MEDICAL ACUPUNCTURE
Volume 30, Number 5, 2018

DOI: 10.1089/acu.2018.1294

Auricular Acupuncture for Chronic Pain and Insomnia: A Randomized Clinical Trial

Betty K. Garner, PhD, ARNP,[1] Susan G. Hopkinson, PhD, RN,[2] Ann K. Ketz, PhD, RN,[1] Carol A. Landis, PhD, RN, FAAN,[3] and Lori L. Trego, PhD, CNM[4]

ABSTRACT

Objective: In the United States, ~1.6 million adults use complementary and alternative or integrative medicine for treating pain and insomnia. However, very few studies have tested the use of auricular acupuncture using a standard protocol for chronic pain and insomnia. The aims of this research were to assess the feasibility and credibility of auricular acupuncture, and to evaluate the effects of auricular acupuncture on pain severity and interference scores, and on insomnia severity over an 8-day study period.

Materials and Methods: Forty-five participants were randomized to either an auricular acupuncture group (AAG) or a usual care group (CG) on study day 4. A standard auricular acupuncture protocol was administered, with penetrating semipermanent acupuncture needles in place for up to 4 days. The main outcome measures were feasibility of conducting the study, credibility of auricular acupuncture as a treatment modality, Brief Pain Inventory pain severity and interference scores, and Insomnia Severity Index (ISI) scores.

Results: There was high interest in the study and the retention was 96%. Credibility of auricular acupuncture as a treatment was high in both groups. The use of the standard auricular acupuncture protocol in the AAG led to significant within- and between-group reduced pain severity and interference scores, compared to the CG. Both groups showed within-group decreased ISI scores. However, the AAG showed significant between-group reduced ISI severity scores compared to the CG.

Conclusions: With the heightened focus on the opioid crisis in the United States, this easy-to-administer protocol may be an option for treating military beneficiaries who have chronic pain and insomnia.

Keywords: auricular acupuncture, Battlefield Acupuncture, insomnia, chronic pain, military, veterans

INTRODUCTION

Chronic pain affects more than 100 million people, and an estimated $565–$635 billion are spent annually for direct and indirect patient care costs.[1] Pain is a persistent problem among the U.S. military health care beneficiary population, which includes active-duty service members, veterans, and their family members. Chronic pain prevalence has been reported as high as 74% for U.S. veterans,[2,3] 56% for nonveterans,[3] and 44% for active-duty service members recently returned from deployment.[4]

[1]Landstuhl Regional Medical Center, Landstuhl, Germany.
[2]Tripler Army Medical Center, Honolulu, HI.
[3]Professor Emerita, University of Washington, Seattle, WA.
[4]University of Colorado, Aurora, CO.

REGISTRATION: This study is registered with clinicaltrials.gov under study ID M-10395 OR NCT 03503695.
FUNDING: TriService Nursing Research Program (TSNRP), USU, HU0001-14-TS02 (P14-09). This research was sponsored by the TSNRP, Uniformed Services University (USU); however, the information or content and conclusions do not necessarily represent the official position or policy of, nor should any official endorsement be inferred by, the TSNRP, the USU, the Department of Defense, or the U.S. Government.

Of individuals with chronic pain, ~63% have reported fair-to-very poor sleep quality and were three times more likely to have been diagnosed with a sleep disorder.[5] Insomnia affects ~10%–20% of the U.S. population,[5,6] 2.5%–13.5% of the U.S. veteran population,[7,8] and 5% of active-duty service members.[9] More than half of service members deployed in combat zones are sleep-deficient,[10] and more than one-third of service members post deployment report having insomnia.[11]

A common treatment for pain is the prescription of pain medications. Of 164 million patient visits that involved a pain diagnosis, ~20% were treated with an opioid and 27% with a nonopioid such as a nonsteroidal anti-inflammatory drug or acetaminophen. It is estimated that close to 2 million adults in the United States misuse opioid pain medications.[12] Across all military services, 20% of members reported using prescription pain relievers, of which 4% used other patients' prescriptions and 3% used greater amounts than prescribed.[13] Clinical practice guidelines for the U.S. Department of Defense (DoD) recommend against long-term opioid use for chronic pain and instead favor patient behavioral self-management, nonpharmacologic treatment, and nonopioid medications.[14]

Among military personnel, various sedative medications follow pain medications as the most commonly prescribed drugs.[13] Sedative use was reported by 13% of military personnel, with 3% using other patients' prescriptions and 3% using amounts that were more than prescribed. The most common reasons reported for use were to control pain (58%) and help with sleep (48%).

In the United States ~1.6 million people use complementary and alternative or integrative medicine (CAM/IM) for pain and insomnia.[15] In military beneficiaries, the use of CAM/IM ranges from 37% to 81%.[16–18] The predominant reasons were for pain (33%), stress, (30%) and anxiety (16%). Individuals who participated in multiple CAM/IM visits perceived them to be beneficial because they resulted in the patients feeling more relaxed (95.9%), having less pain (75%), and having improved sleep (71%), with auricular acupuncture (51%) reported as the most common treatment modality.

Auriculotherapy, which includes the modalities of ear acupressure and auricular acupuncture by stimulation of specific acupuncture points on the external ear, is an alternative nonpharmacological treatment for chronic pain. It is thought that different auricular regions correspond to particular somatotopic areas of the body.[19] Auriculotherapy has been shown to be superior to control approaches (e.g., placebo pills, sham, usual care, or medications) for reducing chronic pain intensity (standardized mean difference [SMD]: 1.84; 95% confidence interval [CI]: 0.60–3.07) in various studies.[20]

Auriculotherapy has been associated with reducing symptoms of insomnia. In a meta-analysis of six randomized clinical trials (RCTs; $n = 60$–193) of auriculotherapy, compared to sham or medication, in 1–120 days, the effectiveness of auricular acupuncture was statistically and clinically better than that of controls (relative risk: 1.32–3.83; 95% CI: 1.05–6.66; $p < 0.05$) based on subjective and objective sleep measures.[21] However, effects of auriculotherapy on both relieving pain and improving sleep are limited due to varied study designs, including different acupuncture or pressure points and techniques used, questionable methodological rigor, and small samples with insufficient power in some studies.[20,21]

In the military setting, a specific auricular acupuncture protocol known as Battlefield Acupuncture (BFA), which involves the placement of small semipermanent acupuncture needles (Aiguille Semi-Permanente; ASP), was developed in 2001 as a nonpharmacologic modality for rapid relief of pain.[22] These small semipermanent acupuncture needles are designed to stay in place due to their dartlike design. BFA has been used effectively for patients who have acute pain[23,24] and was found to be acceptable and effective for veterans with chronic pain.[25–27]

Benefits of using auricular acupuncture include the need for few supplies, cost-effectiveness (compared to medications), minimal side-effects, and the ability to train various health care providers through a brief training curriculum to administer BFA safely in a variety of clinical and field settings.[22,26,28] Few studies have tested the use of BFA using a standard auricular acupuncture protocol (penetrating and in place up to 4 days) in patients with chronic pain and insomnia. The purpose of this RCT was to assess the feasibility (e.g., recruitment, enrollment, randomization, and retention) and credibility of auricular acupuncture treatment and to evaluate the effectiveness of auricular acupuncture using a standard protocol on pain severity and interference scores and insomnia severity, compared to usual care.

MATERIALS AND METHODS

Design

This study was conducted at a U.S. military regional medical treatment facility (MTF) located in Germany. As the largest American hospital outside the United States, this MTF provides primary and tertiary care, hospitalization, and treatment for more than 52,000 U.S. military personnel stationed in Europe along with injured service members and civilians from military operations in Europe, Africa, and the western Middle East. The MTF provides specialty care services such as the Pain Management Clinic, a Physical Medicine Rehabilitation Center, and a Sleep Medicine Clinic. The current study was approved by a U.S. military institutional review board and was conducted from November 2014 to July 2017.

Sample

The target population for the study were military beneficiaries with chronic pain and insomnia. The convenience sample was drawn from beneficiaries (active-duty service

members, retirees, or family members) who were eligible for care at the MTF, with recruitment through print, audio, and visual advertisements at the MTF and affiliated community clinics. Public radio and newspaper announcements were also used. Eligibility criteria were established to permit participation of patients with a variety of chronic pain conditions and to maximize potential representation of military beneficiaries with both pain and insomnia.

Participants who met the inclusion criteria were English-speaking beneficiaries between the ages of 18 and 65, who were experiencing pain and insomnia. Insomnia criteria were met by self-reported sleep-onset latency or wakefulness after sleep onset of ≥30 minutes at least three times per week for ≥3 months duration and included a complaint of nonrestorative or unrefreshing sleep. The inclusion pain criterion was a numeric rating scale (NRS) pain rating of ≥3 (mild-to-severe level) for ≥3 months duration. Exclusion criteria were allergy to metals, pregnancy or planning pregnancy during the study, participating in another research protocol with a device or drugs, piercing or scar tissue in any of the auricular acupuncture point areas, working in a job with variable hours, and using acupuncture within 3 months prior to screening.

Study Procedures

Screening, enrollment, and data collection were conducted at the nursing research office of the MTF. Individuals who contacted the study staff with an interest in the study were screened for eligibility either in person or via telephone by a study team member. A study team member met with patients who were eligible to explain the research protocol and obtain signed informed consents (day 1/baseline). Following enrollment, participants completed self-report questionnaires for sociodemographics, medical conditions, the Insomnia Severity Index (ISI), and a modified Borkovec and Nau's Credibility Scale.

In addition, during the day 1/baseline visit, all participants were instructed how to complete a daily pain and sleep diary, which included the Brief Pain Inventory (BPI) and daily sleep parameters, and to wear an actigraph device continuously for 8 days. Participants were to maintain their ''current level of care'' for pain without modifications, which was defined as the ongoing pain management modalities being used by the participants at the time of enrollment. Other modalities included, but were not limited to, usual care with prescribed or over-the-counter medications and physical therapy.

On day 4, all participants returned to repeat the ISI and to be randomized into an auricular acupuncture group (AAG) or a usual care control group (CG) by a blinded study team member using an Excel random number generator, in blocks of 8, prepared in sealed opaque envelopes. Group assignment was based on selecting the next envelope in sequence for each participant.

On day 8, all participants returned the actigraph devices and their daily pain and sleep diaries to the nursing research office. At this time, the ISI was repeated. This concluded the study.

Intervention

On day 4, advanced practice nurses (APNs) trained in BFA administered a single auricular acupuncture treatment, based on the auricular acupuncture protocol, to participants in the AAG. The auricular acupuncture protocol included the application of ASP needles to five ear acupuncture points starting in either ear and alternating left and right until ten ASP needles were placed, with a maximum of five ASP needles in each ear. The ASP needles were inserted sequentially to the following acupuncture points: Cingulate Gyrus, Thalamus point, Omega 2, Point Zero, and *Shenmen* (Fig. 1).

Sterile ASP gold needles (Sedatelac, Lhasa OMS®) are 24-karat, gold-plated, single-use dart-shaped needles that are designed to stay in external auricular points. Each needle is housed in a needle injector, which enhances the accurate positioning of the needle (Fig. 2). The depth of insertion is determined by the standardized length of the ASP needles (2.1 mm). Prior to placement of the ASP needles, each APN ensured that each participant had no trauma, unhealed wounds, piercing, or scarring on the ears that might interfere with administration of the ASP needles. Participants were able to request the provider to stop the needle insertions at any point. The needles could remain in the auricular acupuncture points for 3–4 days or longer before spontaneously being pushed out to the surface and falling out. Participants returned to the research office on day 8, when a study team member removed any remaining ASP needles.

In this study, the single auricular acupuncture treatment was administered in medical clinics at the MTF by 1 of 5 APNs trained in auricular acupuncture, according to a standardized BFA curriculum. The one day training was taught by a medical acupuncturist in accordance with the *U.S. Air Force Auricular Stimulation Procedure Training Booklet and Manual*[29] and included 4 hours of didactic and 4 hours of hands-on training. The trainees included three nurse–practitioners and two Certified Registered Nurse Anesthetists, with an average of 23 years (standard deviation [SD] = 10.3) of nursing experience.

Usual Care Control Group

Participants who were randomized to the CG were instructed to continue wearing the actigraph device and complete the daily pain and sleep diaries until day 8. These patients were instructed to maintain their current levels of care for pain without modifications and record this information in the daily pain and sleep diaries.

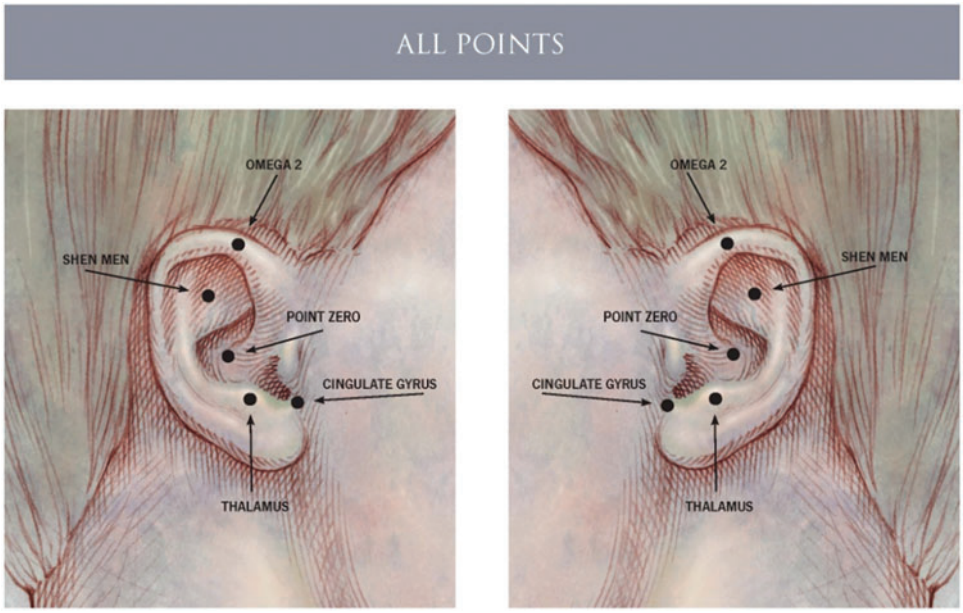

FIG. 1. Five auricular (Battlefield) acupuncture points in each ear for the study.

Measures

The following instruments were used to measure the feasibility of auricular acupuncture, credibility of auricular acupuncture, pain severity, pain interference, and insomnia severity.

Feasibility and credibility. Feasibility was measured by number of participants recruited, enrolled, randomized, and retained in the study. Credibility of the treatment was measured with the 4-item Borkovec and Nau's Credibility Scale. It is used to assess how believable, convincing, and logical the treatment is on a 9-point Likert scale (1 = not at all to 9 = very) for a total possible score from 4 to 36, with a higher score indicating higher credibility.[30,31] As is common in various studies, the items were modified to reflect the type of treatment and the specific outcome. Therefore, the 4 items were posed separately for pain and insomnia to all participants. Internal consistency for this study for the 4-item pain and 4-item insomnia subscales was $\alpha = 0.92$ and $\alpha = 0.87$, respectively.

Brief Pain Inventory. The BPI includes 4 items—(1) "pain now"; (2) "pain at its worst"; (3) "pain at its least"; and (4) "average pain" over the last 24 hours—that are used to assess pain severity and 7 items that are used to assess the degree of interference with functioning—(1) general activity; (2) mood; (3) walking ability; (4) normal work; (5) relationships; (6) sleep; and (7) enjoyment in life.[32] Items are rated on a 0–10 NRS (0 = no pain/no interference and 10 = most pain/most interference). The arithmetic mean of the 4 pain items is used as a measure of pain severity and the arithmetic mean of the 7 interference items is used as a measure of pain interference. Validity and reliability are high in various chronic pain populations (0.77 – 0.91).[33–35] The internal consistency for both pain severity and interference scores was greater than $\alpha = 0.92$ for this study.

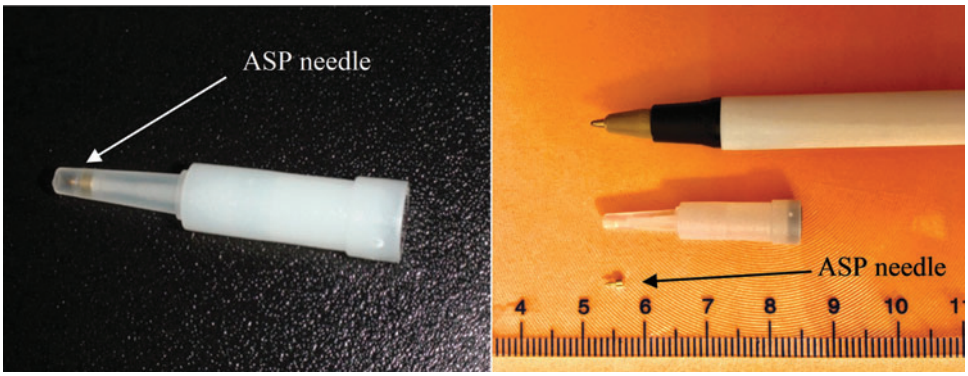

FIG. 2. Two views of Aiguille Semi-Permanente (ASP) needle.

Insomnia Severity Index. Insomnia was measured by the 7-item ISI,[36] which is used to assess perceived severity and impact of insomnia symptoms, scored on a 5-point Likert scale with a total score from 0 to 28 with >14 indicating moderate-to-severe insomnia. The sensitivity and specificity are 94% using a cutoff score of 14. The ISI has demonstrated good test–retest face validity (0.78) as defined by the *Diagnostic and Statistical Manual of Mental Disorders—IV*,[37] and concurrent validity (0.32 – 0.99).[36] Internal consistency for this study was $\alpha = 0.78$ for day 1, $\alpha = 0.77$ for day 4, and $\alpha = .84$ for day 8.

Sample Size

Power analysis was performed using G*Power software[38,39] for this 2×3 (group × time) design, setting the parameters at a power of $1 - \beta = 0.8$, a level of significance of $\alpha = 0.05$, and an autocorrelation parameter ranging from 0.3 to 0.7. To detect a 40% decrease in pain score, or a mean change in pain score of ~ 3.6, a sample size of ~ 32, with 16 subjects in each group, was required.

Statistical Methods

IBM SPSS Statistics for Windows (version 22.0) was used for data analysis. Repeated measures analysis of variance (ANOVA) with time as a within-subject factor and group as a between-subjects factor was used to examine the treatment effects of pain severity, pain interference, and insomnia. One-way ANOVA was used to analyze quantitative variables (e.g., age, credibility scores). Categorical variables were analyzed using χ^2 tests.

RESULTS

Participant Flow

The research team screened 110 potential participants between November 2014 and June 2017. Of these, 63 participants were excluded for not meeting the inclusion criteria. Thus, 47 participants signed the consent forms and were enrolled into the study. Two participants withdrew prior to randomization due to conflicts in their personal schedules. As such, 45 participants were randomized to either the AAG ($n = 22$) or the CG ($n = 23$). See Figure 3.

Baseline Data

The average age of the sample was 45 (SD = 10.5; range: 24–64). The majority of the study participants were female (56%), married (87%), Caucasian (77%), and highly educated with college- (27%) or graduate-level degrees (47%). For the military-related background variables, the majority of participants were family members (38%) or active-duty service members (36%). The average number of medical conditions was 5.6 (SD = 3.0). The top five medical issues were (1) back pain (75.6%); (2) chronic pain (73.3%); (3) joint pain (66.7%);

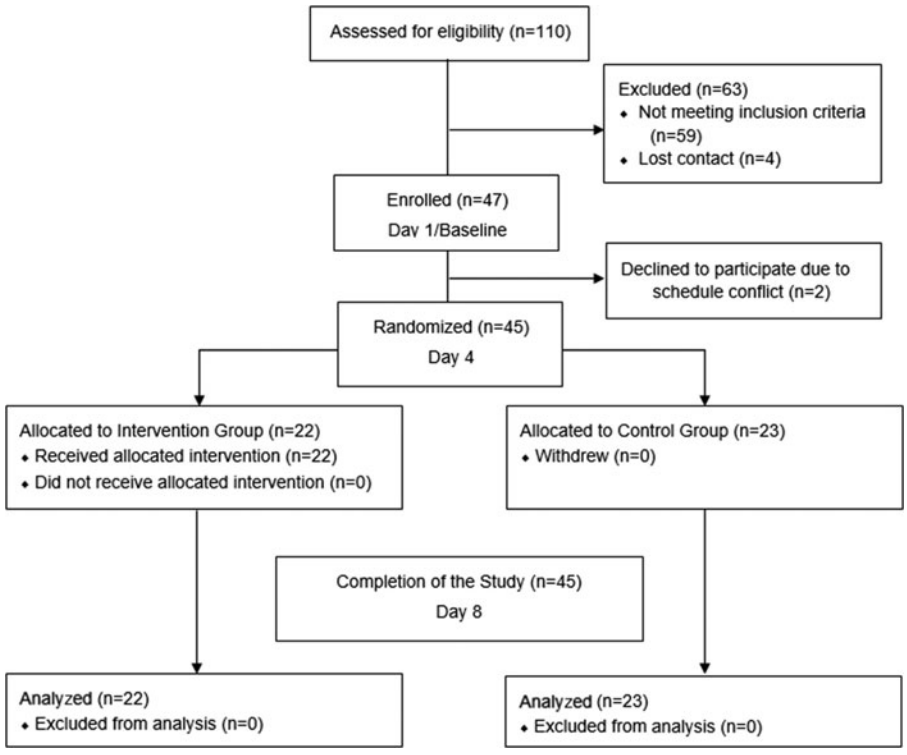

FIG. 3. *Con*solidated *S*tandards *o*f *R*eporting *T*rials (CONSORT) diagram.

(4) sleep disorder (51.1%); (5) and headache (42.2%). There were no differences in baseline characteristics between the groups, except in the total number of medical issues $F(1, 43) = 14.01$, $P = 0.001$. See Table 1.

Feasibility and Credibility

As shown in Figure 3, the feasibility of conducting the study was shown by the number of potential participants who were interested in the study. Most importantly, the retention of participants was 96% for the study.

Credibility was high in both groups for auricular acupuncture treatment of pain and sleep problems (Table 2). For the full sample ($n = 45$), the test of between-group differences via one-way ANOVA was not significant for the total credibility pain score, $F(1, 42) = 0.79$, $p = 0.378$, and the total credibility sleep score, $F(1, 42) = 0.46$, $p = 0.502$.

Primary Outcomes

BPI Pain Severity and Interference (Fig. 4). The two-way interaction (group × time) was significant for the BPI mean pain severity score: $F(2, 82) = 9.17$, $p = 0.001$. The nature of the interaction was such that that the AAG had a higher mean than the CG on day 1 and on day 4, whereas the CG had a higher mean on day 8. The two-way interaction (group × time) was significant for the mean pain interference score: $F(2, 80) = 4.66$, $p = 0.012$. The AAG had a higher mean than the CG on day 1 and on day 4, whereas the CG had a higher mean on day 8, indicating that at day 8, the AAG's pain level had less of an impact in the overall areas of daily functioning. Of the 7 daily functioning scores, there was a significant impact on sleep and enjoyment of life. See Table 3.

ISI. The two-way interaction (group × time) was significant for the total ISI score: $F(2, 84) = 7.03$, $p = 0.002$. See Figure 4 and Table 3. The AAG had a higher mean ($M = 19.5$) than the CG ($M = 18.3$) at day 1 and at day 4 ($M = 17.9$ for AAG versus $M = 16.0$ for CG) whereas the CG had a higher mean than the AAG at day 8 ($M = 15.7$ for CG versus $M = 13.1$ for AAG).

Adverse Events

Nine adverse events were reported in seven participants. These included pain, irritation, or redness at the insertion

Table 1. Baseline Characteristics of Participants

Characteristics	*CG* (n = *23*)	*AAG* (n = *22*)	*Total* (n = *45*)	p-*value*
Age, mean (SD)	42.4 (9.4)	47.7 (11.0)	45.0 (10.5)	NS
Female gender, *n* (%)	12 (52.2)	13 (59.0)	25.0 (55.6)	NS
Marital status, *n* (%)				NS
Married	20 (87.0)	19 (86.4)	39 (86.7)	
Single/divorced	3 (13.0)	3 (13.6)	6 (13.3)	
Ethnicity, n (%)				NS
Caucasian	19 (82.6)	13 (59.1)	32 (77.1)	
African American	1 (4.3)	2 (9.1)	3 (6.7)	
Hispanic	3 (13.0)	3 (13.6)	6 (13.3)	
Other	0 (0.0)	4 (18.1)	4 (8.9)	
Education level, *n* (%)				NS
High-school graduate	1 (4.3)	0 (0.0)	1 (2.2)	
Some college	4 (17.4)	7 (31.8)	11 (24.4)	
College degree	4 (17.4)	8 (36.6)	12 (26.7)	
Graduate degree	14 (60.9)	7 (31.8)	21 (46.7)	
Service, *n* (%)				NS
Active duty	10 (43.5)	6 (27.3)	16 (35.6)	
Retired	3 (13.0)	7 (31.8)	10 (22.2)	
Spouse	9 (39.1)	8 (40.9)	17 (37.8)	
Not answered	1 (4.3)	0 (0.0)	1 (2.2)	
Rank, *n* (%)				NS
Enlisted	10 (43.5)	12 (54.5)	22 (49)	
Officers	10 (43.5)	4 (18.2)	14 (31)	
Not answered	3 (13.0)	6 (27.3)	9 (20)	
Total # of medical conditions, mean (SD)	4.1 (2.4)	7.1 (2.9)	5.6 (3.0)	0.001

p-values calculated using χ^2 for categorical variables and one-way analysis of variance for quantitative variables.
CG, control group; AAG, auricular acupuncture group; SD, standard deviation; NS, nonsignificant.

Table 2. Credibility Scores for Pain and Sleep

Scores	*CG* (n = *23*)	*AAG* (n = *22*)	*Total* (n = *45*)	p-*value*
Credibility score, mean (SD)				
Pain	30.4 (4.0)	29.0 (6.2)	29.8 (5.1)	NS
Sleep	27.1 (5.3)	28.2 (5.6)	27.6 (5.4)	NS

One-way ANOVA was used to test the difference between groups.
CG, control group; AAG, auricular acupuncture group; SD, standard deviation, NS, nonsignificant.

sites. Two participants reported being ''light headed'' immediately after the insertion. This effect resolved prior to the patients leaving the clinic. Although auricular acupuncture can cause associated pain/discomfort, inflammation at the insertion site, dizziness, local bleeding, nausea, or headache, these events are typically transient, minor, and tolerable in nature.[18] No participants sought, or were referred for medical attention.

DISCUSSION

This is the first study conducted to test the feasibility and credibility—and to determine the impact—of a standard auricular acupuncture protocol on chronic pain and sleep problems in military beneficiaries. The majority of ongoing studies of acupuncture in military populations are conducted in the Department of Veterans Affairs and include the effect

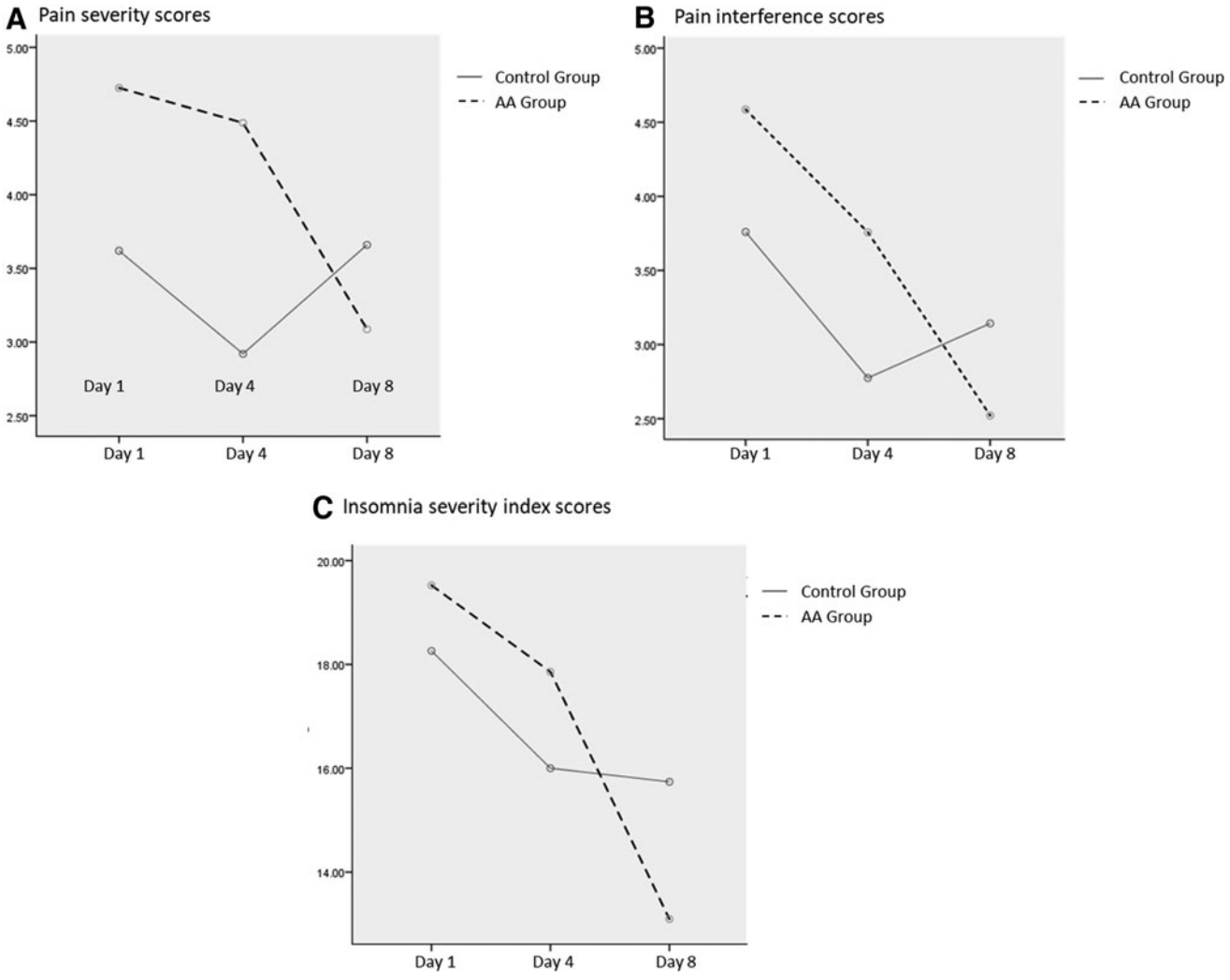

FIG. 4. Mean scores at three timepoints. **(A)** Pain severity scores. **(B)** Pain interference scores. **(C)** Insomnia severity index scores.

Table 3. Outcome Measures for Pain and Sleep

	CG			*AAG*			
	Day 1	*Day 4*	*Day 8*	*Day 1*	*Day 4*	*Day 8*	p-*value*
Pain Severity, mean (SD)	3.6 (1.7)	2.9 (1.8)	3.6 (2.3)	4.7 (2.0)	4.5 (2.2)	3.1 (1.8)	.001
Pain Interference, mean (SD)	3.8 (2.2)	2.8 (2.4)	3.1 (2.4)	4.6 (2.1)	3.8 (2.3)	2.5 (1.9)	.012
General activity	3.8 (2.5)	3.0 (2.7)	3.5 (2.6)	4.8 (2.3)	4.0 (1.8)	3.0 (2.0)	NS
Mood	4.0 (2.3)	2.6 (2.1)	3.3 (2.9)	4.6 (2.6)	3.1 (2.5)	2.5 (2.0)	NS
Walking ability	3.3 (2.8)	2.3 (2.3)	2.5 (2.3)	4.6 (3.1)	3.9 (2.8)	2.5 (2.4)	NS
Normal work	3.4 (2.5)	2.6 (2.6)	3.0 (2.4)	3.8 (2.1)	3.5 (2.3)	3.0 (2.4)	NS
Relationships	2.6 (2.7)	2.0 (2.5)	2.2 (2.3)	3.0 (2.4)	3.1 (2.7)	1.9 (2.1)	NS
Sleep	5.2 (2.6)	4.0 (3.2)	4.3 (3.3)	5.9 (2.6)	4.8 (3.0)	3.1 (2.2)	.018
Enjoyment of life	4.0 (2.7)	2.8 (2.8)	3.3 (2.9)	5.5 (2.9)	4.1 (2.8)	2.6 (2.3)	.007
ISI, mean (SD)	18.3 (5.2)	16.0 (5.5)	15.7 (6.1)	19.2 (4.1)	17.9 (3.3)	13.1 (5.1)	.002

p-values were calculated using a repeated-measures analysis of variance.

CG, control group; AAG, auricular acupuncture group; ISI, Insomnia Severity Index; SD, standard deviation; NS, nonsignificant.

of acupuncture on sleep difficulties related to post-traumatic stress disorder (PTSD)/traumatic brain injury (TBI), acute pain, and headaches related to TBI.[40–42]

For the feasibility aspect of the study, it was determined that training providers in the auricular acupuncture protocol and administration of the auricular acupuncture protocol to participants were uncomplicated. A very high participant-retention rate for the short study period, no withdrawal in either group after randomization, the ability to train providers with a brief training curriculum to administer auricular acupuncture safely, and high credibility of auricular acupuncture as a treatment for pain and sleep problems all indicated that auricular acupuncture was a feasible treatment.

The use of the standard auricular acupuncture protocol led to significant within- and between-group reduction in pain severity and interference scores, compared to usual care. The positive findings regarding pain severity and interference scores were consistent with Asher et al.'s[20] meta-analysis of auriculotherapy RCTs, in which auriculotherapy produced better outcomes than placebo pills, sham acupuncture, or usual care for acute- and chronic-pain management. A wide variation existed in use of acupuncture interventions (e.g., sites of auricular acupuncture, laser stimulation, acupressure, and sites for sham points), outcome measures, and years of experience for the administering acupuncture specialists. Thus, the current study provided useful information on the effect of a standard auricular acupuncture protocol on chronic pain on a widely accepted outcome measure for pain.

Both the AAG and CG had significant within-group decreases in insomnia severity, but the AAG had a significant reduction in ISI severity scores from moderate to subthreshold insomnia. A 2016 meta-analysis of 30 RCTs of various acupuncture methods for insomnia ($n = 2363$), compared to sham/placebo (3 studies) and pharmacotherapy (27 studies), revealed statistically significant results for acupuncture in reduction of insomnia.[43] Of the various sleep outcome measures, the Pittsburgh Sleep Quality Index and a one-item sleep quality question were the most commonly used measures. Use of the ISI—a well-accepted measure of insomnia in both clinical and research settings—for the current study and the reductions of insomnia severity adds further knowledge on the evaluation of the effects of auricular acupuncture on insomnia.

There has been much discussion about the role of belief or treatment credibility on treatment outcomes and/or drugs. A systematic review was conducted on 58 acupuncture-related RCTs on how credibility and expectations were measured and affected various pain outcomes (e.g., visual analogue scale, Short Form–36, etc.).[44] Twenty-nine of 49 studies were rooted in the rating used by Borkovec and Nau's Credibility Scale. The overall result on treatment expectancies, as reported by the direction of effect on outcomes (decreased, increased, or no effect) were mixed due to wide variations in questions and response scales as well as methodological differences. A secondary analysis of three RCTs with 116 participants to determine the predictors (sociodemographic variables, clinical characteristics, baseline sleep variables, and treatment expectancy) of a positive response to acupuncture for insomnia revealed that the numbers of years spent in full-time education was the main predictor of treatment responses[45.46] and not the expectation of the acupuncture. As the current participants were highly educated, it was not possible to eliminate the possibility that either the expectancy or being highly educated had an important influence on the outcomes. Hence, further analysis needs to be conducted to elucidate the predictors of positive responses.

Generalizability

Auricular acupuncture treatment was administered to participants with a variety of medical conditions, multiple

types of chronic pain, and a wide range in ages. However, these findings are only generalizable with providers and patients within the military setting due to the nature of the study.

Limitations

Although the retention rate for the study was high, there were many challenges to conducting the study as evidenced by the 3 years it took to complete the study. The movement of military personnel associated with conducting the study, the geographic spread of military bases from which the sample was drawn, and the potential for a military uniform violation to occur when wearing the ASP needles may have affected recruitment for qualified participants.

Other limitations of this study included: (1) lack of short or long-term follow up to assess the duration in the effectiveness of a one-time auricular acupuncture treatment on chronic pain and sleep difficulties; (2) lack of a sham acupuncture control condition; (3) lack of a comparison with cognitive-based therapy, which has shown to be more effective and had a longer effect at the 6-month period than traditional auricular acupuncture points[47]; and (4) lack of PTSD measurement as studies have found that there were high prevalence and association of sleep disorders with PTSD.[7,48] Future studies should include these important aspects to strengthen the study protocols.

CONCLUSIONS

This study was carried out to assess the feasibility and effectiveness of auricular acupuncture using a standard protocol both for chronic pain and insomnia. While there were challenges, qualified retention of participants and credibility of treatment were very high. Auricular acupuncture reduced pain and insomnia, compared to usual care. With the heightened focus on the opioid crisis in the United States today, this easy-to-administer protocol can be a treatment modality for military beneficiaries who have chronic pain and insomnia.

ACKNOWLEDGMENTS

The study team would like to thank all the practitioners, participants, and research assistants, especially Cheryl Napier, BA, who ensured rigor and completion of the study.

Registration

This study has been registered with clinicaltrials.gov under the study ID M-10395 OR NCT 03503695.

Funding

TriService Nursing Research Program (TSNRP), USU, HU0001-14-TS02 (P14-09). This research was sponsored by the TSNRP, Uniformed Services University (USU); however, the information or content and conclusions do not necessarily represent the official position or policy of, nor should any official endorsement be inferred by, the TSNRP, the USU, the DoD, or the U.S. government.

AUTHOR DISCLOSURE STATEMENT

The authors declare that there is no conflict of interest regarding the publication of this paper and they have no professional relationships with companies who might benefit from the results of this study.

REFERENCES

1. Alford DP, Krebs EE, Chen IA, Nicolaidis C, Bair MJ, Liebschutz J. Update in pain medicine. *J Gen Intern Med.* 2010;25(11):1222–1226.
2. Higgins DM, Kerns RD, Brandt CA, Haskell SG, Bathulapalli H, Gilliam W, Goulet JL. Persistent pain and comorbidity among Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn veterans. *Pain Med.* 2014;15(5):782–790.
3. Nahin RL. Severe pain in veterans: The effect of age and sex, and comparisons with the general population. *J Pain.* 2017;18(3):247–254.
4. Toblin RL, Quartana PJ, Riviere LA, Walper KC, Hoge CW. Chronic pain and opioid use in US soldiers after combat deployment. *JAMA Intern Med.* 2014;174(8):1400–1401.
5. Knutson K. Sleep and pain: Summary of the 2015 Sleep in America Poll. *Sleep Health.* 2015;1(2):85.
6. Ram S, Seirawan H, Kumar SK, Clark GT. Prevalence and impact of sleep disorders and sleep habits in the United States. *Sleep Breath.* 2010;14(1):63–70.
7. Alexander M, Ray MA, Hebert JR, et al. The national veteran sleep disorder study: Descriptive epidemiology and secular trends, 2000–2010. *Sleep.* 2016;39(7):1399–1410.
8. Jenkins MM, Colvonen PJ, Norman SB, Afari N, Allard CB, Drummond SP. Prevalence and mental health correlates of insomnia in first-encounter veterans with and without military sexual trauma. *Sleep.* 2015;38(10):1547–1554.
9. Department of Defense Deployment Health Clinical Center (DHCC). *Mental Health Disorder Prevalence Among Active Duty Service Members in the Military Health System, Fiscal Years 2005–2016*. Falls Church, VA Deployment Health Clinical Center, Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury Center; 2017.
10. Taylor MK, Hilton SM, Campbell JS, Beckerley SE, Shobe KK, Drummond SP. Prevalence and mental health correlates of sleep disruption among military members serving in a combat zone. *Mil Med.* 2014;179(7):744–751.

11. McLay RN, Klam WP, Volkert SL. Insomnia is the most commonly reported symptom and predicts other symptoms of post-traumatic stress disorder in U.S. service members returning from military deployments. *Mil Med.* 2010;175(10): 759–762.
12. Substance Abuse and Mental Health Services Administration. Detailed tables. In: Quality CfBHSa, eds. *2015 National Survey on Drug Use and Health:* Rockville, MD: Substance Abuse and Mental Health Services Administration; 2016.
13. Barlas FM, Higgins DM, Pflieger JC, Diecker K. *2011 Department of Defense Health Related Behaviors Survey of Active Duty Military Personnel: TRICARE Management Activity.* Fair-fax, VA: ICF International; 2013.
14. Veterans Administration/Department of Defense. Clinical practice guideline for opioid therapy for chronic pain. In: Office of Evidence Based Practice USAMC, eds. *The Office of Quality SaV.* Washington, DC: The Opioid Therapy for Chronic Pain Work Group: 2017.
15. Pearson NJ, Johnson LL, Nahin RL. Insomnia, trouble sleeping, and complementary and alternative medicine: Analysis of the 2002 National Health Interview Survey data. *Arch Intern Med.* 2006;166(16):1775–1782.
16. McPherson F, Schwenka MA. Use of complementary and alternative therapies among active duty soldiers, military retirees, and family members at a military hospital. *Mil Med.* 2004;169(5):354–357.
17. Smith TC, Ryan MA, Smith B, Reed RJ, Riddle JR, Gumbs GR, Gray GC. Complementary and alternative medicine use among US Navy and Marine Corps personnel. *BMC Complement Altern Med.* 2007;7:16.
18. Tan JY, Molassiotis A, Wang T, Suen LK. Adverse events of auricular therapy: A systematic review. *Evid Based Complement Alternat Med.* 2014;2014:506758.
19. Cabyoglu MT, Ergene N, Tan U. The mechanism of acupuncture and clinical applications. *Int J Neurosci.* 2006;116(2): 115–125.
20. Asher GN, Jonas DE, Coeytaux RR, Reilly AC, Loh YL, Motsinger-Reif AA, Winham SJ. Auriculotherapy for pain management: A systematic review and meta-analysis of randomized controlled trials. *J Altern Complement Med.* 2010; 16(10):1097–1108.
21. Chen HY, Shi Y, Ng CS, Chan SM, Yung KK, Zhang QL. Auricular acupuncture treatment for insomnia: A systematic review. *J Altern Complement Med.* 2007;13(6):669–676.
22. Niemtzow RC. Battlefield Acupuncture. *Med Acupunct.* 2007; 19(4):225–228.
23. Goertz CM, Niemtzow R, Burns SM, Fritts MJ, Crawford CC, Jonas WB. Auricular acupuncture in the treatment of acute pain syndromes: A pilot study. *Mil Med.* 2006;171(10):1010–1014.
24. Usichenko TI, Kuchling S, Witstruck T, et al. Auricular acupuncture for pain relief after ambulatory knee surgery: A randomized trial. *CMAJ.* 2007;176(2):179–183.
25. Federman DG, Poulin LM, Ruser CB, Kravetz JD. Implementation of shared medical appointments to offer Battlefield Acupuncture efficiently to veterans with pain. *Acupunct Med.* 2018:36(2):124–126.
26. Walker PH, Pock A, Ling CG, Kwon KN, Vaughan M. Battlefield Acupuncture: Opening the door for acupuncture in Department of Defense/Veteran's Administration health care. *Nurs Outlook.* 2016;64(5):491–498.
27. Niemtzow RC, Gambel J, Helms J, Pock A, Burns SM, Baxter J. Integrating ear and scalp acupuncture techniques into the care of blast-injured United States military service members with limb loss. *J Altern Complement Med.* 2006;12(7):596–599.
28. Federman DG, Gunderson CG. Battlefield Acupuncture: Is it ready for widespread dissemination? *South Med J.* 2017; 110(1):55–57.
29. Niemtzow RC. *U.S. Air Force Auricular Stimulation Procedure Training Booklet and Manual*. Andrews Air Force Base, MD: Malcolm Grove Medical Center; 2006.
30. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther Exp Psychiatry.* 1972;3(4):257–260.
31. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry.* 2000;31(2):73–86.
32. Cleeland CS, Ryan KM. Pain assessment: Global use of the Brief Pain Inventory. *Ann Acad Med Singapore.* 1994;23(2): 129–138.
33. Keller S, Bann CM, Dodd SL, Schein J, Mendoza TR, Cleeland CS. Validity of the Brief Pain Inventory for use in documenting the outcomes of patients with noncancer pain. *Clin J Pain.* 2004;20(5):309–318.
34. Mendoza T, Mayne T, Rublee D, Cleeland C. Reliability and validity of a modified Brief Pain Inventory Short Form in patients with osteoarthritis. *Eur J Pain.* 2006;10(4):353–361.
35. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. *J Pain.* 2004;5(2):133–137.
36. Bastien CH, Vallieres A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Med.* 2001;2(4):297–307.
37. American Psychiatric Association (APA). *Diagnostic and Statistical Manual of Mental Disorders–IV*. Washington, DC: APA; 1994.
38. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behav Res Methods.* 2009;41(4):1149–1160.
39. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods.* 2007; 39(2):175–191.
40. Clinicaltrials.gov. Online document at: www.clinicaltrials.gov Accessed January 2, 2018.
41. Jonas WB, Bellanti DM, Paat CF, et al. A randomized exploratory study to evaluate two acupuncture methods for the treatment of headaches associated with traumatic brain injury. *Med Acupunct.* 2016;28(3):113–130.
42. King CH, Moore LC, Spence CD. Exploring self-reported benefits of auricular acupuncture among veterans with posttraumatic stress disorder. *J Holist Nurs.* 2016;34(3): 291–299.

43. Shergis JL, Ni X, Jackson ML, et al. A systematic review of acupuncture for sleep quality in people with insomnia. *Complement Ther Med.* 2016;26:11–20.
44. Prady SL, Burch J, Vanderbloemen L, Crouch S, MacPherson H. Measuring expectations of benefit from treatment in acupuncture trials: A systematic review. *Complement Ther Med.* 2015;23(2):185–199.
45. Yeung WF, Chung KF, Yu BY, Lao L. Response to placebo acupuncture in insomnia: A secondary analysis of three randomized controlled trials. *Sleep Med.* 2015;16(11):1372–1376.
46. Yeung WF, Chung KF, Yu YB, Lao L. What predicts a positive response to acupuncture? A secondary analysis of three randomised controlled trials of insomnia. *Acupunct Med.* 2017;35(1):24–29.
47. Bergdahl L, Broman JE, Berman AH, Haglund K, von Knorring L, Markstrom A. Sleep patterns in a randomized controlled trial of auricular acupuncture and cognitive behavioral therapy for insomnia. *Complement Ther Clin Pract.* 2017; 28:220–226.
48. Foster SN, Hansen SL, Capener DC, Matsangas P, Mysliwiec V. Gender differences in sleep disorders in the US military. *Sleep Health.* 2017;3(5):336–341.

Address correspondence to:
Betty K. Garner, PhD, ARNP
595 Haybale Court
Sparks, NV 89441

E-mail: betty.garner2011@yahoo.com