

A Pilot Project to reduce PTSD symptoms in U.S. Veterans Using an Innovative Therapy

By

Shu-Wen Cheng

University of Kansas School of Nursing

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Lisa Ogawa, Ph.D., RN, CNE
Faculty Project Committee, Chair

JoAnn M. Peterson, DNP, APRN, FNP, WHNP
Faculty Project Committee, Co-Chair

E. LaVerne Manos, DNP, RN-BC
Faculty Project Committee, Co-Chair

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The DNP Project committee for Shu-Wen Cheng certifies that this is the approved version of the following DNP Project:

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Lisa Ogawa, Ph.D., RN, CNE
Faculty Project Committee, Chair

JoAnn Peterson, DNP, APRN, FNP, WHNP
Faculty Project Committee, Co-Chair

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Faculty Project Committee, Co-Chair

Date Approved:

1 September 2017

Abstract

PTSD is a common psychological disorder affecting numerous U.S. veterans, especially those returning from deployment. This psychological distress poses tremendous negative impacts not only on the physical health of the veterans but also on the well-being of the veterans and their family. Although several interventions, including non-pharmacological treatments, have been used to assist veterans in treating their PTSD symptoms, barriers related to perceived stigma, access to care, and engagement in treatments remain a concern. An innovative therapy overcoming these barriers is needed to increase the effectiveness of the existing therapies and to increase treatment-seeking and engagement in treatment.

The purpose of this pilot project is to examine the effectiveness of using an innovative therapy to improve the PTSD symptoms of the participants with PTSD in this project. This innovative therapy combines several complementary alternative therapies (CAT) such as mindfulness meditation, auricular acupoint stimulation, and light/music therapies and is added to their current treatment plan. The goal is to use this innovative therapy to reduce the PTSD symptoms in U.S. veterans suffering with PTSD.

The CAT was delivered through a headphone with the capability of providing guided visualization/meditation, light/music therapy, and auriculotherapy. The CAT was added to the current treatment regime of five U.S. veterans recruited in Greater Kansas City for six weeks. One measurement was completed for initial assessment of the level of PTSD symptoms and was repeated during and at the end of the six weeks of treatment. Data is presented on an individualist basis as opposed to a combined basis due to the small number of participants. The results of this pilot project do not necessarily represent the population targeted because statistical significance cannot be ascertained without using statistical comparison. Further projects with larger

participants or with a control group are encouraged to examine the effectiveness of this innovative therapy that is unique with its characteristics of self-directed, autonomous use, and combined CAT.

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Introduction

Statement of the Problem

Posttraumatic stress disorder (PTSD), which is a mental/psychiatric problem, has been identified among U. S. veterans, with an especially high prevalence among those returning from deployment. It affects 23% of veteran soldiers from the Afghanistan and Iraq wars (Fulton et al., 2015). The stress of trauma exposure disrupts one's self-trust and ability to form relationships and therefore places these veterans at high risk for depression, substance abuse, suicide, and domestic violence perpetration (Marotta-Walters, Choi, & Shaine, 2015). Left untreated, this mental health problem results in tremendous negative impacts not only on the physical health of the veterans but also on the well-being of veterans' family members, friends, and coworkers. Consequently, with the numerous veterans that are or will be reintegrating into the community and society, the long-term impact of untreated or undertreated mental health problems to this nation has become and will continue to become a concern (Collinge, Kahn, & Soltysik, 2012).

Barriers, such as perceived stigma, difficulty scheduling an appointment/getting time off for treatment, and high treatment costs, prevent treatment-seeking veterans from receiving treatments (Ramchand, Rudavsky, Grant, Tanielian, & Jaycox, 2015). The barriers for those who do not even seek treatment are (a) the perceived stigmas of admitting or accepting having a mental problem; (b) the fear of mental problem would jeopardize their career; (c) difficult access to care; and (d) distrust about mental health treatment all represent important barriers to the seeking of mental health service (Zinzow, Britt, McFadden, Burnette, & Gillispie, 2012). These barriers result in 50% or less of the veterans in need of mental health treatment received care (Ramchand, Rudavsky, Grant, Tanielian, & Jaycox, 2015).

Project Purpose Statement

Because of these psychological, geographical, and financial barriers to seeking treatment, innovative therapies are needed to facilitate mental health treatment-seeking in U. S. veterans. An innovative therapy combining CAT such as mindfulness meditation, auricular acupoint stimulation, and light/music therapies was used in this pilot project. The CAT was delivered through a commercially available headphone product. This headphone product was chosen to be used in this project due to its use of CAT and its unique characteristic design of autonomous use to eliminate the treatment barriers mentioned above. Therefore, the purpose of this pilot project is to examine the effectiveness of adding CAT to the current treatment plan of the U. S. veterans with PTSD to mitigate their symptoms.

Concept of Interest and The Definition

Most people experience various levels of stress in their daily lives, including U. S. veterans who developed PTSD due to their duties in serving and protecting this country. Stress occurs when one “perceives that the demands these events impose tax or exceed a person’s adaptive capacity” and chronic exposure to stress can result in long-term or permanent changes in the physiological, emotional, and behavioral responses that influence susceptibility to diseases (Cohen & Janicki-Deverts, 2012, p. 1320).

PTSD is defined as “a disorder that develops in some people who have experienced a shocking, scary, or dangerous event” (National Institutes of Health [NIH], 2016., para. 1). Not every traumatized person develops chronic or acute PTSD, nor has everyone with PTSD been through a dangerous event. Some experiences, like the sudden, unexpected death of a loved one, can also cause PTSD (NIH, 2016). Four categories characterize this disorder: (a) re-experiencing symptoms such as recurrent intrusive memories or flashback of trauma events with physical

symptoms like a racing heart or sweating, bad dreams, frightening thoughts; (b) avoidance symptoms such as avoiding places, events, objects, thoughts, or feelings that are reminders of the traumatic experience; (c) alteration in arousal and reactivity symptoms such as being easily startled, feeling tense and irritable, hypervigilance, having difficulty concentrating and sleeping, angry outbursts; and (d) negative changes in cognition and mood symptoms such as negative thoughts about oneself or the world, distorted feelings like guilt or shame, loss of interest in enjoyable activities, inability to recall key details of the trauma (Lancaster, Teeters, Gros, & Back, 2016). These disturbing symptoms may cause problems in a person's everyday routine, paralyze a person in the performance of their daily activities, make a person feel stressed and angry, make it difficult to sleep, eat, or concentrating on tasks, or make a person feel alienated or detached from friends or family members (NIH, 2016).

Mindfulness-based approaches have gained an increasing acceptance and have been used in the treatment of PTSD in U.S. veterans. Mindfulness is to be aware of thoughts and sensations emerged, to pay attention on purpose in the present moment, and to unfold the experience moment by moment (Kearney, McDermott, Malte, Martinez, & Simpson, 2012). Mindfulness practice promotes acceptance and constructive cognitive and behavioral changes and therefore reduces avoidance behavior, enhances functionality despite ongoing symptoms, reduces the level of distress caused by intrusive thoughts and the tendency to avoid or suppress these thoughts, and decrease conditioned fear responses (Kearney et al., 2012).

Variable of Interest and The Measure

Normally three approaches are adopted to assess stress levels. The environmental approach identifies the occurrence of demanding events (stressors), the psychological approach evaluates the perceived individual stressfulness of each stressor, and the biological approach

focuses on the biological elements of the stress response (Andreou et al., 2011). Questionnaires and interviews are the main measurement tools of the first two approaches (Andreou et al., 2011). A questionnaire was utilized in this project as the psychological approach to measure the level of PTSD symptoms.

The variable of this project is the changes of the level of PTSD symptoms reported by the U. S. veteran participants before, during and after the use of CAT. These symptoms are measured by (a) the frequency of unwanted memories, nightmares, or reminders of the events; (b) the efforts made to avoid thinking or talking about the events; (c) the extent of lost enjoyment for things and avoidance of people; (d) the levels of concentration, irritability, jumpiness and feeling watchful; (e) the levels of pain, aches, or tiredness; (f) the amount of symptoms interfered with the ability to work or carry out daily activities and with the relationships with family or friends (Connor & Davidson, 2001).

The Importance of This Project

PTSD is the third most prevalent psychiatric diagnosis among veterans using the Veterans Affairs hospitals (Ralevski, Olivera-Figueroa, & Petrakis, 2014). As part of its center-wide operational priorities of developing strategies to enhance engagement in treatment, the U. S. Veterans Affairs (USVA) has set its goals of developing strategies to enhance access to PTSD treatments. Some of these PTSD treatments include using telehealth and technology (including the internet, mobile apps and social media) and non-traditional methods requiring little or no therapist involvement outside of specialty mental health settings such as community setting (USVA, 2016). The CAT design in the project meets these criteria and, if effective, will help USVA to achieve the goal of facilitating PTSD treatment access. Moreover, the CAT in this pilot

project can also be used by Nurse Practitioners and other health care providers to treat U. S. veterans suffering PTSD.

Literature Review

The database search on PubMed, CINAHL, and Google Scholar was conducted to identify research articles/studies related to non-pharmacological, complementary, and alternative interventions for veterans suffering from PTSD. The key words used to search included *veterans, PTSD, treatment, phototherapy, sound therapy, beats and tones, meditation, visualization, guided image, auriculotherapy, acupuncture, innovative therapy, and CAT*. Our search criteria included articles published in the last five years, except the articles related to the questionnaire. Research articles were not considered if they were not written in English.

PTSD Prevalence and Current Treatments

Statistics from the USVA show the estimated lifetime prevalence of PTSD was 30.9% for men and 26.9% for women among the Vietnam veterans, 10.1% among the total Gulf War Veteran population, and 13.8% among previously deployed for Operation Enduring Freedom and Operation Iraqi Freedom (Afghanistan and Iraq) service members (Gradus, 2016). A review of 29 studies by Ralevski, Olivera-Figueroa, and Petrakis found that the prevalence rates of men and women who served in Iraq and Afghanistan range from 5% to 20% for those who do not seek treatment, and around 50% for those who do seek treatment with PTSD (Ralevski et al., 2014). Moreover, they also found that the prevalence rate in Vietnam veterans ranges from 10% to 31% (Ralevski et al., 2014).

In addition to the core symptoms of PTSD, pain-related conditions, psychiatric disorders, and depression frequently overlap and result in high rates of comorbidity and multiple morbidity (Stecker, Fortney, Owen, McGovern, & Williams, 2010). A review of numerous studies shows

that Gulf war veterans diagnosed with PTSD or with PTSD-like symptom have worse physical health outcomes, higher levels of suicide ideation, higher risk of dying by suicidal ideation, and suffer both economically and socially (Ramchand et al., 2015). In addition, these studies have also found relationships between PTSD, substance misuse, aggression and criminal outcomes (Ramchand et al., 2015).

Numerous studies have shown effective results using non-pharmacological non-conventional therapies to treat psychological disorders, especially PTSD. A study reviewing evidence-based treatments for PTSD reported positive outcomes using exposure-based therapy, cognitive processing therapy, and eye movement desensitization and reprocessing therapy (Lancaster et al., 2016). Clinical trials using therapies such as group music therapy (Carr et al., 2011), mindfulness based meditation and stress reduction massage (Collinge et al., 2012), light therapy (Naeser et al., 2014), and acupuncture (King et al., 2015) were also conducted to evaluate the effectiveness of these treatments. However, no studies or trials have been conducted to evaluate the feasibility and effectiveness of combining these therapies to obtain a more effective therapeutic outcome.

Mindfulness Based Therapy

Mindfulness based therapy such as sitting meditation is a training to intentionally regulate a person's attention and awareness of the present moment and to accept the ongoing stream of sensations, thoughts, and emotions experienced in a nonjudgmental way (Cole et al., 2015). Mindfulness practice encourages participants to bring forth an attitude of curiosity and openness to experience which includes difficult experience. In addition, this enhanced ability hypothetically brings sustained nonjudgmental attention to difficult emotional states and decreases emotional numbing and hypervigilance (Kearney et al., 2012).

Recent research has explored the use of mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR) as a component in treatments of veterans suffering PTSD with significant improvements clinically. King et al. found that veterans with PTSD using MBCT scored lower on PTSD symptoms total and the subscales of intrusive, avoidant, and hyperarousal levels (King et al., 2013). Polusny et al. (2015) conducted a randomized clinical trial using MBSR among 116 veterans with PTSD and found clinically significant improvement in the severity of PTSD symptoms during treatment (Polusny et al., 2015). An adapted MBSR class that included enhanced attentional training showed effectiveness in improving cognitive control (such as working memory and regulation of attention) as well as in improving quality of life and perceived self-efficacy (Cole et al., 2015). The effectiveness went beyond treatment and lasted months thereafter. In a study conducted by Cole et al. (2015), a significant reduction in PTSD symptoms was found immediately after MBSR, and were sustained three months following MBSR completion (Cole et al., 2015). Two clinical studies conducted by Kearney and his colleagues in 2 consecutive years found that veterans with PTSD who participated in MBSR and a mindfulness program experienced significant improvements. The results showed mental health improvement in measures of PTSD, depression, experiential avoidance, behavioral activation, and mental/physical health-related quality of life over a 6-month period (Kearney et al, 2012). The results studied in the following year showed a clinically meaningful change in PTSD symptoms even at 4-month follow-up after the completion of the treatment (Kearney et al., 2013).*

Acupuncture/Acupuncture points(Acupoints) therapy

Few studies on using acupuncture or acupoint therapies in treatment of veterans with PTSD have been found. A feasibility study examined the use of auricular acupuncture for sleep disturbance in veterans with PTSD, suggested that sleep quality and daytime dysfunction improved

(King et al., 2015). In a systematic review and meta-analysis of the effectiveness of emotional freedom techniques in treatment of PTSD, the component of stimulating acupoints, as a somatic component in addition to the cognitive component of the techniques, indicated significant effectiveness in relaxation and anxiety reduction (Sebastian & Nelms, 2017). It is believed in this study that acupoint stimulation, in addition to regulating the stress hormone cortisol, releases opioids/serotonin/GABA, shuts off the fight/flight/freeze response, reduces pain, slows heart rate, and decreases anxiety (Sebastian & Nelms, 2017).

Light therapy

No study has been conducted to examine the effectiveness of light therapy on veterans with PTSD. However, Naeser et al. (2011 & 2014) conducted two studies in 2011 and 2014 to examine the cognitive performance of people with closed-head traumatic brain injury (TBI) before and after treatment with red or near-infrared red (NIR) light-emitting diodes (LEDs). Red or NIR LEDs is a low-level laser light therapy used to produce beneficial cellular and physiological effects. Transcranial LED, using NIR light that penetrates the scalp and skull, was found to significantly reduce brain damage from acute stroke and to reduce depression and anxiety in patients diagnosed with chronic or major depression (Naeser et al., 2011). The 2 case studies in 2011 showed both patients had significant improvements in their cognitive functions. In one of the cases, “neuropsychological testing after 9 months of transcranial LED indicated significant improvement (+1, +2SD) in executive function (inhibition, inhibition accuracy) and memory, as well as reduction in post-traumatic stress disorder” (Naeser et al., 2011, p. 351). Another study on 11 participants was conducted a few years later and it reported improved sleep, and fewer PTSD symptoms, better ability to perform social, interpersonal, and occupational functions (Naeser et al., 2014). The rationale for using light therapy is that photons in the red and near-infrared light

wavelengths have the potential to improve subnormal, cellular activity of damaged brain tissue by improving mitochondrial function and promoting increased adenosine triphosphate important for cellular metabolism (Naeser et al., 2014).

Music therapy

Supportive music and imagery and other elements of music therapy increase relaxation - related melatonin levels, enhance immune response, change stress-related gene expression, increase positive mood, reduce burnout, and result in generating positive emotions to facilitate performance on concrete tasks (MacCoon et al., 2012). There is a gap in the literature on music therapy in PTSD treatment. However, only one related study found in this research showed group music therapy had a significant reduction in severity of PTSD symptoms and a marginally significant reduction in depression in patients with persistent PTSD (Carr et al., 2011).

Current Technology

The adoption of technological advances such as using virtual reality devices and providing mental health treatment via telehealth (i.e., via telephone, Internet, or videoconferencing) has been explored to reduce the barriers and stigmas associated with difficult access to care or non-seeking treatment, and to increase treatment engagement (Zinzow et al., 2012). In addition, mobile health has also been widely used to treat veterans with PTSD. It refers to the use of mobile technology such as smart phone and software such as applications (apps) to facilitate mental health care (Erbes et al., 2014). Various psychotherapy treatments have been incorporated into the development of cellphone apps. In a randomized controlled trial, two smartphone apps, one based on behavioral activation and the other on mindfulness, were developed and evaluated as treatment options for mental disorders (Ly et al., 2013). Furthermore, a study of 188 veterans receiving outpatient care for PTSD showed 76% of accessibility to

cellphone or tablet capable of running apps, 82% of interest in the potential uses of mobile health apps, and 71% of utilization of one or more of the apps provided (Erbes et al., 2014). The unique characteristics of using this headphone to deliver CAT anytime and anywhere provides a new way to access and to provide a quality improvement of mental health care through “enhancing communication, improving compliance, enriching the available health care data, and encouraging patient engagement” (Shore et al., 2014, p. 866). A preliminary study of evaluating the smartphone app “PTSD coach” for managing acute distress and PTSD symptoms reported almost 90% of the veterans endorsed being moderately to extremely satisfied with the app (Kuhn et al., 2014).

The CAT Used in This Pilot Project

The CAT used in this pilot project was delivered by a headphone accompanied by smartphone apps with pre-recorded meditation instruction. It combines CAT such as light/music therapy, beats and tones, auriculotherapy, as well as guided visualization/meditation to overcome the negative effects of the fight-or-flight response and to strengthen physical, mental and emotional balance (BrainTap Technology, 2015b). Its light and sound technology combines sound frequencies with light synchronization to provide relaxation and diversion from day-to-day stress. Its light frequencies train the brain to produce a desired brainwave activity with a mindset to accomplish a goal. Its beats and tones guide the brain to a high level of focus and performance that may only be achievable through many years of practice. Its auriculotherapy is delivered by earphones equipped with 9 LED lights set at the optimum frequency which stimulates trigger points in the ears, called meridians, to directly balance the body’s organs and systems which are typically activated using acupuncture needles. Its audio-recording music is designed to create an

experience that delights the mind with calming thoughts and images. The Guided Visualization is an audio-session to help reinforce positive thoughts (BrainTap Technology, 2015a).

A case study of 50 people conducted in North Carolina showed a 27.5 % improvement in regulatory system function after a single 20-minute use of the CAT (BrainTap Technology, 2015a). The post session measurement included 36% improvement on stress index, 31% on the autonomic nervous system, 33% on vital force, 16% on Neuro-Hormonal Regulation, 17% on Psycho-Emotional State, and 33% on Biorhythm Coherence. The measurement device, called Alfa Scan, is used to measure brainwave changes from an ECG reading and the classic heart rate variability which reflects the autonomic nervous system and its adapting capacity to internal and external stressors (BrainTap Technology, 2015b).

Theoretical Framework

A model called Supportive Accountability, developed by Mohr, Cuijpers and Lehman (2011), provides human support to enhance adherence to electronic health (eHealth) interventions (Mohr, Cuijpers, & Lehman, 2011). It is used as the theoretical framework of this pilot project due to the design of using an electronic product to deliver the CAT. This model, as shown in Figure 1, depicts the process from using human support, which is mediated by intrinsic to extrinsic motivations and communications media to ultimately achieve adherence.

They developed this model based on the belief that the effectiveness of and adherence to eHealth interventions is enhanced by human support. Human support can be obtained by bonding, accountability, and legitimacy and increases adherence “through accountability to a coach who is seen as trustworthy, benevolent, and having expertise” (Mohr et al., 2011, p. 1). Among the components of human support, performance monitoring is introduced with adequate

justification and patient agreement and is an important predictor of outcome in distance treatments (Mohr et al., 2011).

It is believed that the more intrinsically motivated patients are, the less support they likely require. Adherence to an eHealth intervention may be achieved by coaching to aspire and help patients identify with the goals of the intervention. It may also be extrinsically enhanced by verbally rewarding patients “by acknowledging good performance and good effort, without seeking to control behavior” (Mohr et al., 2011, p. 6).

Lean media used in this model as communication media is also discussed. It lacks the features of face-to-face communications such as immediate feedback as well as cues coming from speech, hearing and social interaction. Communications via e-mail, bulletin boards, text message are some of the examples (“What is Lean Media”, n. d.). Lean media is effective in communication because people tend to “form stronger impressions based on more limited, sometimes stereotyped social and interpersonal cues” and “make more positive, idealized attributions of their communication partners” (Mohr et al., 2011, p. 7). Therefore, communication using both email and the telephone may “permit potentially difficult or embarrassing information to initially be provided via email, offer a sympathetic response email to underscore bond and the coach’s benevolence, and then follow up telephone, which can provide greater social presence” (Mohr et al., 2011, p. 8).

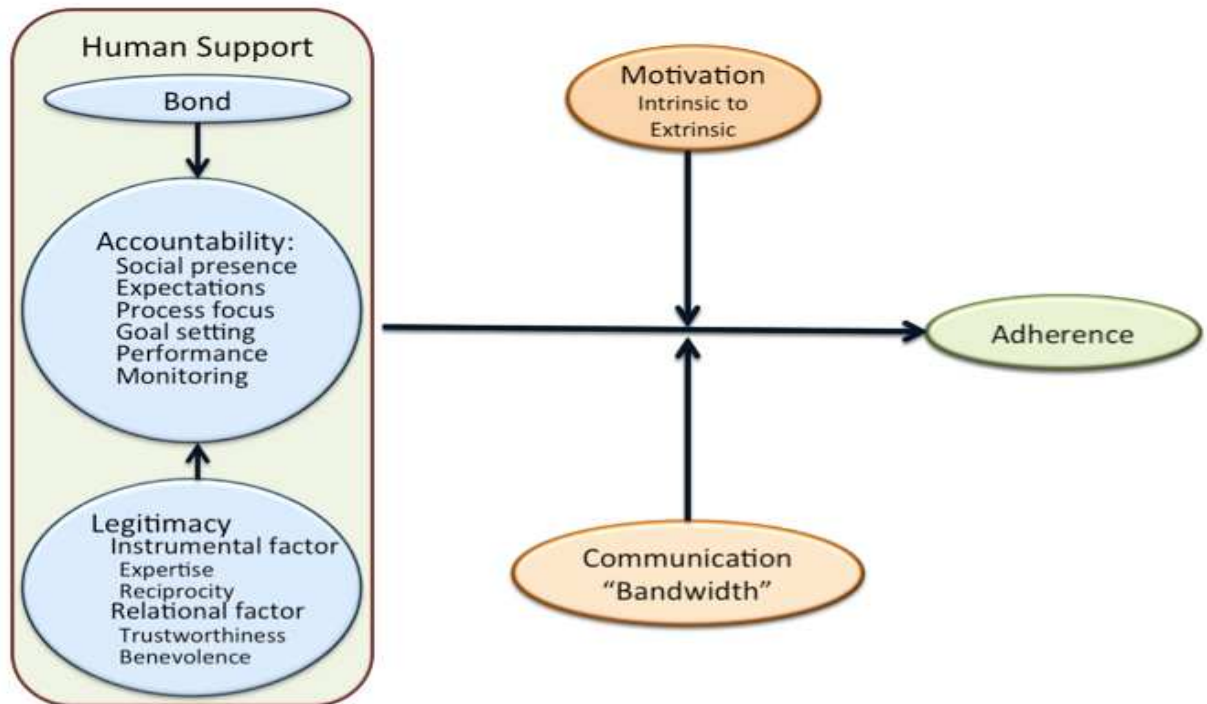


Figure 1: Model of Supportive Accountability. (Mohr et al., 2011, p. 3)

Author's Assumptions

Participants will be more likely to use the CAT of this pilot project to treat their PTSD symptoms due to its design of autonomous use at home, at work, or anywhere the participants need treatments. Participants may use the CAT as frequently as desired or any time when they find it helpful. Using this CAT requires neither traveling to a USVA hospital nor to other facilities. The CAT may be more acceptable by those veterans who are geographically isolated from mental health services or by those who are reluctant to use mental health care services. Therefore, this CAT used in this pilot project will facilitate the utilization of treatment to reduce their level of PTSD symptoms.

The assumption for this pilot project is that adding CAT to the current treatment plans for six weeks will reduce the PTSD symptoms in U. S. veterans suffering with PTSD.

Conflict of Interest

The idea of conducting this pilot project purely results from the author's desire of finding an innovative, self-directed therapy to help U.S. veterans suffering PTSD, and the author's interest in knowing if CAT is effective in reducing the level of PTSD symptoms. No sponsoring company or personnel are involved in this project. The headphone used to deliver the CAT in this pilot project was purchased by the author. The author conducted the orientation training at the site of a local business, which has been donated to this pilot project by a local business owner (see Appendix K for the support letter). No personal, financial or professional gain in any way was obtained by the author, the author's Primary Investigator of this pilot project, and the author's family.

Methods

Project Design

A pilot project was conducted to examine the effectiveness of the CAT and to evaluate the change of the level of PTSD symptoms. One-group pretest-posttest design was utilized for this pilot project due to the very small sample size. In this design, a single group underwent a pre-treatment observation or evaluation, then the treatment was administered, and finally was observed or evaluated again after the treatment (Leady & Ormrod, 2013). In the project, an evaluation was performed using one questionnaire to obtain a baseline of the levels of PTSD symptoms. Then a 6 week-session using the CAT was conducted and recorded. Finally, an evaluation was performed again by the same questionnaire during and at the end of the use of the CAT to assess for any change.

Project Sample

The project sample was recruited from Kansas City Chapter of Association of the United States Army (KCAUSA), an organization for U. S. veterans' leadership network and a coalition of community resources. The project sample size was limited to five participants due to the budget. The inclusion criteria for this project sample are U.S. Veteran and the age of 18 years and older. The exclusion criteria are medical condition or history of photo epilepsy, seizure, and Traumatic Brain Injury (TBI). The participants were prescreened based on the inclusion and exclusion criteria. In addition, because of the very small numbers of participants required in the pilot project, the selection of participants was prioritized based on the inclusion and exclusion criteria, the diagnosis of PTSD, the years of suffering PTSD, and the status of current treatment regimen.

Human Subject Protection

Participants volunteered to be part of the project and were given the right to stop at any time without reason. Participants were identified with initials, not their names, to preserve anonymity. Participants were instructed to use the CAT at anytime and anywhere they wanted. This project began after obtaining the approval from the Institutional Review Board (IRB) of University of Kansas Medical Center (KUMC).

Participants were prescreened and those with epilepsy, seizure disorders, brain injury, or photosensitivity were excluded from this project because flashing lights have been known to cause problems in people who suffer from these serious medical conditions (Panischev, Demin, & Rusanova, 2015).

Although no known psychological side effects or issues have been reported, there was a certified psychiatric mental health Nurse Practitioner (NP) on call to provide consultation

services to the participants if a psychological issue occurs after they used the headphone. The participants were instructed to call the author to report their psychological issue and to request the consultation service. The author contacted the mental health NP to do a brief triage and determine participant's need, level of urgency and availability for a return phone call. Then the NP called the participant to provide a consultation. The NP was given the author's cell number in her contact so whenever the author called, the NP knew that there was an issue and responded to the author's call immediately. The NP would also refer the participants to their primary care providers, their psychologists, the USVA healthcare system, or to the closest emergency room if suicidal ideation or symptoms occurred. This consultation service was at no cost to the participants during the pilot project (see Appendix G the letter to the certified psychiatric nurse practitioner). The author's contact information for this free consultation service was provided to the five selected participants in the Informed Consent. Resume here

In addition, the participants were instructed to return to the KCAUSA, a coalition of community resources and a network of supporting services such as health and spiritual services for U. S. veterans, for support and services (see Appendix J for Veterans' Leadership Network).

All the data including project pre-screening form, informed consent, PTSD questionnaires, daily usage forms gathered from the participants throughout the project were stored in a locked file system at the office of the author's primary investigator at the KUMC's School of Nursing building. The data gathered, after analysis, was stored for the designated time dictated by the IRB policies of KUMC.

Project Process

After receiving the approval letter from KUMC's IRB, recruitment was conducted with the cooperation of the KCAUSA (see Appendix D for this approval letter). An invitation letter

was sent out through email to the U. S. veterans served by this association (See Appendix A for the Informational/Explanatory letter to the potential participants). Contact information was provided in the letter for potential participants if they had any questions regarding the project and the headphone used. The veterans who were interested in participating in this pilot project applied to participate by filling out a project pre-screening form (see Appendix B for the project pre-screening form). Five veterans who met the selection criteria were chosen to participate. These five people were provided with more detailed information by email and with a contact number to ask any questions regarding this project. They were asked to attend an orientation to learn more about the project and how to use the headphone. After this orientation, the participants were given up to 48 hours to decide whether they wanted to participate. At the time of their final decision, they signed an informed consent letter (see Appendix C for the Informed Consent Letter). After signing the informed consent letter, the 5 participants were asked to complete the PTSD questionnaire to be used as a baseline measure. Upon completion of the PTSD questionnaire, they were given the headphone, 6 copies of the daily usage form, 6 copies of the PTSD questionnaire, 5 postage paid envelopes, and 1 postage paid box. The 5 participants were asked to use this headphone to deliver the CAT at least once a day for 6 weeks. They were asked to complete the daily use form at the end of each day. In addition, they were asked to complete the PTSD questionnaire at the end of each week and place it into the postage paid envelope along with the daily usage form used for the week and mail it to the address provided. At the end of the sixth week the 5 participants were asked to complete the PTSD questionnaire and put it, the daily usage form, and the headphone into the postage paid box and mail it to the address provided.

Data Collection: The Instrument

The change of the level of PTSD symptoms was measured by using a questionnaire called the Short PTSD rating interview (SPRINT). The SPRINT, designed by Connor and Davison, measures the core symptoms of PTSD (re-experiencing, avoidance, cognitions/mood, arousal/reactivity) and assesses somatic malaise, stress vulnerability, and role and social functional impairment (Connor & Davidson, 2001). It responds to symptom change over time, correlates with comparable PTSD symptom measures, demonstrates solid psychometric properties, and can serve as a reliable and valid measure of PTSD illness severity and of global improvement (Connor & Davidson, 2001). It is used to identify the symptoms occurring in the past week and is measured on a 5-point scale, from 0 being having no symptoms at all to 4 being having the symptoms very often (see Appendix F for the SPRINT).

The permission to use the SPRINT in this project was obtained from Davidson via email prior to the project proposal.

Data Collection: Procedure

Participants were asked to complete the SPRINT on the day they attended the orientation. This score from the SPRINT was used as a pre-treatment evaluation or baseline level of PTSD symptoms. The headphone delivering the CAT was given to the participants after orientation to use on their own. The participants were asked to use the CAT at least once a day and to record the date and the time when they used the CAT (see Appendix H for the daily usage form).

At the end of week 1, 2, 3, 4 and 5, the participants were asked to fill out the SPRINT for evaluating the change of the level of their PTSD symptoms. Finally, at the end of the sixth week, the participants were asked to complete the SPRINT again.

All the forms were printed out and placed in separate packages with labels of the dates the participant needed to complete the forms. A reminder was sent to each participant, if agreeable, by text message or email. Participants were asked to mail the forms and questionnaires at the end of each week to the address provided. All the data collected from the participants were stored in a locked file system at the office of the author's primary investigator at the KUMC's School of Nursing building.

Data analysis

PTSD symptom level is measured by SPRINT with 10 questions. Question 1 to 8 are recorded by participants on a 5-point scales from 0 meaning having no symptoms at all to 4 meaning having the symptoms very much. The possible total scores to these 8 questions range from 0 to 32. Total score 0 indicates having no symptom at all where total score of 32 indicates having very strong symptoms to all 8 questions. The higher the total score, the more severe PTSD symptoms the participants experience.

In addition, question 9 records how much better participants feel since beginning treatment as a percentage ranging from 0% - 100%. Question 10 records how much participants have the symptoms from question 1-8 improved since starting treatment on a 5-point scale from 1 being worse to 5 being very much.

Results

Participant 1 is a 30-year-old male US veteran who was diagnosed with PTSD in 2017. He does not have a history of seizure or TBI. He was not on any form of therapy prior to participating in this project. His baseline PTSD total score was 25 prior to the use of the headset product. His total score was 17 at the end of week 1, 16 at the end of week 2, 16 at the end of week 3, 11 at the end of week 4, 6 at the end of week 5, and was 3 at the end of week 6 (see the

following table 1). The daily usage reported was using the CAT once a day at 8:30 pm each week for 6 weeks with the light turned on at every usage.

| | baseline | Week 1 | Week 2 | Week 3 | Week4 | Week 5 | Week 6 |
|---|----------|----------------|----------------|----------------|----------------|--------|-------------------|
| total score of Question 1-8 | 25 | 17 | 16 | 16 | 11 | 6 | 5 |
| Question 9: the level of feeling better | | 10% | 30% | 40% | 40% | N/A | 50% |
| Question 10: the level of improvement | | 3 Minimally | 3 Minimally | 3 Minimally | 3 Minimally | N/A | 5 Very much |

(Table 1 N/A: not available)

Participant 2 is a 31-year-old male US veteran who was diagnosed with PTSD in 2011. He does not have history of seizure or TBI. He was using medication as well as meditation and counseling to treat his PTSD prior to the participating in this project. His baseline PTSD total score was 30 prior to the use of the headset product. He did use the headset product but did not want to fill out the daily usage forms or any SPRINT questionnaires due to personal issues. He did give verbal feedback that he likes using the headset product because it helped to calm him down and sleep better, and helped him not to overreact during stressful situations.

Participant 3 is a 39-year-old female US veteran who was diagnosed with PTSD in 1997. She does not have any history of seizures or TBI. She was using counseling to treat her PTSD. His baseline PTSD total score was 25 prior to the use of the headset product. According to the forms sent back, she used the headset product with the light on once at 8am for the first week and

reported total score of 25 with 0% improvement and having worse symptoms. The author contacted her and advised her to use the free consultation provided. She agreed and spoke with the certified psychiatric mental health NP via phone. Per the NP’s note after consultation, “her issue was not associated with the headset, lights, or audio. It was more of a personal issue and did not impact her personal safety in any way”. She reported she would continue to use the headset product, but unfortunately, according to the forms she sent back, the headset product did not work for the following weeks until the end of this project. However, no issue of the dysfunction of the headset product was reported at all during the project.

Participant 4 is a 26-year-old male US veteran who was not officially diagnosed with PTSD by a health care provider but has had PTSD-like symptoms for years. He does not have a history of seizure or TBI. He was using counseling therapy to treat his PTSD prior to participating in this project. His baseline PTSD total score was 30 prior to the use of the headset product. His total score was 21 at the end of week 1, 23 at the end of week 2, 15 at the end of week 3, 12 at the end of week 4, 14 at the end of week 5, and was 24 at the end of week 6 (see the following table 2). He did not fill out most of the daily usage forms and the only usage reported were one time use each day in 2 consecutive days in the last week of the project.

| | baseline | Week 1 | Week 2 | Week 3 | Week4 | Week 5 | Week 6 |
|---|----------|--------|--------|--------|-------|--------|--------|
| total score of Question 1-8 | 30 | 21 | 23 | 15 | 12 | 14 | 24 |
| Question 9: the level of feeling better | | 0% | 0% | 70% | 70% | 70% | 60% |

| | | | | | | | |
|---|--|-------------------|------------|-----------|-----------|-----------|-----------|
| Question 10: the level of improvement | | 2 No change | 1 worse | 4 much | 4 much | 4 much | 4 much |
|---|--|-------------------|------------|-----------|-----------|-----------|-----------|

(Table 2)

Participant 5 did not send back any forms or information and therefore was not considered in the data analysis.

Project Limitations

Out of 5 participants, only 2 engaged in the full length of the six weeks and filled out the questionnaires SPRINT. Personal issues were reported and could be the reasons that interfered with the engagement and compliance of the other 3 participants who did participate but did not complete in the project. Other reasons needed to be examined include the complexity of technology using the headphone and the difficulties resulting from the frequency of daily use, keeping tracking of usages, filling out the questionnaires SPRINT, and mailing the forms weekly.

Due to the small number of participants and limited data obtained, the results of this pilot project do not necessarily represent the population targeted because statistical significance cannot be ascertained without using statistical comparison. Further projects with larger participants or with a control group are encouraged to examine the effectiveness of this CAT that is unique with its characteristics of self-directed, autonomous use, and combined CAT.

Clinical Implications

As mentioned in the Introduction section, this project's utilizing telehealth and technology (headphone set and mobile apps) and the non-traditional PTSD treatment (CAT) meets one of the USVA's goals of developing strategies to enhance access to PTSD treatments.

In addition, this project enhances and facilitates PTSD treatment because of its design of autonomous use at anytime and anywhere requires neither traveling to a USVA hospital nor to other mental health care facilities. Moreover, it may be more acceptable to those veterans who are geographically isolated from mental health services or reluctant to use the services.

Numerous studies have shown effective results using individual non-pharmacological non-conventional therapies such as mindfulness meditation, auricular acupuncture, light therapy, and music therapy to treat PTSD. Little or no studies have been found to combine these therapies. This project was conducted to evaluate the feasibility and effectiveness of combining several therapies to obtain a more effective therapeutic outcome. The number of U. S. veterans suffering PTSD is very large and continues to grow. The tremendous negative impacts of undertreated or untreated PTSD are not only to the veterans themselves, but also to their family, the community, the society, and at the end to the nation. Nurse Practitioners or other health care providers can add this combination of therapies to their patients' current treatment plans to reduce their symptoms and to ultimately improve the quality of their lives.

Conclusion

PTSD is prevalent among U. S. veterans and poses tremendous negative impacts not only for the veterans and their family, but also on the community, the society, and the nation. Non-pharmacological treatments such as the CAT, have been widely used in treating U. S. veterans suffering PTSD. This pilot project, with an innovative therapy, combines several CATs and utilizes a commercially available product delivering the combined CAT to synergize the effectiveness of the CAT and to increase the access and engagement of PTSD treatments.

Although the sample size is extremely small and therefore the limited data obtained is not conclusive, the data obtained from the participants who responded shows from 40 to 70%

improvement of their PTSD symptoms. The result of a decrease in PTSD symptoms suggests the innovative therapy in this pilot study a potential effective approach for health care providers to treat their PTSD patients and to improve their qualities of lives.

References

- Andreou, E., Alexopoulos, E. C., Lionis, C., Varvogli, L., Gnardellis, C., Chrousos, G. P., & Darviri, C. (2011). Perceived Stress Scale: Reliability and Validity Study in Greece. *International Journal of Environmental Research and Public Health*, 8(8), 3287–3298. <http://doi.org/10.3390/ijerph8083287>
- Braintap Technology. (2015a). Relax, Reboot, and Strengthen your Busy Brain. Retrieved from <http://braintaptechnology.com/braintap/>
- Braintap Technology. (2015b). Case Study Shows BrainTap Booster Regulatory Systems of The Body By 27.5% in Just One Session. Retrieved from <https://braintaptechnology.com/2017/01/31/case-study/>
- Braintap Technology. (2015c). BrainTap and On Demand Library FAQ's/Is it safe? Retrieved from <https://braintaptechnology.com/faqs/>
- Carr, C., d'Ardenne, P., Sloboda, A., Scott, C., Wang, D. & Priebe, S. (2011). Group Music Therapy for Patients with Persistent Post-Traumatic Stress Disorder – An Exploratory Randomized Controlled Trial with Mixed Methods Evaluation. Full publication history. DOI: 10.1111/j.2044-8341.2011.02026.x
- Cohen, S. & Janicki-Deverts, D. (2012). Who's Stressed? Distributions of Psychological Stress in the United States in Probability Samples from 1983, 2006, and 2009. *Journal of Applied Social Psychology*. 42, 6, pp. 1320–1334. DOI: 10.1111/j.1559-1816.2012.00900.x
- Cole, M. A., Muir, J. J., Gans, J. J., Shin, L. M., D'Esposito, M., Harel, B. T., & Schembri, A. (2015). Simultaneous Treatment of Neurocognitive and Psychiatric Symptoms in Veterans with Post-Traumatic Stress Disorder and History of Mild Traumatic Brain

- Injury: A Pilot Study of Mindfulness-Based Stress Reduction. *Military Medicine*, 180(9), 956-963 8p. doi:10.7205/MILMED-D-14-00581
- Collinge, W., Kahn, J., & Soltysik, R. (2012). Promoting Reintegration of National Guard Veterans and Their Partners Using a Self-Directed Program of Integrative Therapies: A Pilot Study. *Military Medicine*, 177(12), 1477–1485.
- Connor, K., & Davidson, J. (2001). PTSD: National Center for PTSD- SPRINT. U.S. Department of Veterans Affairs. Retrieved on January 28, 2017 from <http://www.ptsd.va.gov/PTSD/professional/assessment/screens/index.asp>
- Erbes, C. R., Stinson, R., Kuhn, E., Polusny, M., Urban, J., Hoffman, J., ... & Thorp, S. R. (2014). Access, utilization, and interest in mHealth applications among veterans receiving outpatient care for PTSD. *Military Medicine*, 179(11), 1218-1222.
- Fulton, J. J., Calhoun, P. S., Wagner, H. R., Schry, A. R., Hair, L. P., Feeling, N., ... & Beckham, J. C. (2015). The prevalence of posttraumatic stress disorder in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) Veterans: a meta-analysis. *Journal of anxiety disorders*, 31, 98-107.
- Gradus, J. L. (2016). U.S. Department of Veterans Affairs. PTSD: National Center for PTSD: Epidemiology of PTSD. Retrieved from <http://www.ptsd.va.gov/professional/PTSD-overview/epidemiological-facts-ptsd.asp>
- Kearney, D. J., McDermott, K., Malte, C., Martinez, M., & Simpson, T. L. (2012). Association of participation in a mindfulness program with measures of PTSD, depression and quality of life in a veteran sample. *Journal of Clinical Psychology*, 68(1), 101-116. doi:10.1002/jclp.20853

- Kearney, D.J., McDermott, K., Malte, C., Martinez, M., & Simpson, T.L. (2013). Effects of Participation in a Mindfulness Program for Veterans with Posttraumatic Stress Disorder: A Randomized Controlled Pilot Study. *Journal of Clinical Psychology*. 69(1): 14–27. DOI: 10.1002/jclp.21911
- Kim, Y. D., Heo, I., Shin, B. C., Crawford, C., Kang, H. W., & Lim, J. H. (2013). Acupuncture for posttraumatic stress disorder: a systematic review of randomized controlled trials and prospective clinical trials. *Evidence-Based Complementary and Alternative Medicine*, 2013.
- King, A. P., Block, S. R., Sripada, R. K., Rauch, S., Giardino, N., Favorite, T., ... & Liberzon, I. (2016). Altered Default Mode Network (DMN) Resting State Functional Connectivity Following Mindfulness-Based Exposure Therapy for Posttraumatic Stress Disorder (PTSD) in Combat Veterans of Afghanistan and Iraq. *Depression & Anxiety*, (1091-4269), 33(4), 289-299 11p. doi:10.1002/da.22481
- King, A. P., Erickson, T. M., Giardino, N. D., Favorite, T., Rauch, S. A.M., Robinson, E., Kulkarni, M. and Liberzon, I. (2013). A Pilot Study of Group Mindfulness-Based Cognitive Therapy (MBCT) for Combat Veterans with Posttraumatic Stress Disorder (PTSD), *Depress, Anxiety*, 30: 638–645. doi: 10.1002/da.22104
- King, H. C., Spence, D. L., Hickey, A. H., Sargent, P., Elesh, R., & Connelly, C. D. (2015). Auricular Acupuncture for Sleep Disturbance in Veterans with Post-Traumatic Stress Disorder: A Feasibility Study. 180(5):582-90. doi: 10.7205/MILMED-D-14-00451
- Kuhn, E., Greene, C., Hoffman, J., Nguyen, T., Wald, L., Schmidt, J., ... & Ruzek, J. (2014). Preliminary evaluation of PTSD Coach, a smartphone app for post-traumatic stress symptoms. *Military Medicine*, 179, 1:12, 2014

- Lancaster, C. L., Teeters, J. B., Gros, D. F., & Back, S. E. (2016). Posttraumatic Stress Disorder: Overview of Evidence-Based Assessment and Treatment. *Journal of Clinical Medicine*, 5(11), 105. <http://doi.org/10.3390/jcm5110105>
- Leady, P. & Ormrod, J. (2013). *Practical research: Planning and design* (10th Edition). Boston: Pearson. ISBN: 978-0132693240
- Ly, K. H., Trüschel, A., Jarl, L., Magnusson, S., Windahl, T., Johansson, R., ... & Andersson, G. (2013). Behavioural Activation versus Mindfulness-Based Guided Self-Help Treatment Administered through A Smartphone Application: A Randomised Controlled Trial. *BMJ Open* 2014;4:e003440. doi: 10.1136/bmjopen-2013-003440
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., ... & Lutz, A. (2012). The Validation of an Active Control Intervention for Mindfulness Based Stress Reduction (MBSR). *Behaviour Research and Therapy*, 50(1), 3–12. <http://doi.org/10.1016/j.brat.2011.10.011>
- Marotta-Walters, S., Choi, J., Shaine, M. D. (2015). Posttraumatic growth among combat veterans: A proposed developmental pathway. *Psychological Trauma: Theory, Research, Practice, and Policy*, Vol 7(4), Jul 2015, 356-363. <http://dx.doi.org/10.1037/tra0000030>
- Mohr, D., Cuijpers, P., & Lehman, K. (2011). Supportive accountability: a model for providing human support to enhance adherence to eHealth interventions. *Journal of medical Internet research*, 13(1), e30.
- Naeser, M. A., Saltmarche, A., Krenget, M. H., Hamblin, M. R., & Knight, J. A. (2011). Improved Cognitive Function After Transcranial, Light-Emitting Diode Treatments in Chronic, Traumatic Brain Injury: Two Case Reports. *Photomedicine and Laser Surgery*. 29 (2011): 351-358. ©2011 Mary Ann Liebert, Inc.

- Naeser, M. A., Zafonte, R., Krengel, M. H., Martin, P. I., Frazier, J., Hamblin, M. R., ... & Baker, E. H. (2014). Significant Improvements in Cognitive Performance Post-Transcranial, Red/Near-Infrared Light-Emitting Diode Treatments in Chronic, Mild Traumatic Brain Injury: Open-Protocol Study. *Journal of Neurotrauma*, 31(11), 1008–1017. <http://doi.org/10.1089/neu.2013.3244>
- National Institutes of Health. (2016). Post-Traumatic Stress Disorder. Retrieved from <https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd/index.shtml>
- Panischev, O., Demin, S., & Rusanova, I. (2015). Studying Properties of Abnormal Human Brain Activity in Photosensitive Epilepsy Caused by Light Stimulation. *Biomedical Engineering*, 49(4), 236-239. doi:10.1007/s10527-015-9537-3
- Polusny, M. A., Erbes, C. R., Thuras, P., Moran, A., Lamberty, G. J., Collins, R. C., ...& Lim, K. O. (2015). Mindfulness-Based Stress Reduction for Posttraumatic Stress Disorder Among Veterans: A Randomized Clinical Trial. *JAMA*. 2015;314(5):456-465. doi:10.1001/jama.2015.8361
- Ralevski, E., Olivera-Figueroa, L. A., & Petrakis, I. (2014). PTSD and comorbid AUD: a review of pharmacological and alternative treatment options. *Substance Abuse and Rehabilitation*, 5, 25–36. <http://doi.org/10.2147/SAR.S37399>
- Ramchand, R., Rudavsky, R., Grant, S., Tanielian, T., & Jaycox, L. (2015). Prevalence of, Risk Factors for, and Consequences of Posttraumatic Stress Disorder and Other Mental Health Problems in Military Populations Deployed to Iraq and Afghanistan. *Current Psychiatry Reports*. 17: 37. doi:10.1007/s11920-015-0575-z

- Sebastian, B. & Nelms, J. (2017). The Effectiveness of Emotional Freedom Techniques in the Treatment of Posttraumatic Stress Disorder: A Meta-Analysis. *Explore (NY)*. 2017 Jan - Feb 13(1):16-25. doi: 10.1016/j.explore.2016.10.001.
- Shore, J. H., Aldag, M., McVeigh, F. L., Hoover, R. L., Ciulla, R., & Fisher, A. (2014). Review of mobile health technology for military mental health. *Military medicine*, 179(8), 865-878.
- Stecker T., Fortney J., Owen R., McGovern M. P., & Williams S. (2010). Co-occurring medical, psychiatric, and alcohol-related disorders among veterans returning from Iraq and Afghanistan. *Psychosomatics*. 2010;51(6):503–507
- U.S. Department of Veterans Affairs. (2016). PTSD: National Center for PTSD. Retrieved from http://www.ptsd.va.gov/about/mission/looking_ahead.asp
- What is Lean Media. (n.d.). In IGI Global online. Retrieved from <http://www.igi-global.com/dictionary/lean-media/16753>
- Zinzow, H. M., Britt, T. W., McFadden, A. C., Burnette, C. M., & Gillispie, S. (2012). Connecting active duty and returning veterans to mental health treatment: Interventions and treatment adaptations that may reduce barriers to care. *Clinical psychology review*, 32(8), 741-753.

Appendix A --- Informational/Explanatory Letter to Potential Participants

Dear Potential Project Participants:

We are asking for your help and cooperation in a pilot project investigating whether a headphone delivering light, sound and meditation therapy can reduce the negative symptoms associated with PTSD. The project is important in finding ways for US Veterans suffering from PTSD to treat themselves.

Five participants will be selected and be asked to use this product at least once a day for 6 weeks. They will be asked to complete a daily usage form at the end of each day. In addition, they will be asked to complete a PTSD questionnaire at the end of each week. At the end of each week, they will be asked to place the daily usage form and one PTSD questionnaire into the pre-paid envelope and mail to the address provided. At the end of the sixth week the 5 participants will be asked place the headphone in a pre-paid box and mail it to the address provided along with the daily usage and PTSD questionnaire.

The headphones are to be used in addition to your current or ongoing therapy so please do not stop any of your current or ongoing therapies.

There will also be a certified psychiatric mental health nurse practitioner on call to provide free consultation services if you feel stressed and want to talk about your feeling after using the headphone during the six-week session of this project.

Due to resource limitations, only 5 applicants will be chosen to participate in this project. It has been determined for safety purposes that if you have been diagnosed with epilepsy, photo epilepsy, or traumatic brain injury, you will not be an optimal candidate for using the headphones.

In this project, there are no known economic, legal, physical, psychological, or social risks to participants in either immediate or in long-range outcomes. Your decision to participate in this project is completely voluntary. You are not required to participate and declining to participate in no way impacts your ability to seek other treatment offered by the Veterans Administration.

If you are interested in participating in this project, please fill out the Project Pre-Screening Form. To ensure anonymity, please write your initials, not your full name, on the form. All data collected from you will be completely confidential and will only be used for this project. In addition, All the forms and questionnaires we gathered from you throughout the project will be stored in a locked file system at Dr. Lisa Ogawa's office located at the school of nursing building of University of Kansas.

Five participants will be selected from those who completed the project pre-screening form. If you are selected, you will be provided with more detailed information by email and with a contact number to ask any questions you will have regarding this project. If you decide to participate, you will be asked to attend an orientation to learn more about the project and learn

how to use the headphones. After orientation, you will have up to 48 hours to decide whether you want to participate. If you agree to participate, you will sign an informed consent letter. At the same time, you will be asked to complete a PTSD questionnaire, which will be used as a baseline measure. Upon completion of the PTSD questionnaire each participant will be given a headphone, 5 pre-paid envelopes, and one pre-paid box with mailing to address. There is one copy of the daily usage form and one copy of the PTSD questionnaire in each envelop to be filled out during each week of the project.

You may choose not to answer any given questions at any time or you may withdraw your consent and discontinue your participation at any time. Discontinuing participation at any time will in no way impact the normal care you receive for PTSD or your ability to seek other treatment offered by the Veterans Administration. We will simply ask you to return the headphone and documentation in the pre-paid and pre-addressed envelopes and box provided by us.

The informed consent letter to participate in this project will document your willingness to participate. If you have any questions about your participation in this project, please ask them before you begin.

If you have any questions or concerns about the nature of this project, please contact Shu-Wen Cheng at 913-605-0134 or wcheng@kumc.edu or Lisa Ogawa at 913-588-1684 logawa@kumc.edu or School of Nursing, University of Kansas, Kansas City, KS 66160. Thank you for considering helping in this project.

Sincerely,

Shu-Wen Cheng

Dr. Lisa Ogawa

Appendix B – Project Pre-Screening Form

1. Initials of First, Middle, and Last Name: _____
2. Age: _____ Gender: ___ Male ___ Female
3. Cellphone number _____
4. Email address: _____
5. Are you a US Veteran? Yes No
6. Have you been diagnosed with PTSD by a health care provider? Yes No
If yes, in what year? _____
7. Do you have a history of seizures? Yes No
8. Have you been diagnosed with Traumatic Brain Injury? Yes No
9. Are you currently using any form of therapy to treat PTSD? Yes No
If Yes, what kind? (Please circle)
Medication Acupuncture Meditation Counseling
Other: _____
10. In the past 6 months, have you ever had any suicidal thought or attempt? Yes No

Appendix C – Informed Consent

Dear Participant,

This is Shu-Wen Chen, BSN-CCRN and I am a DNP student University of Kansas School of Nursing. My contact information is: 913-605-0134 or email at wcheng@kumce.edu. Dr. Lisa Ogawa, is my professor at the University of Kansas School of Nursing and her contact information is: Phone: 913-588-1684 or email logawa@kumc.edu. We are contacting you because you are a U.S. veteran suffering from PTSD. We are recruiting participants to help us determine if a pilot project using a headphone called BrainTap that hooks up to your smart phone or tablet (see picture below) may reduce your level of PTSD symptoms. By using this headphone delivering meditation therapy, lights and sound along with usual plan of care by your primary provider for PTSD, you may experience a decreased level of PTSD.

First, we will have you pre-screened to determine if you all eligible for the project. Then we will ask you to attend a one-hour orientation. You will be given up to 48 hours to be part of the project and sign this informed consent.

We will ask you to do the follow as part of this project:

- Complete a PTSD questionnaire before the project begins;
- Use the headphone at least once a day for 6 weeks (you may use the headphone more often as you wish);
- Complete the PTSD questionnaire at the end of each week;
- Record your usage of the headphone on a daily usage form each day;
- Each week mail the PTSD questionnaire and the daily usage in a pre-paid and pre-addressed envelope;
- At the end of the six weeks, mail the headphone and the final PTSD questionnaire and daily use form back to Shu-Wen Cheng using the pre-paid and pre-addressed box.

The orientation will allow you to answer any questions you may have about the study. We will also teach you how to use the headphone. The PTSD questionnaire enables us to measure your level of PTSD symptoms and the changes in them. It will take about 2-3 minutes each time you complete the PTSD questionnaire. The daily usage form enables us to know how much time you spent using the headphone each day. It will take less than 1 minute to complete each day.

In addition to the survey questions, we will collect your age, gender, the status of your PTSD, and any treatment you are seeking for demographic data of the project. We will also collect contact information such as your cellphone number and email address for the project only. This will provide us a means to communicate with each other. Any contact we have with you will be directly related to the project. All the data we collect from you throughout the project will be stored in a locked file system at Dr. Lisa Ogawa's office located at the school of nursing building of University of Kansas.

There are no known personal risks nor are there any financial benefits to participating in this project. You may experience a decrease in your levels of PTSD if the headphone is helpful to you.

During the six-week session of this project, Dr. Cindy Whitney, a certified psychiatric mental health nurse practitioner, will be on call to provide free consultation services if you feel stressed and want to talk about your feeling after using the headphone. Please call me first at 913-605-0134 and let me know what problem you have encountered or what you need to talk about. Then I will contact Dr. Cindy Whitney to inform her of your need. You will then receive a call from her at her earliest availability.

Participation is voluntary, and you can stop participating at any time, which will in no way impact the normal care you receive for PTSD. If you decide to stop using the headphones, please call Shu-Wen Cheng and mail the headphone back to her using the pre-paid and pre-addressed box. You will not be required to fill out the PTSD questionnaire or daily use form.

If you have any questions, please contact Shu-Wen Cheng at 913-605-0134 or wcheng@kumc.edu, School of Nursing, University of Kansas, Kansas City, KS 66160 or Dr. Lisa Ogawa at 913-588-1684 or logawa@kumc.edu. For questions about the rights of research participants, you may contact the KUMC Institutional Review Board (IRB) at (913) 588-1240 or humansubjects@kumc.edu

Sincerely,

Shu-Wen Cheng and Dr. Lisa Ogawa

If you agree to be in the project, please sign and date below:

Printed name of participant: _____

Signature of participant: _____ Date: _____

Printed name of person obtaining consent: _____

Signature of person obtaining consent: _____ Date: _____

Picture of the Headset



Appendix D – Project Approval for Human Subject Protection

The University of Kansas Medical Center

Human Research Protection Program

APPROVAL OF SUBMISSION

May 1, 2017

Lisa Ogawa
913-588-1684
logawa@kumc.edu

Dear Lisa Ogawa:

On 5/1/2017, the IRB reviewed the following submission:

| | |
|---|--|
| Type of Review: | Initial Study |
| Reviewing IRB: | IRB00000161 |
| FWA#: | 00003411 |
| IRB#: | STUDY00140874 |
| Title: | A Pilot Project to reduce PTSD symptoms in U.S. Veterans Using an Innovative Therapy |
| Investigator: | Lisa Ogawa |
| IRB ID: | STUDY00140874 |
| Funding: | None |
| Expedited Category(ies): | (7)(b) Social science methods, (5) Data, documents, records, or specimens |
| Documents submitted for the above review: | <ul style="list-style-type: none"> • Cindy Witney LOS.pdf • Information Letter SWC Version 1.docx • LOS for Volunteer Site.pdf • Protocol Version 3.docx • SWC Daily Usage Form Version 2.docx • PTSD Questionnaire SPRINT FORM Version 2.pdf • SWC Expedited IRB Form Version 2.doc • Prescreening tool Version 2.docx • Informed Consent Version 3.docx |
| Special Determinations: | None |

The IRB approved the study from 5/1/2017 to 4/30/2018 inclusive.

Your approved documents are stored in the “Documents” tab for this study in the eCompliance system. The IRB stamped consent form(s) can be found under the “Final” column on the right side of the screen. These are the **only** valid versions for documenting informed consent.

Mail-Stop 1032, 3901 Rainbow Blvd., Kansas City, KS 66160
Phone: (913) 588-1240 Fax: (913) 588-5771 humansubjects@kumc.edu

If continuing review approval is not granted on or before 4/30/2018, approval of this study expires after that date.

Approval of this research is contingent upon your agreement to:

- (1) Adhere to all KUMC Policies and Procedures Relating to Human Subjects, as written in accordance with the Code of Federal Regulations (45 CFR 46).
- (2) Ensure that all study personnel are adequately trained for their role on the study.
- (3) Maintain current training in human subjects protection and current disclosure of conflicts of interest as required by KUMC policy.
- (4) Except where informed consent and HIPAA authorization have been formally waived by the IRB, seek, document and maintain records of informed consent and HIPAA authorization from each prospective subject or his/her legally authorized representative.
- (5) Maintain copies of all pertinent information related to the research study including, but not limited to, video and audio tapes, instruments, copies of written informed consent agreements, and any other supportive documents in accordance with the KUMC Research Records Retention Policy.
- (6) Report adverse events, non-compliance and other problems to the IRB by submitting a Report of New Information.
- (7) Follow the IRB-approved protocol. Submit Modifications to the IRB for any proposed changes from the previously approved project. Changes may not be initiated without prior IRB review and approval, unless a delay in implementation would place subjects at risk.
- (8) Submit a Continuing Review to the KUMC IRB before the expiration date. Federal regulations and IRB policies require continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

For more information on Human Subjects Research Policies or using the eCompliance system, please see our website at: <http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board.html>

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office at 913-588-1240 or humansubjects@kumc.edu.

Sincerely,

Karen Blackwell

Appendix E - Short PTSD Rating Interview (SPRINT)

ID number or initials

Date:

Short PTSD Rating Interview (SPRINT)

Please identify the most distressing traumatic event:
.....

| In the past week..... | | Not at all 0 | A little bit 1 | Mode- rately 2 | Quite a lot 3 | Very much 4 |
|-----------------------|--|--------------------|-------------------------|----------------------|---------------------|-------------------|
| 1 | How much have you been bothered by unwanted memories, nightmares, or reminders of the event? | | | | | |
| 2 | How much effort have you made to avoid thinking or talking about the event, or doing things which remind you of what happened? | | | | | |
| 3 | To what extent have you lost enjoyment for things, kept your distance from people, or found it difficult to experience feelings? | | | | | |
| 4 | How much have you been bothered by poor sleep, poor concentration, jumpiness, irritability, or feeling watchful around you? | | | | | |
| 5 | How much have you been bothered by pain, aches, or tiredness? | | | | | |
| 6 | How much would you get upset when stressful events or setbacks happen to you? | | | | | |
| 7 | How much have the above symptoms interfered with your ability to work or carry out daily activities? | | | | | |
| 8 | How much have the above symptoms interfered with your relationships with family or friends? | | | | | |

SUM of 1-8 -

9 How much better do you feel since beginning treatment?
(As a percentage) (%)

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

| | |
|----|---|
| 10 | How much have the above symptoms improved since starting treatment? |
| | Worse No change Minimally Much Very much |
| | 1 2 3 4 5 |

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Appendix F – The letter to the certified Psychiatric Nurse Practitioner



Date: February 27, 2017

To: Dr. Cindy Whitney
Clinical Instructor
The University of Kansas School of Nursing
3901 Rainbow Blvd Mail Stop 4340
Kansas City, KS, 66160

From: Dr. Lisa M. Fink Ogawa
Clinical Assistant Professor
The University of Kansas School of Nursing
3901 Rainbow Blvd. Mail Stop 4340
Kansas City, KS 66160

Re: Psychology consultation services during Shu-Wen (Wendy) Chang's DNP Project
Dear Dr. Whitney,

We are delighted to invite you to be a consultant for Shu-Wen (Wendy) Cheng's DNP Project entitled *Reducing Symptoms of PTSD and Stress in U.S. Veterans Using an Innovative Intervention*. This is a pilot project that will last six weeks. The tentative start date is May 2017 and will finish in July 2017. There will be five United States Veterans volunteering to use a technology called BrainTap Technology (copyright ©). The Veterans will use this device at least once a day and fill out a Post-Traumatic Stress Disorder (PTSD) called the PSS Scale and stress scale called the SPRINT Questionnaire at least once a week.

We will need you to be available during the six weeks in case a Veteran would like to debrief about their symptoms of PTSD or stress and refer the Veteran on to their usual primary care provider, their psychologist, the United States Veterans Affairs Healthcare System or to the closest emergency room if they feel symptoms of suicide. This consultation is completely voluntary and there is no financial funding or payment for this service if a Veteran would like to speak to you after using the BrainTap device. There is no literature stating the BrainTap device induces symptoms of PTSD or suicide. In fact, it is known to negate these symptoms. The Veterans will be prescreened and excluded from the project if they have a traumatic brain injury and/or seizures. All Veterans will be over the age of 18 and will have a diagnosis of PTSD for at least six month. The Veterans have been recruited through a Veterans support group called The Association of the United States Army, Greater Kansas City Chapter run by Emma Tops.

We will provide you with a one-on-one orientation to the BrainTap technology. In addition, we are holding an orientation to the project at Transcendence Wellness Center to provide the directions to the Veterans on how to use the device and complete the weekly surveys. You will be invited to attend this orientation along with the Veterans and the project personnel. The date will be set after the KUMC Institutional Review Board (IRB)/Human Subject Committee has approved the project.

Do not hesitate to contact me if you have any questions about this project and we are grateful for your assistance during this project.

Sincerely,

Lisa M. Ogawa

This letter of invitation will be submitted to the IRB/Human Subject Committee and we ask for your signature acknowledging that you have received a copy of this document for your records.

Cindy Whitney

Appendix H - Project Timeline

| Project Timeline | | | | | |
|---|------|-----|-----|-----|--|
| Implementation activities | Year | | | | Personnel/Agency responsible |
| | Q 1 | Q 2 | Q 3 | Q 4 | |
| Project proposal defense | X | | | | Author KUMC SON Committee |
| Submit project proposal to KUMC IRB for approval | X | | | | Author KUMC SON Committee IRB |
| Send out invitations to U.S. veterans | X | | | | KC AUSA |
| Application collected and Participants selected | | | x | | KC AUSA Author KUMC SON Committee |
| Orientation to participants | | | x | | Transcendence Wellness Center, Overland Park, KS |
| Informed consent signed | | | x | | Author |
| Collect pre-treatment evaluation data (SPRINT) The headphone given to the participants Date package given to the participants | | | x | | Author |
| Participants start using the headphone | | | x | | Author |
| Collect the SPRINT data each week | | | x | | Author KC AUSA |
| Collect post-treatment data (SPRINT) at the end of the 6 th week | | | | x | Author |
| Analyze the data | | | | x | Author KU biostatistics lab |
| Draw conclusion | | | | x | Author |
| Complete project report paper | | | | x | Author |
| DNP project public presentation | | | | x | Author |
| | | | | | |

Appendix I - Project Budget

| Description | Cost |
|-------------------------|---------|
| 5 Headphone | \$1,750 |
| Travel/Mailing Expenses | \$250 |
| Printing | \$50 |
| Total Expenses | \$2,050 |

Appendix J – Veterans Leadership Network

Veterans' LDRSHIP Network: The Purple Connection

VISION: Create AWARENESS, Enable ACCESS, Empower ACTION

MISSION:

- Expedite and support the reintegration, personal and professional growth, and healing of military personnel and their families
- Regularly bring together subject matter expertise and facilitate efficient connections

Follow us at www.facebook.com/VLN.TPC

Follow us at www.facebook.com/VLN.TPC

Veterans' LDRSHIP Network is a Coalition of Community Resources



Red = Network
Blue = Military, Veteran, or Military Family
Red + Blue = Purple

The Purple Connection is a Networking Event

Appendix K – The Support Letter



January 26, 2017

Lisa M. Fink Ogawa, PhD, RN, CNE
 Clinical Assistant Professor, Director of Quality and Safety Scholarship
 3901 Rainbow Blvd, Mail Stop 4043
 Kansas City, KS 66160

Shu Wen Wendy Cheng, FNP, RN (DNP Student Graduate School of Nursing and Jonas Scholar)
 3901 Rainbow Blvd, Mail Stop 4043
 Kansas City, KS 66160

Dear Dr. Lisa Ogawa and Wendy,

We support the use of the tool/device called BrainTap to examine it to usefulness to decrease PTSD and/or stress in any military veteran who is over the age of 18 and who does not have a history of seizures.

We will support Dr. Ogawa and Wendy to recruit participants through our organization for this project.

I/we understand that this letter will be submitted with the proposal to the Human Subjects Protection Committee at The University of Kansas Medical Center.

Thank you,

Susie Dressel

[Redacted Signature]
 Owner
 Transcendence Wellness Center
 12700 W. 119th St. Overland Park, KS 66213
 913-387-4631
transcendencekc@gmail.com
www.transcendencekcbraintap.com

Jessica Alstrom

[Redacted Signature]
 Owner
 Transcendence Wellness Center
 12700 W. 119th St. Overland Park, KS 66213
 913-387-4631
transcendencekc@gmail.com
www.transcendencekcbraintap.com

Transcendence Wellness Center
 Overland Park, KS 66213
www.transcendencekc.com
 (913) 387-4631