld, 2012, Harvey & Bryant, 1998; Mellman, David, Bustamante, Torres, & Fins, 2001; Koren, Arnon, Lavie, & Klein, 2002), and have been a hallmark symptom of PTSD. Studies have found that sleep disturbance, such as nightmares, are more prevalent in victims who experienced trauma and developed PTSD before the trauma occurred (Mellman et al., 1995; Van Liempt, 2012). Sleep disturbances can also be residual symptoms after PTSD treatment (Zayfert & DeViva, 2004). Furthermore, having

persistence of sleep disturbances after PTSD treatment can be a negative sign for long-term consequence in various psychopathological and somatic domains of the body (Belleville, Guay, & Marchand, 2011). Sleep disturbances and difficulties due to intrusive thoughts or bad dreams about a certain event seem to have a strong relationship with reactivating symptoms of PTSD (Boe et al., 2010).

Recurring military-related nightmares, such as avoiding sleep because of nocturnal checking 'safety perimeter' behaviors or frequent checking of windows and doors in the home environment, are all-incongruent with sleep initiation. Abnormalities in rapid eye movement (REM) support findings of centrally measured hyperarousal during sleep in PTSD (Mellman, 1995). Some researchers have found co-morbid mild sleep-disordered breathing (SDB) to be common in patients with PTSD while others have not (Breslau et al., 2004; Krawkow et al., 2004). Actigraphic data in PTSD is not common, but a few studies have used this method to estimate total sleep time (TST) and awakenings in veterans with PTSD (Westmeyer et al., 2007). Most studies of returning Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans and civilians' sleep quality have relied on subjective responses to a single-item sleep embedded instrument that have not focused on validated sleep questionnaires from the objective aspect in home environments (Lundin, de Boussard,, Edman, & Borg,, 2006; Seelig, 2006; Lew et al, 2007; Lew et al., 2010; McLay, Klam & Volkert, 2010).

Insomnia in particular appears to be associated with both severity and chronicity of PTSD. Pigeon, Campbell, Possemato, and Ouimette (2013) reported insomnia being associated with significantly higher severity of PTSD and depression at the six-month assessment. Contingency table analyses comparing baseline insomnia status to rates of diagnostic level PTSD six months later revealed that 20 of 53 participants with insomnia (37.7%) had PTSD at six

months compared to only 1 of 19 (5.3%) of those without insomnia ($df = 1$; $X^2 = 7.14$; $p < .01$) (Pigeon, Campbell, Possemato, and Ouimette, 2013). Again, these data reinforce the need for better understanding of the relationships between PTSD and sleep disturbances.

Theory of Unpleasant Symptoms TOUS Component #2. *Symptom Experience:*

Insomnia. Insomnia is a major symptom experience of PTSD with inadequate treatment options today. Although veterans with PTSD seem to experience poor sleep overall, there is not unexpectedly night-to-night variability in the severity, as has been documented in individuals with primary insomnia (Perlis et al., 2010). One potential source of this variability is the participants' daytime experiences. Self-reported stress levels are known to correlate with sleep disturbances across individuals (Healey et al., 1981). It is reasonable to suspect that, within an individual, days with higher levels of stress may be followed by worse sleep and more nightmares the following night. According to Gehrman et al. (2014), greater pre-treatment PTSD severity, as assessed by the PCL-M, is associated with more awakenings, shorter sleep time, longer sleep latency, and more nightmares over the six weeks of diary completion. In terms of potential treatment options, there are some encouraging indications.

Abramowitz, *et al.* (2008) conducted a randomized controlled study to compare the efficacy of symptom-oriented hypnotherapy ($n=17$) versus pharmacotherapy with 10mg zolpidem ($n=16$) among chronic combat-related PTSD patients with insomnia. All participants were assessed for PTSD and sleep disturbances symptoms. There was a significant main effect in the treatment group, $F(1, 30)=4.96$; $p=0.034$, with PTSD symptoms as measured by the Posttraumatic Disorder Scale (PDS) being lower in the hypnotherapy group (HT) compared to the zolpidem group (ZT). Cognitive behavioral therapy for insomnia (CBT-I) has been shown to improve sleep in individuals with PTSD, with durable gains at 6 month (Roszell, McFall, Malas,

1991). In addition, overall psychosocial functioning improved following CBT-I. The initial evidence regarding CBT-I and nightmares is promising, but further research (i.e. the present proposed use of ART) is needed (Talbot, et al. 2014).

Nightmares. Nightmares are also highly prevalent symptoms in the setting of PTSD. Up to 90% of individuals with PTSD report nightmares and insomnia (Roszell, McFall, Malas 1991; Ohayon & Shapiro, 2000). Participants with nightmares, compared to those without significant nightmares, also had higher baseline levels of PTSD severity as measured by the PCL checklist (Pigeon, W.R, Campbell, C.E., Possemato, K., and Ouimette, P, 2013). Regarding potential treatment options for nightmares, Rhudy, *et al.* (2010) conducted a randomized control study (n=30) to assess the impact of Exposure, Relaxation, & Rescripting Therapy (ERRT) on physiological and subjective measures of negative affect and fear in response to personal, nightmare-related imagery. ERRT is a brief, 3-session treatment that directly targets nightmares in trauma-exposed persons. It was predicted that ERRT would decrease physiological and subjective reactivity to nightmare imagery. Physiological reactions to nightmare imagery were lower at post treatment than baseline for the treatment group ($p < 0.01$), whereas physiological reactions of the control group did not change over time ($p > 0.40$). Limitations include the relatively small sample size, the fact that procedures did not control for physiological-emotional reactivity due to the personal relevance of the nightmare script, and no objective measurements of sleep disturbances.

Germaine, *et al.* (2007) piloted a single, behavioral intervention session that combined image rehearsal therapy (IRT), stimulus control, and sleep restriction in a sample (n=7) of adult victims of violent crimes with PTSD. Participants received a single, 90-minute intervention session and were instructed to change a nightmare they experienced in any way they wanted, and

to rehearse one or two new dream scenarios during the day, at least three times per day for a minimum duration of 5 minutes. Overall, participants showed small-to-moderate improvements in self-report sleep quality and sleep disturbances. Self-reported dream frequency was markedly decreased post-intervention. Improvements in sleep were accompanied by marked improvements in overall daytime PTSD symptom severity and individual PTSD symptom clusters. This included improvement on the Pittsburgh Sleep Quality Index (PSQI) and nighttime PTSD symptoms ($p < 0.1$) and daytime PTSD, intrusion, and hyperarousal symptoms ($p < .05$). Findings from this study are limited due to small sample size and reliance on self-report measurement of sleep disturbances.

Fragmentation and Awakenings. Individuals with PTSD report specific types of sleep disturbances including fragmented sleep and multiple awakenings. A recurrent nightmare among individuals with PTSD is a principal source of awakenings and among the most common and distressing symptoms. Historically, most sleep studies among PTSD subjects have been based upon subjective reports. However, some studies have objectively tested sleep quality and REM fragmentation by use of polysomnography (e.g. Mellman, *et al.*, 2007). Sleep has a restorative function and affects emotional regulation whereas poor sleep adversely affects emotional processing of traumatic experiences (Maher, *et al.*, 2006). Future research using objective measurements of sleep quality, including fragmentation and awakenings, is needed for proposed treatment options.

Non-restorative Sleep.

With sleep's restorative nature, it affects emotion regulation and poor sleep may affect the emotional processing of traumatic experiences for individuals (Horne, 1993; Walker, 2009, Maher et al., 2006). When compared to control subjects, studies using objective sleep measures

have suggested that patients with PTSD have: (1) greater REM density (frequency of rapid eye movements that is characteristic of a dream state); (2) hyperarousal and nonrestorative sleep with frequent brief awakenings of less than one minute across all sleep stages; (3) a greater number of shifts from REM to lighter sleep per hour of sleep; and (4) decreased stage 4 (slow wave) sleep, the most restorative sleep stage (Neylan, *et al.*, 2003, Breslau, *et al.*, 2004). Importantly, the REM state is the only time during sleep when the chemistry of the brain is changing. Somewhat paradoxically, Khawaja et al. (2013) reported that shorter sleep time was associated with more awakenings among veterans with a lifetime history of PTSD, and not surprisingly, such impaired sleep was linked to not awakening refreshed from sleep in the morning and daytime sleepiness.

In terms of treatment, quality of sleep (i.e. restorative sleep) has been shown to be higher in a hypnotherapy (HT) group compared to a group treated with zolpidem (ZT)($p=0.003$), and was improved from the first to the second assessment ($p < 0.0005$) (Krakow et al, 2000). In this trial, findings are limited because the hypnotherapeutic intervention was added to ongoing treatment and thus its sole contribution is difficult to tease out. In addition, only self-report sleep disturbances data were collected.

Comorbidities. There is much comorbidity that may result as a symptom experience to PTSD. Kimbrel et al. (2014) examined the relationship between clinician-based PTSD diagnoses and screening positive on non-PTSD Psychiatric Diagnostic Screening Questionnaire (PDSQ) subscales. As a result, veterans who met criteria for PTSD were significantly more likely to screen positive for depression, $\chi^2=28.010(1)$, $p<0.001$, panic disorder, $\chi^2=38.065(1)$, $p<0.001$, social phobia, $\chi^2=19.636(1)$, $p<0.001$, and generalized anxiety disorder, $\chi^2=23.303(1)$, $p<0.001$ (Kimbrel et al., 2014). There was an absence of a relationship between substance use and trauma. Irwin et al., 2014 conducted a study on relationship and impact of depression and anxiety

on PTSD. The results of this study support the theory that anxiety and depression symptoms may mediate the relationship between PTSD symptoms.

Emergence of Accelerated Resolution Therapy (ART). The emergence of Accelerated Resolution Therapy (ART) is based in large part on the limitations of current evidence-based therapies endorsed for treatment of military PTSD. In brief, evidence-based cognitive-behavioral therapy (CBT) has been recognized as the first-line treatment for PTSD by both the Veterans Administration and the Department of Defense. Presently, the most commonly used and practiced therapies for the treatment of PTSD for veterans are Prolonged Exposure (PE) therapy, Cognitive Processing Therapy (CPT) and Eye Movement Desensitization and Reprocessing (EMDR) (Resick, Schnicke, 1992; Ballenger et al., 2004; Nemorff, 2006; Foa, Hembree & Rothbaum, 2007; Resick et al., 2012).

Prolonged exposure therapy involves 10-12 sessions approximately 90 minutes each with corresponding homework assignments (Foa, Hembree & Rothbaum, 2007). The homework requirement is quite demanding. There are two assignments every day that require 1.5 to 2 hours to complete (Resick et al., 2007). This totals approximately 30 to 35 hours of dedicated treatment time over two weeks. In addition, treatment is far from absolute with dropout rates of 50% in some clinical trials of PE and non-response rates between 20-67% (Minners & Hagenaaars, 2002; Hembree et al. 2003; Schurr et al., 2007; Schottenbauer et al., 2008). Cognitive processing therapy (CPT) for treatment of PTSD consists of 12 sessions lasting 60-90 minutes with practice of learned skills outside of the therapy skills (Resick and Schnicke, 1996). The dropout rates for this therapy are approximately 4-29% with non-response rates between 4-48% (Hembree et al., 2003; Schottenbauer et al., 2008). Eye Movement Desensitization Reprocessing (EMDR) consists of 8-12 weekly 90-minute sessions with dropout rates up to 36% and non- response rates

between 7 and 92% (Friedman, 2003; Schottenbauer et al., 2008). Thus, despite these therapies being universally endorsed as first-line treatment for PTSD, they all portend significant limitations including variable efficacy, frequent dropout rates, and lengthy treatment regimens (Kip et al., 2013).

In response to limitations of the current endorsed treatments for military PTSD, ART is an emerging brief exposure-based psychotherapy that was developed in 2008. The ART protocol uses the evidence-based components of imaginal exposure, imagery rescripting, and smooth pursuit eye movements. ART addresses the sentinel PTSD features of distressing emotions, thoughts, sensations, and images in particular, by viewing the development and maintenance of PTSD symptoms as a consequence of a failure of a traumatized individual to exhibit extinction of the affective component of the memory. To date, two empirical studies of ART have been completed, including a prospective cohort study in civilians and a randomized controlled trial conducted among 57 service members and veterans. Kip et al (2013) reported in their randomized trial the mean pre-/post-change on the PCL-M was -17.2 ± 13.4 in the ART group versus -2.5 ± 6.0 in an Attention Control (AC) group (effect size = 1.39; $p < 0.0001$). These completed studies have resulted in multiple peer-reviewed publications.

For both completed studies of ART, strong, beneficial clinical effects were reported for treatment of symptoms of PTSD in both civilians in veterans. With respect to comorbidities of PTSD, strong effects were reported for concomitant reductions in symptoms of depression and anxiety, and to a lesser extent, reductions in substance abuse and aggression and higher levels of self-compassion. Of note, improvements in self-reported sleep disturbances were also reported with ART, and serve as the basis for more detailed examination of these effects in Aim #3 of this proposal.

Sleep Disturbance. As a risk factor for the development of PTSD during military service and sustainment of PTSD post-deployment, the relationship between PTSD and sleep disturbances was previously reviewed above.

Chapter Three:

Methods

Introduction

This chapter outlines the research methods and procedures used for this study. The first section discusses the research design; this is followed by the setting and sample, instrumentation procedures, and data analysis procedures. The chapter is divided in 2 sections. The first section pertains to Specific Aims 1 and 2 and the examination of the pilot study data of ART and subjective and objective measures of sleep disturbances. The second section pertains to Specific Aim 3 and the secondary data analysis of two previously completed studies of ART.

Research Design.

The previously conducted pilot study data, which corresponds to specific aims 1 and 2, is a prospective cohort study design that made use of self-report and objective (sleep EEG) pre- and post-measurements of symptoms of PTSD and sleep disturbances before and after treatment with ART. The secondary data analysis, which corresponds to specific aim #3, merged “civilian” and “military data from two completed federally funded studies of ART for treatment of psychological trauma. The original “civilian” study made use of an uncontrolled prospective cohort design. The “military study was a randomized controlled trial of ART versus an attention control regimen. All subjects in the attention control regimen were offered ART after 2 sessions of the control condition, and >90% ultimately received ART. Therefore, for this purpose of this analysis, the data from the military

randomized controlled trial are treated as prospective cohort data with treatment response assessed within subjects both before and after treatment with ART.

Specific Aims # 1 and # 2.

Population.

Setting and Sample. This pilot study was originally designed to enroll a total of 10 subjects and ultimately enrolled 8 subjects (veterans). For purposes of analysis, eligibility required participants to have evidence of PTSD and at least a modest level of sleep disturbances. The inclusion criteria were: (1) at least 18 years of age; (2) a U.S. service member or veteran; (3) ability to read and speak English to complete survey questions; (4) denial of suicidal and homicidal ideation or intent, and no evidence of psychotic behavior or being in psychological crisis (determined by the medical form and discretion of the clinician and Psychiatric Diagnostic Screening Questionnaire (PDSQ); and (5) symptoms indicative of comorbid psychological trauma and sleep dysfunction (determined from the 17-item PCL-M (PTSD checklist) and the Pittsburgh Sleep Quality Index (PSQI)).

For PTSD symptoms, a score of >44 on the 17-item PCL-M were used to define significant symptoms of PTSD (Blanchard, 1996). For sleep dysfunction, a score of ≥ 5 on the Pittsburgh Sleep Quality Index (PSQI) (sleep quality screening tool) were used to define significant symptoms of sleep disturbances (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Exclusion criteria were: (1) brain injury prohibiting speech, writing, and purposeful actions; (2) major psychiatric disorder (e.g. bipolar disorder) concomitant to symptoms of psychological trauma (determined by the medical form and Psychiatric Diagnostic Screening Questionnaire (PDSQ); (3) currently undergoing substance abuse treatment (e.g. alcohol, opioid, cocaine) (determined by the PDSQ); and (4) any medical condition that, in the judgment of the Principal Investigator and/or ART therapist, may

place the individual at high risk due to a potential heightened emotional reaction (e.g. previous heart attack, seizure disorder).

Sample Size and Power Analysis. The original proposed sample size of 10 subjects was designed to provide 80% power to detect a “large” within-subject effect size (assuming type I error rate of 0.05) of 0.84. To evaluate the relationship between subjective and objective measures of sleep disturbances (assessed at 3 intervals), and using the same assumptions (i.e. desired sample size of 10 subjects) and within-subject correlation of 0.50, a “medium” non-zero order correlation of 0.48 would be detectable at 80% power. Given these power calculations, it should be recognized that the design was clearly intended to be exploratory and of a pilot nature. Similarly, the pilot study was deemed to be of insufficient size to control for covariates in the analysis and as part of power calculations.

Instrumentation. The instruments described below were used to measure response before and after treatment with ART. Of note, with the exception of the objective measurement of sleep response (described below), the same self-report instruments were used for the secondary data analysis (specific aim #3).

PTSD Response (DSM-IV)

PTSD Checklist (PCL) – This is a 17-item self-report measure of the 17 DSM-IV symptoms of PTSD. Respondents rate how much they were “bothered by that problem in the past month.” Items are rated on a 5-point scale ranging from 1 (“not at all”) to 5 (“extremely”). The PCL can be scored in multiple ways. A total score (range 17-85) can be obtained by summing the scores from each of the 17 items. Cutoff scores for a probable PTSD diagnosis have been validated for some populations, but may not generalize to other populations. Another way to score the PCL is to follow the DSM-IV criteria. It has been suggested that a combination of these two approaches (i.e., the requisite number of

symptoms are endorsed within each cluster AND the total score is above the specified cut point for a specific population) may be best. Cronbach's α reliability has been reported as 0.97 (Blanchard, 1996; King et al., 2013).

Sleep Response – Self Report

Pittsburgh Sleep Quality Index (PSQI): This 15-item self-report developed in 1989 (Buysse et al., 1989) measures the quality and patterns of sleep in adults. It takes approximately 3 to 6 minutes to complete. A global PSQI score greater than five has yielded a diagnostic sensitivity of 89.6% and specificity of 86.5% ($\kappa = 0.75$, $p < 0.001$) in distinguishing good and poor sleepers. Thus, a score of >5 indicates a positive screening for sleep disturbance. The internal consistency reliability coefficient (Cronbach's alpha) for the PSQI has been reported as 0.88 (Farrahi, Nakhaee, Sheibani, Garrusi, & Amirkafi, 2009).

The PSQI-Addendum (PSQI-A): is used to identify disruptive nocturnal behaviors that are characteristic of PTSD among military personnel (Germain et al., 2005). The PSQI-A is comprised of seven different sleep disturbance items such as memories or nightmares of the traumatic experience, and episodes of terror during sleep. Items are rated on a 0 to 3 point scale, where 0 means not in the past month and 3 means three or more times a week. They are summed to create a total score. Thus, the total score can range from 0 (normal) to 21 (severe). Internal consistency is reported as high, with a Cronbach's alpha of 0.89 (Germaine et al., 2005).

Intake Forms:

Medical History Form: This form provides current and past medical history. This includes whether the participant has been previously been treated for PTSD or any other mental condition, as well as current use of medications.

Demographics Form: This form asks the participant about background information including age, gender, ethnicity, marital status, employment status, years of education, military status, branch of the military served in, number of overseas tours served in the military, and deployment and combat experiences.

ART Intake Assessment Form: This form is used by the clinician form to determine an appropriate treatment approach to be used with ART. It specifically asks the number of traumatic memories that are currently impacting one's life, and the specific traumas that the veteran seeks to resolve through treatment with ART. It also inquires about having a current disability for PTSD or another mental health condition, as well as the length of time that the veteran has lived with one or more traumas.

Sleep Response – Objective Measurement (qEEG)

Use of quantitative electroencephalography (qEEG) has a long history in medical research. In brief, the method is used to obtain basic brain patterns of individuals while in a relaxed state (Teplan, 2002). For the pilot study, qEEG measures were collected on each veteran by use of acquisition of multi-channel surface EEG during a daytime nap, with duration of 30 minutes (generic example in Figure 3).

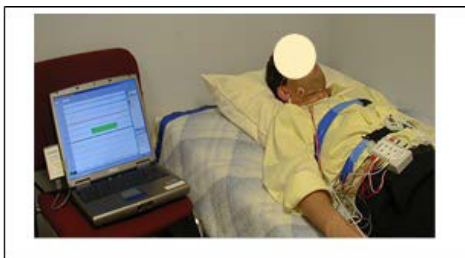


Figure 3. EEG

This occurred before treatment with ART and after completion of treatment with ART. Surface EEG electrodes were attached to the frontal sites: **F3 F4**, central sites: **C3**,

C4, and parietal sites: **P3, P4** of the two hemispheres according to the International 10-20 EEG placement sites (Jasper, 1958). Measurement of the following EEG frequency bands was performed: Delta (δ): 1-3.5 Hz; Theta (θ): 4-7.5 Hz; Alpha (α): 8-12 Hz; Sigma (σ): 13-16 Hz; Beta (β): 16.5-25 Hz; and Gamma (γ): > 30 Hz. For analytical purposes, values were expressed as non-normalized (raw) and normalized by use of a square root transformation. The analyses were based on 5-minutes of data recording following the start of transition to a sleep state.

Comorbidity Measurement

Centers for Epidemiological Studies Depression Scale (CES-D): The CES-D is a widely used 20-item self-report scale which measures the current level of depressive symptomatology in the general population, with an emphasis on depressed mood during the past week. The scale measures frequency of depressive feelings and behaviors on a four-point scale ('rarely or none of the time,' to 'most or all of the time'). The possible range is 0-60 with a score of 16 as being indicative of a positive screening of depression. The CES-D incorporates the main symptoms of depression and was derived from five validated depression scales, including the Beck Depression Inventory (BDI). Internal consistency has been reported as relatively high, with a Cronbach's alpha of 0.79 (Radloff, 1977).

State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA)- The 21-item self-administered questionnaire in the general population, the State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA) was designed to assess cognitive and somatic symptoms of anxiety as they pertain to one's mood in the moment (state) and in general (trait). There are a total of 20 questions with a four-point summated scale ranging from 1 with no anxiety to 4 with extreme anxiety. The cutoff point of being positive for screening of this questionnaire is a score of 39. The instrument items take an estimated 6

minutes to complete. The STICSA is a reliable and valid measure of state and trait cognitive and somatic anxiety, with coefficients ranging from 0.91 (Kim et al., 2008).

Psychiatric Diagnostic Screening Questionnaire (PDSQ): The PDSQ is a 125-item (yes/no) instrument used to screen for Axis I disorders in the general population and serve as a global assessment of psychopathology. It can be quickly hand scored to obtain a total score plus scale scores for 13 disorders: Major Depressive Disorder, Generalized Anxiety Disorder, Panic Disorder, PTSD, Alcohol Abuse/Dependence, Drug Abuse/Dependence, Psychosis, Bulimia/Binge-Eating Disorder, Obsessive-Compulsive Disorder, Somatization Disorder, Social Phobia, Agoraphobia, and Hypochondriasis. Six items on the depression scale provide a measure of suicidal ideation. Internal consistency (Cronbach's alpha coefficient) for the PDSQ has been reported as 0.82 (Zimmerman & Mattia, 1999).

Procedures

Approval. The Institutional Review Board at the University of South Florida previously granted approval for this study (Pro 00011530).

Recruitment Procedures.

Veterans were recruited from multiple sources including community-based organizations and veteran membership organizations within the greater Tampa Bay area, as well as academic programs at USF. Recruitment through the USF Office of Veterans Services was based on the established relationships between Dr. Kip and his research team and retired Lieutenant Colonel Larry Braue, Ed.D., Director of Veteran Services at USF. A recruitment flyer was developed for the study and distributed at community-based events, including local presentations (e.g. Rotary Club) on ART made by Dr. Kip, PI of the parent study.

Upon initial contact, the research coordinator presented the consent form to potential participants based on their inquiry about the study. Potential participants were encouraged to take their time in reviewing the consent form and to discuss study participation with a friend or family member. Veterans who consented to participate signed the informed consent form and were provided a copy for their records. The Informed Consent form stated that partaking in the study would not affect the participant's military benefits including payments, disability status, or diagnosis. Patient confidentiality and security and of all study data was maintained by having password protected computers and locking up all case report forms in Dr. Kip's office.

Data Collection.

Clinical evaluations used for screening and trial eligibility consisted of multiple pre-ART screening instruments including the PCL-M Checklist, Pittsburg Sleep Quality Index (PSQI), Psychiatric Diagnostic Screening Questionnaire (PDSQ), and Accelerated Resolution Therapy (ART) Standard Protocol questionnaire. In addition, participants completed a demographic data form and clinical history on medical and mental health history. The ART Clinical Director, Dr. Hernandez, who conducted the initial intake evaluation with study participants, confirmed their eligibility for the study by reviewing the data.

Description of ART Intervention.

Description of the ART protocol has been published. (Kip et al 2012, Kip et al 2013, Kip et al 2014). In brief, the ART protocol was delivered using the four core elements found in most A-level trauma-focused psychotherapies (U.S. Department of Veterans Affairs 2015). In the first major component of ART, imaginal exposure was used

whereby veterans were asked to recall (verbally or non-verbally) details of the traumatic event while focusing their attention on physiological sensations, thoughts, and emotions. With coaching from the ART clinician, the veteran was composed into a relaxed and alert state of mind, and is then exposed to re-activation of the targeted memory for a very short period of time (30-45 seconds). This short period of exposure to the memory was immediately followed by identification and diminishment (or eradication) of the emergence of any uncomfortable emotional or somatic symptoms. Two complete phases of intermittent exposure to the targeted memory were performed.

In the second major component of ART, imagery rescripting was used whereby the veteran imagined a new way to think about the trauma in order to change (replace) the negative traumatic narrative, including sensory material and images, to positive material. This approach is consistent with memory reconsolidation and the work of Smucker who noted that much of the cognitive-affective disturbance associated with intrusive trauma-related memories is embedded in the traumatic images themselves, and that modifying the traumatic imagery becomes a powerful, if not preferred, means of processing the traumatic material (Smucker 1997).

During both imaginal exposure and imagery rescripting, the veteran followed the therapist's hand back and forth moving their eyes from right to left, with 40 bilateral eye movements performed per set. During both components, the veteran was not speaking, but rather "watching" his or her original or newly imagined scene. Treatment of the scene was considered complete (successful) when an acceptable alternative was imagined to satisfaction, and the physiological and emotional intensity of the memory was altered and minimized. By protocol, the number of planned treatment sessions ranged from 1 to 5 based on the extent of prior trauma history. The individual treatment sessions were

scheduled for approximately one hour with additional time allocated as needed.

Data Management/Analysis.

For aims one and two, qEEG data were gathered from a sample of eight participants and matched with their corresponding PCL-M and PSQI scores from before and after ART. These data were used to assess the differences in self-reported sleep quality (PSQI), Post-Traumatic Stress Disorder symptoms (PCL-M) and qEEG measures taken from Delta, Theta, Alpha, Beta, and Gamma stages of sleep from before to after ART. The same data were used to inform research question two, and quantify the correlational relationships between self-reported (PSQI) and objective (qEEG) measures of sleep quality.

Descriptive statistics were calculated for the primary variables included in Aims 1 and 2. Continuous variables are expressed as mean \pm standard deviation (SD); categorical variables are presented as frequencies and percentages.

Aim # 1: Investigate the effects of ART on comorbid PTSD and sleep disturbances in U.S veterans measured both subjectively (self- report) and objectively (sleep EEG data), from previously collected pilot study data.

Hypothesis # 1: ART will be effective in improving both subjective and objective measures of sleep disturbances in U.S veterans.

Normality. Prior to analysis, normality was assessed for each of the continuous sleep measures using measures of skew and kurtosis for each continuous score. In addition, a student's *t*-test for location was conducted with the null hypothesis that the data are centered on zero. Data are typically considered normal if they meet the following criteria for normality: (a) a skew between -2.0 and 2.0, and (b) kurtosis between -7.0 and 7.1 (Kline, 2011). Next, data regarding the spread and central tendency were assessed for both subjective (i.e., PCL-M and PSQI) and objective sleep measures (i.e., qEEG) before

and after ART.

Paired *t* tests were used to examine the difference in subjective sleep quality (PSQI), subjective PTSD symptoms (PCL-M), and objective sleep disturbances (qEEG) measures from before to after ART. One dependent sample *t*-test was conducted on the self-reported sleep quality (PSQI), one was conducted on self-reported PTSD symptoms (PCL-M), and one was conducted on each stage of sleep measured from qEEG. This resulted in a series of five dependent sample *t*-tests, with one for Delta, one for Theta, one for Alpha, one for Beta, and one for Gamma.

Aim # 2: Assess the relationship between objective and subjective measures of sleep disturbances before and after treatment with ART for symptoms of PTSD in U.S veterans, from the previously collected pilot study data.

Hypothesis # 2: There will be a strong association between objective and subjective measures of sleep disturbances in U.S. veterans before treatment with ART, after treatment with PTSD, and based on treatment-related change in PTSD symptoms.

To assess the correlational relationship between measures of subjective sleep disturbances (as measured by the qEEG), and subjective sleep quality (as measured by the PSQI) before and after ART, a Pearson correlation matrix was created. Both objective and subjective measurements were taken before and after ART was delivered, and a change score was also calculated for each. Each time point was assessed for correlations with other time points to determine if there were significant relationships. Change scores were also created for this analysis, which measured the difference in each score from baseline to post-ART.

Any correlation with a coefficient of over .50 may provide insight into a correlation that may be detected with a larger sample size (Tabachnick & Fidell, 2012). As such,

correlations with an r coefficient of .50 or greater were further examined. An r coefficient of .50 or greater indicates that 25% or more of the variance between two variables are related (Pallant, 2010) and was chosen based on Cohen's (1988) suggestion that this r indicates a medium effect size.

Specific Aim # 3.

Design. Data were pooled from 2 completed studies of ART directed by Dr. Kip in a secondary data analysis. The overall description for the 2 studies, one conducted in civilians ($n=75$) and the other conducted in service members and veterans ($n=50$) were treated for PTSD, are as follows:

Population. For the civilian study, a total of 97 persons were screened, of whom, 17 (17.5%) were determined to be ineligible for the study. Among the 80 enrolled participants, 66 (82.5%) completed the full course of treatment including initial post-treatment assessment. For the military study, a total of 63 service members/veterans were assessed for trial eligibility, of whom, 57 (90.5) were clinically eligible and enrolled.

Measures. For assessment of PTSD among veterans, the 17-item PCL-M (Military) Checklist was used. This is a self-report instrument of DSM-IV symptoms of PTSD in response to stressful military experiences, and is used with service members and veterans. The 17-item PCL-C Checklist is the civilian version of the PTSD assessment, and was used for data collected in the civilian study. Cronbach's α reliability has been reported as 0.97 (Blanchard, 1996; King et al., 2013).

For assessment of sleep function, the 15-item self-report Pittsburgh Sleep Quality Index (PSQI) developed in 1989 (Buysse et al., 1989) was used. The PSQI measures the quality and patterns of sleep in adults. It takes approximately 3 to 6 minutes to complete. A global PSQI score greater than five yielded a diagnostic sensitivity of 89.6% and specificity

of 86.5% (kappa = 0.75, p less than 0.001) in distinguishing good and poor sleepers. A score of >5 indicates a positive screening for sleep disturbance. The internal consistency reliability coefficient (Cronbach's alpha) has been reported as 0.88 (Farrahi, Nakhaee, Sheibani, Garrusi, & Amirkafi, 2009).

Data Management/Analysis. To inform aim # 3, secondary data were gathered from the two previous studies described above, and included a total of 125 observations. These data were used to examine the relationship between self-reported PTSD symptoms (PCL-M) and self-reported sleep quality (PSQI) among study participants who received ART. Since the study hypothesis involved comparison of treatment response between civilians and veterans, an initial step was to compare demographic and presenting clinical characteristics between the 2 groups. This included use of student *t*-tests to compare continuous variables and use of chi-square tests to compare categorical variables.

Civilian versus military status was used in stratified analyses. Pearson correlation coefficients were calculated to examine the strength of association between self-report scores on the PCL (PTSD) checklist and PSQI. These calculations were performed before treatment with ART, after treatment with ART, at 3-month follow-up, and based on the pre-to-post treatment change. This was followed by use of multiple linear regression analysis. With this approach, the PSQI score served as the dependent variable with PCL score as the primary independent variable, along with a main effect term for military status (civilian vs. military) and an interaction term (military status x PCL score). The interaction term (military status x PCL score) was included to examine whether the relationship between PTSD score and PSQI varies (is modified) by military status.

Chapter Four:

Results

Introduction

This chapter describes the results obtained for examination of the 3 specific aims and 3 corresponding hypotheses. As with earlier chapters, the results are presented separately for aims 1 and 2 (pilot study) and then for aim 3 (secondary data analysis).

Research Aim # 1: From previously collected pilot study data investigate the effects of ART on comorbid PTSD and sleep quality in U.S veterans measured both subjectively (self-report) and objectively (sleep EEG data).

Hypothesis # 1: ART will be effective in improving both subjective and objective measures of sleep disturbances in U.S veterans.

Demographic and Clinical Presentation Characteristics

Table 1 provides descriptive characteristics for demographic and clinical presentation variables that were measured on a continuous scale. As seen, the mean age was 37.6 ± 6.5 years. The mean PSQI score was 14.5 ± 4.4 which is much higher than the screening score of ≥ 5 used to indicate impaired sleep function (Buysse, 1989). Similarly, the mean PCL-M score of 63.7 ± 10.4 was high given the potential score range on this instrument from 17 to 85. These high mean values for sleep disturbance and symptoms of PTSD reflect the study inclusion criteria. In addition, the mean depression score of 28.9 ± 9.2 was much higher than the cutpoint of ≥ 16 used to indicate a possible diagnosis of depression (Radloff, 1997).

Table 1. Descriptive Characteristics for Continuous Demographic and Clinical Presentation Variables.

Variable	<i>N</i>	<i>M</i>	<i>SD</i>	Minimum	Maximum
Age in years	8.00	37.63	6.50	28.00	47.00
Pittsburgh Sleep Quality Index at baseline	8.00	14.50	4.38	7.00	20.00
PTSD Checklist (PCL-M) Score at baseline	8.00	63.75	10.44	46.00	78.00
T-score of Psychiatric Diagnostic Screening Questionnaire at baseline	8.00	55.63	6.95	46.00	66.00
Raw Score Brief Symptom Inventory (BSI) at baseline	8.00	31.00	11.59	14.00	46.00
Adjusted score Center for Epidemiologic Studies Depression Scale (CES-D) at baseline	8.00	28.88	9.23	14.00	41.00
Pain Scale (SF-36) at baseline	7.00	41.79	8.50	22.50	45.00

Table 2 provides descriptive characteristics for demographic and clinical presentation variables that were measured categorically. As seen, the majority of study participants were male, of white race, a discharged veteran, and had experienced combat-related activity. Seven of the eight participants screened positive for depression at baseline, along with a high prevalence of other comorbidities including generalized anxiety disorder, and agoraphobia. The range of PSQI scores was 7 to 20, confirming that all participants indicated impaired sleep function (i.e. PSQI score >5).

Table 2. Frequencies and Percentages of Demographic and Clinical Presentation Variables.

Variable	<i>n</i>	%
Gender		
Male	7	87.50
Female	1	12.50
Race		
Black	1	12.50
White	7	87.50
Employment status		
Full-time employment	5	62.50
Part-time employment	1	12.50
Unemployed or disabled	1	12.50
Other	1	12.50
Military status		
Reservist	2	25.00
Discharged/veteran	6	75.00
Experience combat-related activity		
No	1	12.50
Yes	7	87.50
Head trauma		
No	7	87.50
Yes	1	12.50
Number of traumatic memories impacting life		
1 to 2	1	12.50
3 to 4	3	37.50
5 or more	4	50.00
Currently on disability for PTSD/MH problem		
No	4	50.00
Yes	4	50.00
Previous Treatment for PTSD		
No	1	12.50
Yes	7	87.50
Prior Treatment –Psychotherapy		
Yes	8	100.00
Screen Positive for PTSD (PDSQ) at baseline		
No	1	12.50
Yes	7	87.50
Diagnosis of Depression by CES-D at baseline		
No	1	12.50
Yes	7	87.50
Screen positive for Major Depressive Disorder Suicidality (PDSQ) at baseline		
Yes	8	100.00
Screen Positive for Generalized Anxiety Disorder (PDSQ) at baseline		
No	2	25.00
Yes	6	75.00

Table 2 (Continued). Frequencies and Percentages of Demographic and Clinical Presentation Variables.

Variable	<i>n</i>	%
Screen Positive for Social Phobia (PDSQ) at baseline		
No	3	35.50
Yes	5	62.50
Screen Positive for Somatization Disorder (PDSQ) at baseline		
No	4	50.00
Yes	4	50.00
Screen Positive for Obsessive Compulsive Disorder (PDSQ) at baseline		
No	8	100
Screen Positive for Panic Disorder (PDSQ) at baseline		
No	5	62.50
Yes	3	35.70
Screen Positive for Agoraphobia (PDSQ) at baseline		
No	1	12.50
Yes	7	87.50
Screen Positive for Hypochondriasis (PDSQ) at baseline		
No	6	75.00
Yes	2	25.00
Screen Positive for Alcohol Abuse (PDSQ) at baseline		
No	7	87.50
Yes	1	12.50
Screen Positive for Drug Abuse/Dependence (PDSQ) at baseline		
No	8	100.00
Pittsburgh Sleep Quality Index at Baseline		
7	1	12.50
11	2	25.00
16	2	25.00
17	1	12.50
18	1	12.50
20	1	12.50

Medication Use at Baseline. As seen in table 3, the 8 participants reported taking a range of medications. In terms of major classification of medications, respective percentages were: anti-anxiety (100%, anti-depressant (100%%), anti-seizure (20%), sleep (100%), and pain (20%).

Table 3. Medications Taken at Baseline.

ID	Med 1	Med 2	Med 3	Med 4	Med 5	Med 6	Med 7	Med 8
1	Fluoxetine	Vitamin B12	Lisinopril	Prazosin	Inhaler	Clotrimazole		
2	Depoprevera							
3	Hyroxidine							
4	Prozozin	Citalopram						
5	Cymbalta	Seraquel	Prazosin	Meloxicam				
6	Seroquel	Celebrex	Hydrozine	Gabapentin	Tramadol	Mexazoin		
7	Lipitor	Celexa	Buspar	Lamictal	Vitamin D3	Nuvigil	Micardis	Abilify
8	Paxil	Celexa	Bubroxin	Lisinopril	Amlodine	Topomax	Tranadal	Tynelol
		Traziadone	Modafinil	Tricor	Viagra			
			Dexanphatamine	Oxycodone	Meloxicam			

Assessment of Normality. As stated above, normality was assessed for each of the continuous sleep measures. Only the baseline Beta 25-30 frequency measure had a skew outside of conventional boundaries for normality, although, this variable had a kurtosis well within the -7 to 7 boundaries. Each variable had a significantly different central tendency from that of 0, as indicated by the series of *t* tests. After normalizing the sleep measures, each qEEG score's variance dropped to zero. Results of the assessment of normality are presented in Tables 4 and 5. These data confirm appropriate use of parametric analyses.

Table 4. Normality Assessment for Continuous Sleep Measures at Baseline.

Sleep measure	Skew	Kurtosis	Variance	<i>t</i> test for location	<i>p</i> -value
PSQI at baseline	-0.63	-0.62	19.14	9.37	.001
Delta 1.5 – 3.5 baseline	1.00	0.17	49030.08	8.50	.001
Theta 4-6.5 baseline	0.37	-0.74	9827.23	9.46	.001
Alpha 8-11 baseline	0.62	-1.35	146101.87	3.68	.001
Beta 12-15 baseline	0.65	-1.10	6888.37	5.10	.001
Beta 16-20 baseline	0.47	-1.95	1201.68	6.21	.001
Beta 20-25 baseline	1.32	0.67	5602.21	3.36	.012
Beta 25-30 baseline	2.05	5.04	659.19	4.57	.003
Gamma > 30 baseline	1.51	3.37	95.55	5.84	.001

**Note.* Student's *t* test for location against the null hypothesis that $\mu_0=0$.

Mean Scores Before and After Treatment with ART. Descriptive data regarding mean scores for both subjective (i.e., PCL-M and PSQI) and objective sleep measures (i.e., qEEG) before and after ART are presented in Tables 6 and 7. As seen in Table 6, the mean PTSD (PCL-M) score decreased substantially from baseline (63.75) to post-treatment (33.6), as did self-report PSQI scores (14.5 vs. 9.6). As seen in table 7, results were more variable with mean values of different EEG wave frequencies apparently increasing or decreasing after treatment with ART. Results for the normalized values of qEEG scores were similar (data not shown).

Table 5. Normality Assessment for Normalized qEEG Sleep Measures at Baseline

Normalized qEEG measure	Skew	Kurtosis	Variance	<i>t</i> test for location	<i>p</i> -value
Delta 1.5 – 3.5 baseline	-1.05	2.13	0.00	12.91	.001
Theta 4-6.5 baseline	0.80	-0.03	0.00	8.14	.001
Alpha 8-11 baseline	0.46	-1.12	0.00	5.37	.001
Beta 12-15 baseline	0.00	-1.27	0.00	8.28	.001
Beta 16-20 baseline	-0.55	-1.67	0.00	9.51	.001
Beta 20-25 baseline	0.98	0.11	0.00	4.66	.002
Beta 25-30 baseline	0.94	-0.85	0.00	5.95	.001
Gamma > 30 baseline	0.55	-1.50	0.00	7.59	.001

**Note.* Student's *t* test for location against the null hypothesis that $\mu_0=0$.

For formal testing of aim #1, a series of paired sample *t*-tests were conducted to examine the difference in subjective sleep quality (PSQI), subjective PTSD symptoms (PCL-M), and objective sleep quality (qEEG) measures from before to after ART. Specifically, one dependent sample *t*-test was conducted on the self-reported sleep quality (PSQI), one was conducted on self-reported PTSD symptoms (PCL-M), and one was conducted on each stage of sleep measured from qEEG.

Table 6. Mean PCL-M and PSQI Scores Before and After Treatment with ART.

Variable	<i>M</i>	<i>SD</i>	Min	Max
PTSD Checklist (PCL-M) Score at baseline	63.75	10.44	46.00	78.00
PTSD Checklist (PCL-M) Score post-treatment	33.63	13.34	17.00	56.00
Pittsburgh Sleep Quality Index at baseline	14.50	4.38	7.00	20.00
Pittsburgh Sleep Quality Index post-treatment	9.63	5.40	1.00	16.00

As seen in table 8, results indicated a significant improvement in self-reported sleep quality ($t(7) = 2.47, p = .043$), as measured from the PSQI, and a significant reduction in self-reported PTSD symptoms ($t(7) = 9.70, p = .001$). Of the objective sleep disturbances data (qEEG), two sleep stages had significantly different readings from before to after ART; these included increases in the frequency of Delta ($t(7) = -2.67, p = .032$) and Theta ($t(7) = -6.48, p < .001$) waves. Alpha, Beta, and Gamma readings did not differ significantly in their measures from before to after ART. In aggregate, the results suggest that ART reduces symptoms of PTSD, improves subjective reported sleep quality, and appears to increase the frequency of “slow” brain waves during a 30-minute nap protocol, including Delta and Theta waves.

Aim Number Two

Research Aim # 2: From the previously collected pilot study data, assess the relationship between objective and subjective measures of sleep quality before and after treatment with ART for symptoms of PTSD in U.S veterans.

Table 7. Mean qEEG Scores Before and After Treatment with ART (Non-Normalized).

Variable	<i>M</i>	<i>SD</i>	Min	Max
Delta_15_35_Pre	665.26	221.43	444.17	1082.04
Delta_15_35_Post	965.15	340.58	612.60	1394.78
Theta_4_65_Pre	331.52	99.13	198.74	494.48
Theta_4_65_Post	414.59	106.46	296.45	593.82
Alpha_8_11_Pre	497.22	382.11	126.99	1114.44
Alpha_8_11_Post	566.65	586.08	164.65	1837.42
Beta_12_15_Pre	149.52	83.00	51.98	275.91
Beta_12_15_Post	210.46	221.50	69.33	748.08
Beta_16_20_Pre	76.11	34.67	39.40	121.12
Beta_16_20_Post	108.82	76.92	39.47	275.14
Beta_20_25_Pre	88.78	74.85	23.29	232.29
Beta_20_25_Post	132.77	154.14	30.17	486.97
Beta_25_30_Pre	41.48	25.67	18.84	100.46
Beta_25_30_Post	41.51	26.43	21.71	99.89
Beta_gt_30_Pre	35.69	17.28	17.32	73.05
Beta_gt_30_Post	30.57	14.24	17.65	61.23

Hypothesis # 2: There will be a strong association between objective and subjective measures of sleep disturbances in U.S. veterans before treatment with ART, after treatment with PTSD, and based on treatment-related change in PTSD symptoms.

Table 8. Paired Sample t-Test for Pre-ART to Post-ART Measures of Sleep Function and PTSD.

Measure	ΔM		<i>SE</i>	Confidence		<i>t</i> (7)	<i>p</i>
	(pre	<i>SD</i>		interval			
				to	Lower		
PSQI	-4.88*	5.59	1.98	0.20	9.55	2.47	.043
PCL-M	-30.13***	8.79	3.11	22.78	37.47	9.69	.001
Delta: 1.5 – 3.5 Hz	299.89*	317.48	112.25	-565.31	-34.47	-2.67	.032
Theta: 4 – 6.5 Hz	83.07***	36.24	12.81	-113.36	-52.77	-6.48	.000
Alpha: 8 – 11 Hz	69.43	621.43	219.71	-588.96	450.09	-0.32	.761
Beta: 12 – 15 Hz	60.94	170.9	60.41	-203.80	113.00	-1.01	.347
Beta: 16 – 20 Hz	32.71	65.28	23.08	-87.28	43.16	-1.42	.199
Beta: 20 – 25 Hz	43.99	101.90	36.01	-129.10	67.34	-1.22	.261
Beta: 25-30 Hz	43.99	101.86	36.01	-129.15	41.17	-1.22	.261
Gamma: > 30 Hz	-5.12	7.87	2.78	-1.46	11.70	1.84	.109

Note.* * $p < 0.05$; ** $p < 0.01$; * $p < 0.001$

To assess the correlational relationship between measures of subjective sleep disturbances (as measured by the qEEG), and subjective sleep quality (as measured by the PSQI) before and after ART, a correlation matrix was created. Both objective and subjective measurements were taken before and after ART were gathered, and a change score was also calculated for each. Descriptive statistics for these change scores are presented in Table 9.

Table 9. Descriptive Statistics of Change from Baseline for qEEG and PSQI.

Variable	<i>N</i>	<i>M</i>	<i>SD</i>	Sum	Minimum	Maximum
Change in Delta 1.5-3.5 Hz	8	-299.89	317.48	-2399.00	-829.04	125.35
Change in Theta 4-6.5 Hz	8	-83.07	36.24	-664.53	-129.02	-31.49
Change in Alpha 8-11 Hz	8	-69.43	621.43	-555.47	-1057.00	872.83
Change in Beta 12-15 Hz	8	-60.94	170.86	-487.55	-472.17	57.95
Change in Beta 16-20 Hz	8	-32.71	65.28	-261.66	-154.02	51.30
Change in Beta 20-25 Hz	8	-43.99	101.86	-351.93	-254.68	75.79
Change in Beta 25-30 Hz	8	-0.02	8.19	-0.20	-12.52	11.58
Change in Beta > 30 Hz	8	5.12	7.87	40.95	-6.35	14.82
Change in PSQI	8	4.87	5.59	39.00	-1.00	15.00

Baseline (Pre-ART) Correlations. Table 10 presents the Pearson correlation coefficients between qEEG scores measured at baseline (pre-ART) and self-report PSQI score at baseline. As seen, there were significant, strong inverse correlations between self-report PSQI scores and Delta and Alpha brain wave activity prior to treatment with ART.

Given the sample size of 8 subjects, it should be noted that a typical Pearson Correlation with a power of .80 to reject a false null requires approximately 81 observations (Faul, Erdfelder, Buchner, & Lang, 2012). Thus, any correlation with a coefficient of over .50 may provide insight into a correlation that may be detected with a larger sample size (Tabachnick & Fidell, 2012) and may be meaningful and represent a “medium” effect (Pallant, 2010, Cohen, 1988). In this realm, the correlation coefficient between self-report PSQI score at baseline and Beta 16-20 Hz at baseline was 0.50.

Table 10. Pearson Correlations between qEEG and PSQI at Baseline.

qEEG at baseline	PSQI at baseline
Delta 1.5-3.5 Hz at baseline	-0.79*
Theta 4-6.5 Hz at baseline	-0.45
Alpha 8-11 Hz at baseline	-0.89**
Beta 12-15 Hz at baseline	-0.40
Beta 16-20 Hz at baseline	-0.50
Beta 20-25 Hz at baseline	-0.31
Beta 25-30 Hz at baseline	0.01
Beta > 30 Hz at baseline	-0.04

* $p < 0.05$; ** $p < 0.01$

Post-ART Correlations. Table 11 presents the Pearson correlation coefficients between qEEG scores measured after completion of treatment with ART and self-report PSQI score after ART. Unlike the results from the baseline assessment, self-report PSQI scores after treatment with ART were inversely associated with Theta wave activity after treatment with ART. There were non-significant trends for higher PSQI scores after treatment with ART to be associated with higher Beta wave activity. Collectively, the baseline and post-ART correlation results seem to suggest that higher PSQI scores are associated with lower slow wave (Delta and Theta) activity, and that higher PSQI scores seem to be associated with higher Beta wave activity.

Table 11. Pearson Correlations between qEEG and PSQI Post ART.

qEEG after ART	PSQI post ART
Delta 1.5-3.5 Hz post ART	0.03
Theta 4-6.5 Hz post ART	-0.75*
Alpha 8-11 Hz post ART	0.25
Beta 12-15 Hz post ART	0.47
Beta 16-20 Hz post ART	0.66
Beta 20-25 Hz post ART	0.58
Beta 25-30 Hz post ART	0.60
Beta > 30 Hz post ART	0.57

* $p < 0.05$

Pre-ART to Post-ART Change Correlations. Table 12 presents the Pearson correlation coefficients between qEEG change (pre-ART to post-ART) and PSQI change scores. There were no significant associations and all correlation coefficients were below a value of 0.50.

PCL-M and qEEG. Given the suggestion that higher PSQI scores (poorer sleep quality) may be associated with lower slow wave brain activity, parallel analyses were conducted to examine whether higher PTSD scores may be associated with lower slow wave brain activity. Table 13 (see below) presents the Pearson correlation coefficients between qEEG scores measured at baseline (pre-ART) and self-report PTSD score (PCL-M) at baseline. There were no significant associations, although there was a suggestion that higher PCL- M scores were associated with higher Beta 25-30 Hz activity ($r=0.55$, $p=0.16$).

Table 12. Pearson Correlations between Changes from Baseline for qEEG and PSQI.

Change in qEEG	Change in PSQI
Change in Delta 1.5-3.5 Hz	0.21
Change in Theta 4-6.5 Hz	-0.30
Change in Alpha 8-11 Hz	0.17
Change in Beta 12-15 Hz	0.11
Change in Beta 16-20 Hz	0.30
Change in Beta 20-25 Hz	0.26
Change in Beta 25-30 Hz	-0.02
Change in Beta > 30 Hz	-0.41

Table 13 results are consistent with the baseline (pre-ART results). There were no significant associations between post-ART qEEG scores and post-ART PCL-M scores in table 14 (see below). However, there were suggestions of higher PCL-M scores after treatment with ART being associated with higher Beta wave activity.

Finally, there were no significant associations between qEEG change scores and PCL-M change scores in table 15 (see below). Thus, in aggregate, there was minimal evidence of a relationship between PTSD (PCL-M) scores and qEEG scores.

Table 13. Pearson Correlations between qEEG and PCL-M at Baseline.

Baseline qEEG	Baseline PCL-M
Delta 1.5-3.5 Hz at baseline	-0.23
Theta 4-6.5 Hz at baseline	-0.20
Alpha 8-11 Hz at baseline	-0.12
Beta 12-15 Hz at baseline	0.21
Beta 16-20 Hz at baseline	0.34
Beta 20-25 Hz at baseline	0.40
Beta 25-30 Hz at baseline	0.55
Beta > 30 Hz at baseline	0.38

Table 14. Pearson Correlations between qEEG and PCL-M Post ART.

qEEG post ART	PCL-M post ART
Delta 1.5-3.5 Hz post ART	0.48
Theta 4-6.5 Hz post ART	-0.44
Alpha 8-11 Hz post ART	0.04
Beta 12-15 Hz post ART	0.36
Beta 16-20 Hz post ART	0.58
Beta 20-25 Hz post ART	0.51
Beta 25-30 Hz post ART	0.50
Beta > 30 Hz post ART	0.49

Aim Number Three

Research Aim # 3: In a secondary data analysis from two previously conducted studies, compare self-report PTSD and sleep disturbance symptoms between civilians and veterans before and after treatment with ART.

Hypothesis # 3: Civilians and veterans will report similar self-report PTSD and sleep disturbance symptoms before and after treatment with ART.

Table 15. Pearson Correlations between Changes from Baseline for qEEG and PCL-M.

Change in qEEG	Change in PCL-M
Change in Delta 1.5-3.5 Hz	0.38
Change in Theta 4-6.5 Hz	-0.39
Change in Alpha 8-11 Hz	-0.13
Change in Beta 12-15 Hz	-0.18
Change in Beta 16-20 Hz	0.00
Change in Beta 20-25 Hz	0.01
Change in Beta 25-30 Hz	-0.17
Change in Beta > 30 Hz	-0.35

Comparison of Baseline Demographic Characteristics by Military Status. As seen in table 16, the mean age of the 125 participants included in the secondary analysis was 41.0 ± 11.1 years. Of note, the mean age was similar between military and civilian participants enrolled in the two studies.

Table 16. Independent Sample t-test for Demographic Characteristics by Military Status.

Variable	Total Sample (n = 125)		Military (n = 50)		Civilian (n = 75)		<i>t</i> (123)	<i>p</i>
	<i>M</i>	<i>SD</i>	<i>M</i> (<i>SD</i>)	<i>SD</i>	<i>M</i>	<i>SD</i>		
Age	40.98	11.07	41.92	12.75	40.35	9.84	-.78	.439

As seen in table 17, the majority of participants in the civilian study (80.0%) were female compared to only 18% in the military study ($p < 0.001$). In addition, the civilian study had higher representation of those with Hispanic ethnicity compared to the military study.

Table 17. Chi-Square Analyses between Categorical Demographical Variables and Military Status.

Variable	<i>N</i> (%)	Military	Civilian	$\chi^2(1)$	<i>p</i>
		<i>N</i> (%)	<i>N</i> (%)		
Female gender	69 (55.2)	9 (18.0)	60 (80.0)	46.63	<0.001
Hispanic ethnicity	26 (21.1)	6 (12.0)	20 (27.4)	4.22	0.04
Married	72 (57.6)	29 (58.0)	43 (57.3)	0.01	0.94
Sexual trauma	26 (20.8)	7 (14.0)	19 (25.3)	2.34	0.13
Employed	72 (59.0)	29 (58.0)	43 (59.7)	0.04	0.85

Comparison of Baseline Clinical Characteristics by Military Status. Table 18

shows mean PCL and PSQI scores at the 3 time points consisting of baseline (time 1), post-ART (time 2), and at 3-month follow-up (time 3). At baseline, the mean PCL score was similar between military and civilian participants (56.1 vs. 54.2, $p=0.43$). However, when examining the 4 PTSD subscales at baseline, military participants presented with higher levels of arousal compared to civilian participants (18.0 vs. 15.0, $p=0.002$). After treatment completion with ART, the mean PCL score was lower in civilian participants compared to military participants (30.7 vs. 40.7, $p=0.004$). However, at 3-month follow-up, scores were similar (30.0 vs. 33.1, $p=0.26$, respectively).

At baseline, military participants presented with higher mean PSQI scores (12.6 vs. 9.4, $p=0.002$). This relative difference persisted after treatment with ART (9.9 vs. 6.7, $p=0.001$) and with a trend at 3-month follow-up (8.8 vs. 6.7, $p=0.08$).

Table 18. Independent Sample t-Test for Clinical Characteristics by Military Status.

Variable	Total Sample (n=125)		Military (n=50)		Civilian (n=75)		<i>t</i>	<i>p</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Scores at three times (1=Baseline, 2=post ART, 3=3 month follow-up)								
PCL1 (n = 125)	54.9	13.8	56.1	15.3	54.2	12.7	-0.79	0.431
PCL2 (n = 113)	34.9	15.1	40.7	17.8	30.7	11.2	-3.67	0.004
PCL3 (n = 91)	31.3	12.6	33.1	12.7	30.0	12.4	-1.14	0.26
PSQI1 (n = 119)	10.7	4.7	12.6	4.3	9.4	4.4	-3.90	0.002
PSQI2 (n = 101)	8.1	4.9	9.9	4.8	6.7	4.6	-3.37	0.001
PSQI3 (n = 79)	7.5	4.9	8.8	5.5	6.7	4.5	-1.80	0.08
PTSD (PCL) subscales – at baseline								
Intrusion	16.2	4.6	16.0	5.2	16.4	4.2	0.46	0.64
Avoidance	6.6	2.4	6.8	2.5	6.5	2.2	-0.85	0.40
Arousal	16.2	5.4	18.0	4.6	15.0	5.6	-3.13	0.002
Numbing	15.9	5.1	15.3	5.7	16.2	4.7	0.98	0.33

Pearson Correlations between PCL and PSQI Stratified by Military Status.

PCL and PSQI at Time 1 (Baseline).

Pearson Correlation for PCL1 and PSQI1. Among civilian participants, there was a strong association between PCL and PSQI scores at baseline ($r = 0.62, p < 0.0001$). These data are depicted in the scatterplot presented in Figure 4 (left side). Among military participants, there was a modest association between PCL and PSQI scores at baseline ($r = 0.48, p = 0.0004$). These data are depicted in the scatterplot presented in Figure 4 (right side).

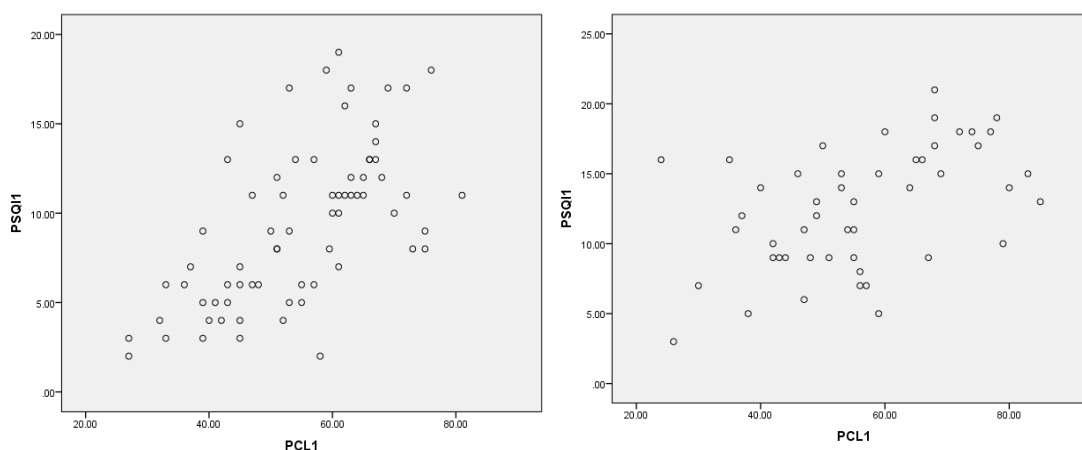


Figure 4. Scatterplot between PCL and PSQI at baseline (civilians left, military right)

Pearson Correlation for PCL2 and PSQI2. Among civilian participants, there was a strong association between PCL and PSQI scores after treatment completion with ART ($r = 0.66, p < 0.0001$). These data are depicted in the scatterplot presented in Figure 5 (left side). Among military participants, there was a similar strong association between PCL and PSQI scores after treatment completion with ART ($r = 0.59, p < 0.0001$). These data are depicted in the scatterplot presented in Figure 5 (right side).

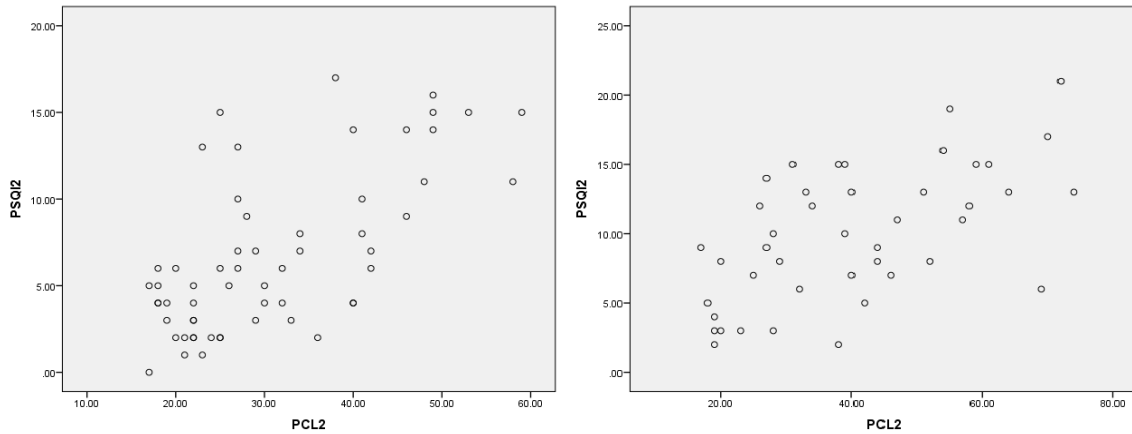


Figure 5. Scatterplot between PCL and PSQI after Treatment Completion (civilians left, military right)

Pearson Correlation for PCL3 and PSQI3. Among civilian participants, there was a strong association between PCL and PSQI scores at 3-month follow-up ($r = 0.66$, $p < 0.0001$). These data are depicted in the scatterplot presented in Figure 6 (left side).

Among military participants, there was a similar strong association between PCL and PSQI scores at 3-month follow-up ($r = 0.71$, $p < 0.0001$). These data are depicted in the scatterplot presented in Figure 6 (right side).

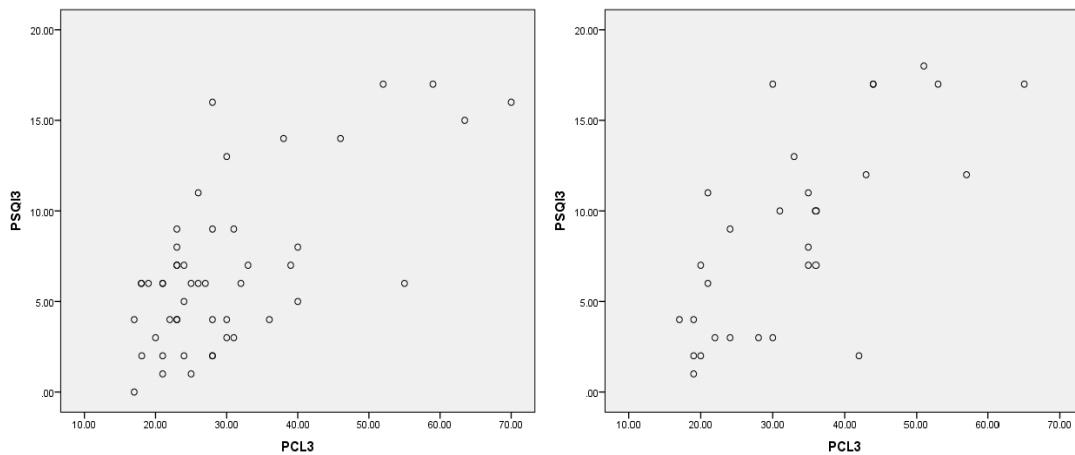


Figure 6. Scatterplot between PCL and PSQI at 3-Month Follow-up (civilians left, military right)

Thus, results of the association between PCL and PSQI scores were relatively consistent between veterans and civilians. This included a strong association being present at all three time points.

Pearson Correlation Between Change in PCL and Change in PSQI Overall and by Military Status. The change in PCL and PSQI scores from before to after treatment with ART was calculated overall and by military status. Among all participants, there was a modest association between change in PCL and change in PSQI scores ($r = 0.38, p < 0.0001$). The scatterplot for these data are depicted in Figure 7.

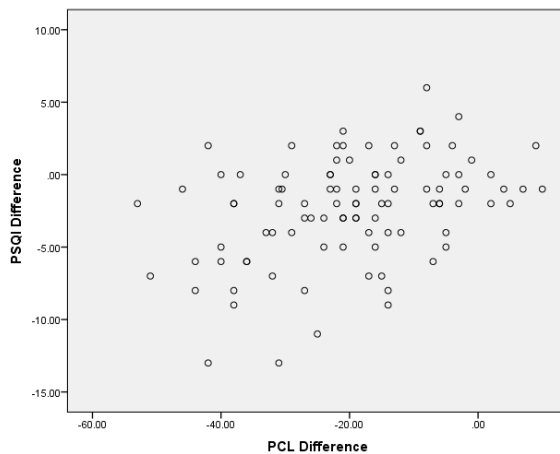


Figure 7. Scatterplot between change in PCL and change in PSQI (total sample)

Among civilian participants, there was also a modest association between change in PCL and change in PSQI scores ($r = 0.43, p = 0.001$). These data are depicted in the scatterplot presented in Figure 8 (left side). Among military participants, there was a similar modest association between change in PCL and change in PSQI scores ($r = 0.40, p = 0.009$). These data are depicted in the scatterplot presented in Figure 8 (right side).

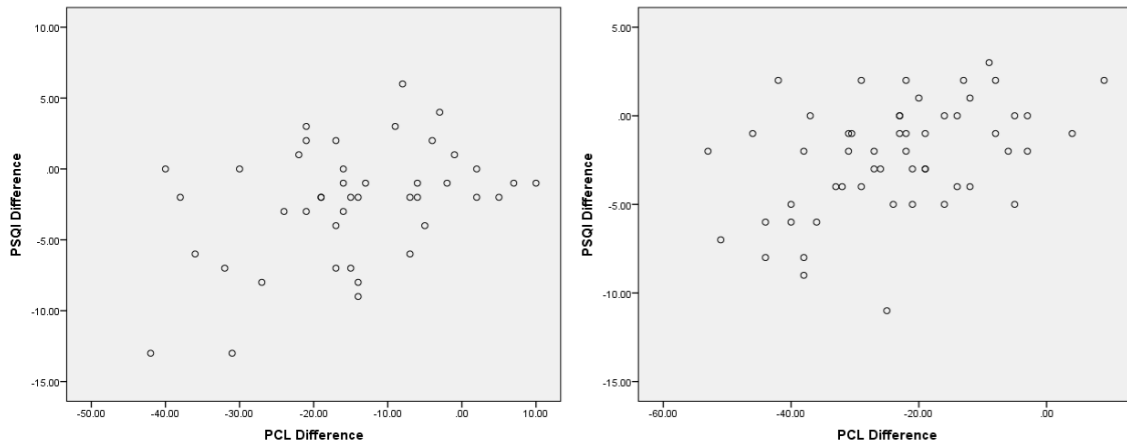


Figure 8. Scatterplot between change in PCL and change in PSQI scores (civilians left, military right)

Multiple Linear Regression Analysis.

As seen in Table 19, at baseline, PCL score was a strong predictor of PSQI score ($t = 6.3, p < 0.001$). Military status was also associated with PSQI score at baseline ($t = 2.7, p = 0.009$). However, the interaction between PCL score and military status was not significant ($p = 0.10$). The model R^2 value of 0.40 suggests that PCL score, military status, and the interaction between the two accounted for 40% of the variance in PSQI score at baseline. For interpretation, each unit increase in PCL score at baseline was associated with an estimated increase in PSQI score of 0.22 points. Compared to civilian status, being a military member indicated a 7.4-point higher score on the PSQI at baseline.

Table 19. Results of Multiple Linear Regression with PCL and Military Status Predicting PSQI Score at Baseline.

Source	<i>B</i>	<i>SE</i>	β	<i>t</i>	<i>p</i>
PCL score	0.22	0.03	.64	6.31	<0.001
Military member	7.38	2.77	.78	2.67	.009
PCL*Military	-0.08	0.05	-.50	-1.64	.103

*Note. $F(3, 115) = 25.96, p < .001, R^2 = .40$

The above regression analysis was replicated based on scores obtained at the completion of treatment with ART (time 2). As seen in Table 20, PCL score again was a strong predictor of PSQI score ($t = 6.3, p < 0.001$). Military status was also associated with PSQI score after completion with ART ($t = 2.3, p = 0.02$). Again, the interaction between PCL score and military status was borderline significant ($p = 0.07$). The model R^2 value of 0.46 suggests that PCL score, military status, and the interaction between the two accounted for 46% of the variance in PSQI score after treatment completion with ART. For interpretation, each unit increase in PCL score after treatment with ART was associated with an estimated increase in PSQI score of 0.27 points. Compared to civilian status, being a military member indicated a 4.7-point higher score on the PSQI after treatment with ART.

Table 20. Results of Multiple Linear Regression with PCL and Military Status Predicting PSQI Score After Treatment Completion with ART.

Source	<i>B</i>	<i>SE</i>	β	<i>t</i>	<i>p</i>
PCL2	0.27	0.04	.80	6.29	<.001
Military Status	4.71	2.06	.47	2.29	.024
PCL2*Military Status	-0.10	0.06	-.46	-1.83	.070

*Note. $F(3, 97) = 27.75, p < .001, R^2 = .46$

Table 21 provides results for the regression analysis for scores obtained at 3-month follow-up. As seen in Table 21, PCL score again was a strong predictor of PSQI score ($t = 5.7, p < 0.001$). However, military status was not associated with PSQI score at 3-month follow-up ($t = -0.4, p = 0.68$), and the interaction between PCL score and military status was

not significant ($p=0.32$). The model R^2 value of 0.49 suggests that PCL score, military status, and the interaction between the two accounted for 49% of the variance in PSQI score at 3-month follow-up.

Table 21. Results of Multiple Linear Regression with PCL and Military Status Predicting PSQI Score Sat 3-Month Follow-up.

Source	<i>B</i>	<i>SE</i>	β	<i>T</i>	<i>p</i>
PCL3	0.24	0.04	.61	5.72	<.001
Military Status	-0.95	2.32	-.09	-0.41	.684
PCL3*Military Status	0.07	0.07	.25	1.00	.321

*Note. $F(3, 75) = 24.27, p < .001, R^2 = .49$

Finally, the analysis was replicated using change in PCL and PSQI scores from baseline to treatment completion with ART. As seen in Table 22, change in PCL score after treatment completion with ART was a strong predictor of change in PSQI score ($t = 2.9, p=0.003$). Military status was not associated with change in PSQI score ($t = -0.30, p=0.77$), and the interaction between change in PCL score and military status was not significant ($p=0.52$)

Table 22. Results of Multiple Linear Regression with Change in PCL and Military Status Predicting Change in PSQI Score.

Source	<i>B</i>	<i>SE</i>	β	<i>t</i>	<i>p</i>
Change in PCL (T2-T1)	0.10	0.03	.37	2.92	.004
Military Status	-0.35	1.19	-.05	-0.30	.767
Change in PCL*Military Status	0.03	0.05	.10	0.64	.522

*Note. $F(3, 75) = 24.27, p < .001, R^2 = .49$

In aggregate, the results of the regression analyses indicated that PCL score was strongly associated with PSQI score at all time points, and that military status (compared to civilian status) was generally associated with higher PSQI scores. The interaction between PTSD score and being a military member was non-significant in all models, suggesting a relatively similar relationship between symptoms of PTSD and sleep quality between both civilians and veterans.

Magnitude of Acute and Sustained Changes

The magnitude of change in PCL and PSQI scores was examined as acute changes (i.e., from pre-ART treatment to immediately post-treatment) and as sustained changes (i.e., from pre-ART treatment, to three months following the treatment). The average acute change on the PCL checklist was a reduction of 19.6 points, whereas the average acute change on the PSQI was a reduction of 2.3 points. Sustained changes for the PCL were an average reduction of 22.9 points, whereas average sustained changes for the PSQI were a reduction of 2.6 points. Thus, the magnitude of change was relatively similar immediately following treatment completion and at 3-month follow-up.

For veterans, the mean acute PCL change was 14.3 ± 12.7 points. Among civilians, the corresponding mean acute PCL change was 23.3 ± 13.1 points. By use of a student *t*-test, the magnitude of acute PCL change was significantly greater in civilians compared to veterans ($t=3.64$, $p=0.0004$). For sustained change, the difference by military status was less pronounced. The mean sustained PCL change among veterans was 20.6 ± 13.8 points compared to 24.5 ± 12.4 points among civilians. By use of a student *t*-test, the magnitude of sustained PCL change was similar between civilians and veterans ($t=1.40$, $p=0.16$).

Finally, for veterans, the mean acute PSQI change was 2.5 ± 4.1 points. Among civilians, the corresponding mean acute PSQI change was 2.2 ± 3.0 points. By use of a

student *t*-test, the magnitude of acute PCL change was similar between veterans and civilians ($t=-0.41$, $p=0.68$). For sustained change, the mean PSQI change among veterans was 3.2 ± 4.3 points compared to 2.0 ± 3.4 points among civilians. By use of a student *t*-test, the magnitude of sustained PCL change was similar between civilians and veterans ($t=-1.28$, $p=0.21$).

Chapter Five

Discussion, Conclusions, and Recommendations

Introduction

The final chapter of this dissertation includes a synthesis of the results from the study with discussion of the findings, conclusions, and implications for nursing and future research recommendations. The focus of this dissertation was to examine the effects of Accelerated Resolution Therapy (ART) on comorbid PTSD and sleep disturbances. This included examination of both subjective and objective measurement of sleep data (U.S. veterans), in addition to examination of results by military versus civilian status. The study was carried out using 2 data sources and approaches. For specific aims 1 and 2, data from a previously completed pilot study among eight U.S. veterans that included objective sleep EEG data were analyzed. For aim 3, a secondary data analysis was conducted between 2 prior treatment studies of ART, which included extensive self-report data on symptoms of PTSD and sleep disturbances. All three specific aims were analyzed considering pre-treatment data, post-treatment data, and change in symptom and EEG measurements as a result of participants being treated with ART.

Summary of the Results

Aim #1. The primary hypothesis for aim #1 was that treatment with ART would be effective in improving both subjective and objective measures of sleep disturbances in U.S. veterans. Objective measurement of sleep quality was based on EEG analysis of brain wave activity based on a 30-minute nap protocol conducted prior to treatment with ART and after treatment completion with ART. From this pilot study of 8 U.S. veterans treated with

ART, there was confirmatory evidence that ART resulted in improved subjective reported sleep quality, in addition to evidence of increased Delta and Theta waves which are in the frequency of “slow” brain waves. Despite the small sample of just 8 veterans, improvements in subjective and objective measures of sleep achieved statistical significance. Thus, these data provide supporting evidence that when ART is used as a primary treatment for PTSD, corresponding improvements in sleep quality measured using different approaches may be expected to occur.

Aim #2. The primary hypothesis for aim #2 was that subjectively reported measurement of sleep function would be associated with EEG-objective measures of sleep function before treatment with ART, after treatment with ART, and based on treatment-related change in PTSD symptoms. Relatively consistent with the results of aim #1, there was evidence of significant, strong inverse associations between self-report (PSQI) scores and Delta brain wave activity prior to treatment with ART. After treatment with ART, there were non-significant trends for higher PSQI scores after treatment with ART to be associated with higher Beta wave activity. Taking these results together, it appears that higher (worse) self-report sleep scores (PSQI) are associated with less frequent slow wave (Delta) activity, and that higher PSQI scores seem to be associated with higher Beta wave activity. These results are in the expected direction (i.e. poorer self-report sleep quality associated with less frequent “slow wave” and more frequent “fast wave” frequency). However, there were no significant associations between qEEG change (pre-ART to post-ART) and PSQI change scores or qEEG change scores and PCL-M change scores. These results indicate that objective (EEG) measurement of sleep disturbances following treatment for PTSD does not correlate directly with self-report symptoms of sleep disturbances or PTSD.

Aim #3. The primary hypothesis for aim #3 was that civilians and veterans would report similar self-report PTSD and sleep disturbances symptoms before and after treatment with ART. As hypothesized, there were modest to large, statistically significant correlations between self-reported PCL (PTSD) and PSQI (sleep) scores observed among both civilians and veterans. These associations were present at baseline, immediately after treatment completion with ART, at 3-month follow-up, and based on change in scores from pre-treatment to post-treatment. In multiple regression analysis, change in PCL (PTSD) score was a strong predictor of change in PSQI (sleep) score, irrespective of military versus civilian status. Thus, even though military members tended to present with higher (worse) PSQI scores at baseline, treatment with ART and reductions in PTSD were associated with comparable reductions (improvement) in PSQI scores for both civilians and veterans.

Scientific Implications of Findings

Aim #1. When ART is used as a primary treatment for PTSD, consistent improvements in sleep disturbances were observed using subjective and objective methods and among both civilians and veterans. Other methods that may be used to examine objective and subjective sleep quality include use of actigraphy and sleeping diaries (King, Spence, Hickey, Sargent, Elesh, and Connelly, 2015). Both subjective and objective measurements play important roles in estimating sleep disturbances and should be incorporated in clinical studies to help address sleep disorders (Lin Zhang, 2007).

Aim # 2: Results indicate that objective or EEG measurements of sleep disturbances after treatment for PTSD may not correlate directly with self-report symptoms of sleep disturbances or PTSD. Recent findings suggest that objective measurements of sleep function (EEG) may not be as effective in capturing manifestations of changes in subcortical circuits during REM and NREM sleep that may contribute to PTSD reliability

(Germain, 2013). However, sleep diaries can be a relatively effective sleep measurement approach (Germain, 2013). Sleep disturbances are considered a hallmark of PTSD, and the present study examined EEG measurements in relation to PTSD and subjective measurement of sleep quality. Human and animal studies have provided evidence for years supporting the notion that sleep plays an important role in PTSD-relevant emotion and memory processing for brain. Sleep diaries and other vigorous objective measurements suggest REM sleep disturbances are implicated in PTSD, and that multiple measurement methods should be used (Germain, 2014).

Aim # 3: Military members presented with higher or worse PSQI scores than civilians at baseline. However, treatment with ART resulted in relatively comparable reductions in symptoms of PTSD as well as reductions (improvement) in PSQI scores for both civilians and veterans. These findings are consistent with earlier work showing that veterans and civilians with PTSD have more severe sleep disturbances than those without trauma (Lewis, Creamer & Failla, 2009).

Implications for Nursing

Whereas additional empirical research is needed in this area, the nurse caring for the individual with PTSD, whether civilian or military, needs to routinely assess sleep disturbances and initiate an open dialogue regarding these conditions. This rapport can make it easier for patients to understand their current symptom experience and address ways in which to heal and maximize wellness. In return, the nurse will be able to provide the patient with the resources needed to help them better understand and address these concerns, including after experiencing restless nights of sleep. While multiple authors (Schoenfeld (2012), Harvey & Bryant (1998); Mellman, David, Bustamante, Torres, & Fins (2001); Koren, Arnon, Lavie, & Klein (2002)) have shown that sleep disturbances

may play a central role in future predicting development of PTSD after exposure to trauma, this also corroborates the need for nurse to be attentive to sleep dysfunction, and the possibility that it may be largely a consequence of recent trauma exposure and early manifestation of PTSD. The presumed bi-directional temporal relationship between PTSD and sleep disturbances places a premium on assessing these conditions collectively, rather than as discrete, independent clinical conditions.

Limitations

Most importantly, there was no control group to compare the results achieved with ART. This uncontrolled pilot study design is standard for an early stage evolving therapy such as ART, but can provide suggestion of effectiveness. Second, for aims 1 and 2, there was a very small sample size of eight participants in the study limiting precision of results. In addition, having seven men and one woman in the aim 1 and 2 analyses limits generalizability, as does the imbalance in aim 3 of having 80% women in the civilian sample compared to 18% in the veterans sample.

Recommendations for Future Study

Based on the existing scientific literature in this area and the findings of the current study, the following are future research recommendations.

1. To continue to examine objective measures of sleep function (in the presence and absence of PTSD) that are non-invasive, provide routine monitoring and export of data, and track very closely with clinical diagnosis and self-report of sleep quality. The EEG approach used in the present study, while useful from a scientific perspective, is not practical for everyday objective monitoring of sleep function. Future studies with an actigraphy will likely be more useful.
2. Establish a clinical recommendation for nurses and advanced practice nurses to

identify those who may be more likely to have sleep disturbances in conjunction with symptoms of PTSD, and therefore, would derive the most benefit from screening and intervention for these symptoms.

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Appendices

**Appendix A:
ART Intake Questionnaire**

- 1) About how many traumatic memories are still impacting your life?
 None 1 to 2 3 to 4 5 or more

Which traumatic memory/memories would you like to resolve with A.R.T.?

- 2) Are you currently on disability for post-traumatic stress disorder (PTSD) or any mental health problem?
 YES NO
- 3) Do you feel that you are ready to let go of your traumatic memories so that you no longer could see them in the same way (i.e. if there was a way to do this)?
 YES NO

If No, what would prevent you from wanting to let go?

- 4) Is there any guilt associated with your traumatic memory or memories?
 YES NO

If Yes, can you briefly explain what the guilt is about?

- 5) How long have you lived with the traumatic memory or memories?
 0-3 months 4 to 6 months 7 to 12 months
 1 to 3 years 4 to 6 years 7 to 10 years 11+ years

- 6) I am motivated to move forward in my life:

Least motivated = 0 Most motivated = 10 (Please circle your answer)

0 1 2 3 4 5 6 7 8 9 10

- 7) Have you been diagnosed with any mental health conditions in the past?

YES NO

If Yes, what is the condition or conditions?

8) What other problems are impacting your life now beside the traumatic memories and other symptoms related to PTSD?

9) If you were able to rid yourself of the symptoms that occur from your traumatic memories, what percentage of your mental health problems would be resolved (circle one number)?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Name of therapist reviewing form: _____

Signature of therapist: _____

Today's Date: _____

Page 2 of 2

**Appendix B:
Medical History Form**

ID# _____

Visit: _____

Date: _____

Medical History Form
Page 1 of 2

1) Current and Past Medical History (check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Diabetes Problems | <input type="checkbox"/> Cancer | <input type="checkbox"/> Vision |
| <input type="checkbox"/> Lung disease | <input type="checkbox"/> Thyroid Problem | |
| <input type="checkbox"/> Intestinal Disorder | <input type="checkbox"/> Liver Disease | <input type="checkbox"/> Muscle/bone |
| <input type="checkbox"/> Kidney Disease | <input type="checkbox"/> Seizures | |
| <input type="checkbox"/> Heart Disease | <input type="checkbox"/> Hearing Problems | <input type="checkbox"/> GYN |
| <input type="checkbox"/> Neurological problems, if female | <input type="checkbox"/> Head trauma | <input type="checkbox"/> Severe |
| <input type="checkbox"/> Spinal cord Injury burns | <input type="checkbox"/> Paralysis (if yes, check all that apply) | |
| <input type="checkbox"/> Upper extremity(ies) | <input type="checkbox"/> Lower limb(s) | <input type="checkbox"/> Upper limb(s) |
| <input type="checkbox"/> Lower extremity(ies) | <input type="checkbox"/> Lower extremity(ies) | <input type="checkbox"/> Upper extremity(ies) |
| <input type="checkbox"/> Amputation (if yes, check below all that apply) | | |

2) Have you previously received any treatment for Post-Traumatic Stress Disorder or any other type of mental health condition? Yes No

If yes, please specify: _____

If applicable, what type of treatment(s) did you receive (check all that applies):

- Individual therapy with a mental health professional
- Type of therapy (check all the apply)
- Psychotherapy:
- Cognitive Behavior (CBT)

_____	_____ Group Psychotherapy	Months of Treatment: _____
_____	_____ Individual Psychotherapy	Months of Treatment: _____
_____	_____ Prolonged Exposure	Months of Treatment: _____
_____	_____ Eye Movement desensitization and reprocessing (EMDR)	Months of Treatment: _____
_____	_____ Prescription Medication	Months of Treatment: _____
_____	_____ Other (Please specify) _____	

3.) Please list the names of any prescription medications you are currently taking:

Medication name	Dose (if known)	Frequency (e.g. daily)
-----------------	-----------------	------------------------

Appendix C: State – Trait Inventory for Cognitive and Somatic Anxiety

13. State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA)

Your mood at this moment

Below is a list of statements which can be used to describe how people feel. Beside each statement are four numbers which indicate the degree with which each statement is self-descriptive of your mood at this moment (eg, 1 = not at all, 4 = very much so). *Please read each statement carefully and circle the number which best indicates how you feel right now, at this very moment, even if this is not how you usually feel.*

In general...

	Not at all	A little	Moderately	Very much so
1. My heart beats fast	1	2	3	4
2. My muscles are tense	1	2	3	4
3. I feel agonized over my problems	1	2	3	4
4. I think that others won't approve of me	1	2	3	4
5. I feel like I'm missing out on things because I can't make up my mind soon enough	1	2	3	4
6. I feel dizzy	1	2	3	4
7. My muscles feel weak	1	2	3	4
8. I feel trembly and shaky	1	2	3	4
9. I picture some future misfortune	1	2	3	4
10. I can't get some thought out of my mind	1	2	3	4
11. I have trouble remembering things	1	2	3	4
12. My face feels hot	1	2	3	4
13. I think that the worst will happen	1	2	3	4
14. My arms and legs feel stiff	1	2	3	4
15. My throat feels dry	1	2	3	4
16. I keep busy to avoid uncomfortable thoughts	1	2	3	4
17. I cannot concentrate without irrelevant thoughts intruding	1	2	3	4
18. My breathing is fast and shallow	1	2	3	4
19. I worry that I cannot control my thoughts as well as I would like to	1	2	3	4
20. I have butterflies in the stomach	1	2	3	4
21. My palms feel clammy	1	2	3	4

**Appendix D:
PTSD Checklist – Military Version (PCL – M)**

PTSD Checklist – Military Version (PCL-M)

Name: _____ Unit: _____
 Best contact number and/or email: _____
 Deployed location: _____

Instructions: Below is a list of problems and complaints that veterans sometimes have in response to a stressful military experience. Please read each one carefully, put an "X" in the box.

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Repeated, disturbing memories, thoughts, or images of a stressful military experience?					
2.	Repeated, disturbing dreams of a stressful military experience?					
3.	Suddenly acting or feeling as if a stressful military experience were happening again (as if you were reliving it)?					
4.	Feeling very upset when something reminded you of a stressful military experience?					
5.	Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful military experience?					
6.	Avoid thinking about or talking about a stressful military experience or avoid having feelings related to it?					
7.	Avoid activities or talking about a stressful military experience or avoid having feelings related to it?					
8.	Trouble remembering important parts of a stressful military experience?					
9.	Loss of interest in things that you used to enjoy?					
10.	Feeling distant or cut off from other people?					
11.	Feeling emotionally numb or being unable to have loving feelings for those close to you?					
12.	Feeling as if your future will somehow be cut short?					
13.	Trouble falling or staying asleep?					
14.	Feeling irritable or having angry outbursts?					
15.	Having difficulty concentrating?					
16.	Being "super alert" or watchful on guard?					
17.	Feeling jumpy or easily startled?					

Has anyone indicated that you've changed since the stressful military experience? Yes ___ No ___

**Appendix E:
Demographics**

ID # _____
Date: _____

Visit: ___

DEMOGRAPHICS (Page 1 of 2)

Please complete the following information. This information is only for research staff reference and will remain strictly confidential.

- 1.) What is your age? _____

- 2.) Please indicate your gender: A) Male _____ B) Female _____

- 3.) Please indicate your race:
A) Black or African America
B) White
 Native
C) Asian
D) Native Hawaiian/Pacific Islander
E) American Indian/Alaskan

- 4.) Please indicate your ethnicity:
A) Non-Hispanic B) Hispanic

- 5.) What is your current marital status? (Circle one)
A) Never married D) Divorced or separated
B) Married E) Widowed
C) Living with someone but not married

- 6.) What is your current employment status? (Circle One)
A) Full-time employment E) Unemployed, disabled
B) Part-Time employment F) Retired due to pain
C) Unemployed, not interested G) Retired not due to pain
D) Unemployed, looking for work H) Other (specify): _____

- 7.) How many years of education have you completed starting with the first grade?

Years

- 8.) Are you currently enrolled in an educational program?
A) Yes B) no C) I am planning to be

ID# _____
Date: _____

Visit: _____

DEMOGRAPHICS (Page 2 of 2)

9.) If you answered Yes to #8, what type of educational program are you enrolled in?

- A) High School (GCSE, etc) B) Vocational School
C) College/Associate Level degree D) College/bachelors Level degree
E) College/Graduate Level Degree F) Other

10.) What is your current military status? (Circle one)

- A) Active Duty B) Reservist C) Discharged/Veteran

11.) What branch of the military have you primarily served in? (Circle one)

- A) Army E) Marine Corps I) Coast Guard
B) Army Reserves F) Marine Corps Reserves J) Coast Guard

Reserves

- C) Navy G) Air Force K) National Guard
D) Naval Reserves H) Air Force Reserves L) National Guard

Reserves

12.) How many overseas tours of duty have you had since joining the military?
(Circle one)

- A) 1 B) 2 C) 3 D) 4 or more

13.) Where were you deployed? (Circle all that apply.)

- A) Persian Gulf D) Vietnam
B) Iraq E) Kosovo
C) Afghanistan F) Other

13a) Length of deployment(s) in months: Shortest _____ Longest _____

14.) During your tour(s) of duty, did you experience any combat-related activities?
(For example, patrols, under enemy fire, being surrounded by the enemy, kidnapped or imprisoned, firing upon the enemy, hand to hand combat, pinned down, shot down)

- A) Yes B) No

15.) What are the principals type(s) of distressing experiences for which you are seeking treatment? (Circle all the apply)

- A) Witness death or execution B) IED blast or combat explosion
C) Witness major injuries (non-lethal) D) Physical assault
E) Sexual assault F) Other Specify:

Thank you for your participation.

**Appendix F:
Pittsburgh Sleep Quality Index (PSQI)**

Subject's Initials _____ ID# _____ Date _____ Time _____ AM
PM

PITTSBURGH SLEEP QUALITY INDEX

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 room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

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

a) Loud snoring

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

b) Long pauses between breaths while asleep

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

c) Legs twitching or jerking while you sleep

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

d) Episodes of disorientation or confusion during sleep

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

e) Other restlessness while you sleep; please describe _____

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

**Appendix G:
Center for Epidemiologic Studies Depression Scale (CES-D)**

Center for Epidemiologic Studies Depression Scale (CES-D), NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the Past			
	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I did not feel like eating; my appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I felt that I could not shake off the blues even with help from my family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I felt I was just as good as other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I felt that everything I did was an effort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt hopeful about the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I thought my life had been a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I felt fearful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I was happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I talked less than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I felt lonely.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. People were unfriendly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I enjoyed life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I had crying spells.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I felt that people dislike me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I could not get "going."	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SCORING: zero for answers in the first column, 1 for answers in the second column, 2 for answers in the third column, 3 for answers in the fourth column. The scoring of positive items is reversed. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

Appendix H: Institutional Review Board Approval



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC055 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

4/23/2013

Marian Hardwick,
College of Nursing
6147 5th Avenue North
Saint Petersburg, FL 33710

RE: **Full Board Approval for Initial Review**

IRB#: Pro00011530

Title: The Relationship Between Post-Traumatic Stress Disorder and Sleep Disturbance Before and After Treatment with Accelerated Resolution Therapy (ART)

Study Approval Period: 4/8/2013 to 4/8/2014

Dear Dr. Hardwick:

On 4/8/2013, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

Approved Item(s):

Protocol Document(s):

[PTSD and Sleep Dissertation Protocol.docx](#)

Accepted Documents:

[Centers for Epidemiological Studies Depression Scale](#)

[Pittsburg Sleep Quality Index](#)

[Psychiatric Diagnostic Screening Questionnaire](#)

[PTSD - C](#)

[PTSD Checklist - M](#)

[State-Trait Inventory for Cognitive and Somatic Anxiety](#)

Consent/Assent Document(s)*:

[PTSD and Sleep Consent Form.pdf](#)

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s).

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,



E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

3/11/2016

Marian Hardwick, MS, RN
College of Nursing
12901 Bruce B. Downs Blvd., MDC22
Tampa, FL 33612

RE: **Expedited Approval for Continuing Review**

IRB#: CR3_Pro00011530

Title: The Relationship Between Post-Traumatic Stress Disorder and Sleep Disturbance Before and After Treatment with Accelerated Resolution Therapy (ART)

Study Approval Period: 4/8/2016 to 4/8/2017

Dear Mrs. Hardwick:

On 3/10/2016, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within including those outlined below.

Approved Item(s):

Protocol Document(s):

[Study Protocol Clean 12-16-2014](#)

Consent/Assent Document(s)*:

[Consent form \(clean\) version 3.0 2-24-2015.pdf](#)

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab on the main study's workspace. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s) and replace the previously approved versions.

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):

(8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for

long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with USF HRPP policies and procedures and as approved by the USF IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,



E. Verena Jorgensen, M.D., Chairperson
USF Institutional Review Board



RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

3/14/2013

Kevin Kip, Ph.D.
College of Nursing
12901 Bruce B. Downs., Blvd
MDC 22
Tampa, FL 33612-4766

RE: **Full Board Approval for Initial Review**

IRB#: Pro00011641

Title: Accelerated Resolution Therapy (ART) for Rapid Resolution of Symptoms of Psychological Trauma

Study Approval Period: 3/14/2013 to 3/14/2014

Dear Dr. Kip:

On 3/14/2013, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below.

Approved Item(s):

Protocol Document(s):

ART SAMHSA Protocol with Appendices 1-25-2011

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John Schinka, Ph.D., Chairperson
USF Institutional Review Board

<< Back Exit | Hide/Show Errors | Print... | Jump To: - 1.1 Study Identification -> Continue >>

Review Notes Next

Filter by Type Go Clear Advanced

Type	Reviewer	Date Created	Date Modified
<input type="checkbox"/> IRBA IRB Staff Change Request	Anna Davis	2/20/2013 3:42 PM	2/20/2013 3:52 PM

1.1.2. - Please revise to include the following additional statement: "Note to IRB: This study was previously approved under IRB# Pro00000894 and expired due to a lapse in filing a continuing review. The research project is being resubmitted for purpose
See More

Change Request Completed - Trudy Wittenberg - 2/20/2013 4:21 PM

Done.

Study Identification Information

1.1

You must complete all of the required questions on this page to create your Human Research Application. As you continue through the application, you will automatically be guided to the appropriate pages needed to complete your submission.

1.1.1 * Study Title (this title must be the same as the title on your protocol, Investigators Brochure and most cases, informed consent document): Accelerated Resolution Therapy (ART) for Rapid Resolution of Symptoms of Psychological Trauma

* Short Title (this title is used throughout the site to identify the study): ART SAMHSA

1.1.2 * Brief Study Description:
Note to IRB: This study was previously approved under IRB# Pro00000894 and expired due to a lapse in filing a continuing review. The research project is being resubmitted for purposes of data analysis only

This is a 1-year, prospective exploratory pilot study whereby consenting individuals with symptoms of psychological trauma (N=100) will be provided with Accelerated Resolution Therapy (ART) by trained ART clinicians. Study participants will complete questionnaires of symptoms of psychological trauma, psychological wellness, trauma-related guilt, depressive symptoms, anxiety

symptoms, anger, sleep quality, positive challenge/growth, self-compassion, and alcohol use. These will be obtained before treatment with ART, immediately following treatment with ART, and at 2- and 4-months follow-up. Within-subject changes in these measures will be compared by use of graphical techniques, paired t tests, and mixed models. Because ART is designed for rapid resolution of psychological distress, participating subjects are anticipated to undergo a minimum of two and a maximum of five ART sessions. The primary study endpoint will be the magnitude of change in symptoms of psychological trauma, as measured by repeated assessments using the PTSD Checklist (PCL-Civilian). Secondary endpoints will include self-report measures of psychological wellness, trauma-related guilt, depressive symptoms, anxiety symptoms, anger, sleep quality, positive change/growth, self-compassion, and alcohol use.

1.1.3 * Is this research being conducted to fulfill an educational requirement (such as a dissertation or thesis)?

Yes No

1.1.4 * Does the University of South Florida and/or any of its senior officials have a potential conflict of interest related to this research (e.g. an ownership interest in an entity related to the research; a patent, trademark, copyright or licensing agreement in the test article or method being studied)?

Yes No

If you answered Yes to this question, before proceeding with the completion of this application please contact the USF Conflict of Interest Program at 813-974-5638 or coi-research@usf.edu for assistance in determining whether there is an institutional conflict of interest. Please note that the USF COI Committee may require human subjects research with a related institutional conflict of interest to be reviewed by an external IRB.

1.1.5 * Principal Investigator / Student Investigator:

Kevin Kip

You are listed automatically as a Study Coordinator. If there is someone else on the study that will assist with the IRB regulatory processes, they should be listed as a Study Coordinator and/or Secondary Study Coordinator.

1.1.6 Study Coordinator / Primary Regulatory Specialist:

Sue Girling

1.1.6a Secondary Study Coordinator / Regulatory Specialist: 

Trudy Wittenberg

The PI does not need to be listed as a Co-Investigator or Key Personnel.

1.1.7 * Are there any Co-Investigators/Faculty Advisors involved in this study? *If you are a student, you must list your Faculty Advisor as a Co-Investigator.*

Yes No

If yes, please add Co-Investigators:

First Name	Last Name	Organization	Profile
Kevin	Kip	College of Nursing	00001020
Helene (Laney)	Rosenzweig	College of Nursing	00003016
Amy	Shuman	College of Nursing	00003771

1.1.8 * Are there any Key Personnel on this study? 

Yes No

If yes, please add Key Personnel/Study Staff and assign roles for their participation on the study:

Name	Organization	Roles on Study	Other Role On Study
Sue Girling	College of Nursing	Obtains Informed Consent	
Marian Hardwick	College of Nursing	Manuscript Preparation	

1.1.9 Is this study a resubmission of a study previously reviewed and/or approved by the USF IRB or another IRB?

Yes No

If yes, please provide the Title and USF IRB/Pro Number if previously submitted to the USF IRB. If submitted to an external IRB, include the name of the IRB, date of submission and outcome of the review.

Accelerated Resolution Therapy (ART) for Rapid Resolution of Symptoms of Psychological Trauma (Pro00000894)



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Institutional Review Boards, FWA No. 00001669
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2/16/2016

Kevin Kip, Ph.D.
College of Nursing
12901 Bruce B. Downs Blvd.,
MDC 22
Tampa, FL 33612-4766

RE: **Expedited Approval for Continuing Review**

IRB#: CR3_Pro00011641

Title: Accelerated Resolution Therapy (ART) for Rapid Resolution of Symptoms of Psychological Trauma

Study Approval Period: 3/14/2016 to 3/14/2017

Dear Dr. Kip:

On 2/16/2016, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within including those outlined below.

Approved Item(s):

Protocol Document(s):

ART SAMHSA Protocol with Appendices 1-25-2011

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):

(8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with USF HRPP policies and procedures and as approved by the USF IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within

five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,



Kristen Salomon, Ph.D., Vice Chairperson
USF Institutional Review Board



DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-5618

October 29, 2010

Kevin Kip, PhD
College of Nursing
MDC 22

RE: **Full Board Approval** for Initial Review

IRB#: Pro00000210

Title: Accelerated Resolution Therapy (ART) for Psychological Trauma
Study Approval Period: 10/15/2010 to 10/15/2011

Dear Dr. Kip,

On 10/15/2010 the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents outlined below. Please note that your approval for this study will expire on 10/15/2011.

Approved Items:
Protocol Document(s):

ART Protocol 10-27-2010 10/28/2010 4:07 PM 0.01

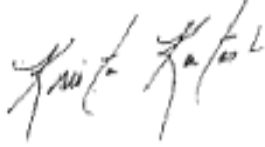
Consent/Assent Document(s)

Appendix B2. ART Informed Consent with
HIPAA 10-27-2010.pdf.pdf 10/29/2010 10:34 AM 0.01

Please note, if applicable, the **informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on the form.** Valid consent must be documented on a copy of the most recently IRB-approved consent form. As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,



Krista Kutash, PhD, Chairperson
USF Institutional Review Board

Cc: Anna Davis, USF IRB Professional Staff

If you answered Yes to this question, before proceeding with the completion of this application please contact the USF Conflict of Interest Program at 813-974-5638 or coi-research@usf.edu for assistance in determining whether there is an institutional conflict of interest. Please note that the USF COI Committee may require human subjects research with a related institutional conflict of interest to be reviewed by an external IRB.

1.1.5 * Principal Investigator / Student Investigator:

Kevin Kip

You are listed automatically as a Study Coordinator. If there is someone else on the study that will assist with the IRB regulatory processes, they should be listed as a Study Coordinator and/or Secondary Study Coordinator.

1.1.6 Study Coordinator / Primary Regulatory Specialist:

Sue Girling

1.1.6a Secondary Study Coordinator / Regulatory Specialist: ☺

The PI does not need to be listed as a Co-Investigator or Key Personnel.

1.1.7 * Are there any Co-Investigators/Faculty Advisors involved in this study? If you are a student, you must list your Faculty Advisor as a Co-Investigator.

Yes No

If yes, please add Co-Investigators:

First Name	Last Name	Organization	Profile
Diego	Hernandez	College of Nursing	00007318
Helene (Laney)	Rosenzweig	College of Nursing	00003016

1.1.8 * Are there any Key Personnel on this study? ☺

Yes No

If yes, please add Key Personnel/Study Staff and assign roles for their participation on the study:

Name	Organization	Roles on Study	Other Role On Study
Marian Hardwick	College of Nursing	Manuscript Preparation	
Hongdao Meng	School of Aging Studies	Data Analysis	
Mariangeli Miranda	College of Nursing		Data Entry Specialist
Trudy Wittenberg	College of Nursing	Addresses Regulatory Issues	

1.1.9 Is this study a resubmission of a study previously reviewed and/or approved by the USF IRB or another IRB?

Yes No

If yes, please provide the Title and USF IRB/Pro Number if previously submitted to the USF IRB. If submitted to an external IRB, include the name of the IRB, date of submission and outcome of the review.



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Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC055 • Tampa, FL 33612-4799
(813) 974-5638 • FAX(813)974-7091

9/21/2015

Kevin Kip, Ph.D.
College of Nursing
12901 Bruce B. Downs Blvd.,
MDC 22
Tampa, FL 33612-4766

RE: **Expedited Approval for Continuing Review**
IRB#: CR5_Pro00000210
Title: Accelerated Resolution Therapy (ART) for Psychological Trauma

Study Approval Period: 10/15/2015 to 10/15/2016

Dear Dr. Kip:

On 9/17/2015, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within including those outlined below.

Approved Item(s):
Protocol Document(s):
ART

The IRB determined that your study qualified for expedited review based on federal expedited category number(s):

(8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

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Sincerely,



Kristen Salomon, Ph.D., Vice Chairperson
USF Institutional Review Board

About the Author

Marian J. Hardwick grew up in Saint Petersburg, Florida. She obtained her first B.S at Florida State University in Health Education and taught Health and Anatomy I Honors at Seminole High for one year. She went back to school where she received her second B.S and attended an accelerated nursing program known as the VA Nursing Academy at the University of South Florida in Tampa, Florida in 2008 to 2009. She worked as a charge nurse in the psychiatric unit at James A. Haley VA Hospital for two years before returning to receive her MSN in Nursing Education and becoming a part- time educator in 2010. She entered the BS-Ph.D. program in 2010.

Marian became a McKnight Scholar that paid her full tuition for four years as well as a Jonas scholar her last two years of school. She is also a member of the Doctoral Nursing Student Organization at the University of South Florida. She is particularly interested in the impact that accelerated resolution therapy (ART) has on veterans with PTSD and civilians who have sleep disturbance.