Feasibility and Acceptability of a Brief Acupuncture Intervention for Service Members with Perceived Stress

CDR Jane Abanes, PhD(c), DNP, NC, USN*; Cynthia Hiers†; Bethany Rhoten‡; Mary S. Dietrich§; Sheila H. Ridner||

ABSTRACT

Introduction

Given the role of perceived stress in disability and suicidality in the military, intervening early before service members become at risk for severe injuries, hospitalizations, and chronic disability could improve health outcomes. The purpose of this study was to explore the feasibility and acceptability of a standardized stress acupuncture (SSA) approach on perceived stress in U.S. military personnel. This study had the following aims: examine feasibility of recruitment for SSA and implementation of study procedures in preparation for a methodologically rigorous study; examine acceptability of SSA treatment in a sample of military personnel with perceived stress; and examine change in perceived stress and general health before and after SSA.

Materials and Methods

This was a single-arm, single-site study protocol which assessed the feasibility of SSA in 16 patients with perceived stress. Upon IRB approval and written informed consent, the participants received 4 weekly sessions of SSA which consisted of 6 acupuncture points.

Results

This study showed that recruitment and implementation of SSA is feasible in service members. Service members found SSA to be acceptable. Statistically significant increases were found on the energy/fatigue, well-being, and social functioning components of the Short Form Health Survey (SF 36) (reliable change: 50%, 56%, and 25% respectively, Cohen's d = 0.72-0.78, all p < 0.05). A statistically significant decrease in perceived stress based was found on the Perceived Stress Scale (PSS) (reliable change 63%, Cohen's d = 1.03, p = 0.001).

Conclusion

These results suggest that SSA is a feasible and acceptable treatment for perceived stress in military personnel. Preliminary findings suggest that SSA may be useful in improving energy/fatigue, social functioning, and perceived stress of service members.

INTRODUCTION

The Global War on Terrorism (GWOT) has resulted in increased rates of mental health problems in military person-

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nel as 35% of deployed and 30% of non-deployed active duty service members endorsed stress-related symptoms requiring mental health treatments. High stress in military families is common as 20% of those who were deployed to Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) and 18% of non-deployed service members experienced debilitating problems such as depression, anxiety, and stress symptoms.1 Perceived stress exacerbates psychological risk factors that contribute to mood disorders, adjustment disorders, anxiety-related disorders, chronic stress disorders, substance-related disorders, and suicide.² Eighty-four percent of active duty service members who have committed suicide have experienced perceived stress.² Given the sequela of perceived stress in military personnel and the continued rise in mental health concerns within this population, research investigating interventions that alleviate stress is paramount.

Acupuncture has been shown to prevent chronic stress as well as improve the complications of posttraumatic stress.^{3–5} The effects of acupuncture are mediated by the sympathetic nervous system (SNS) and the hypothalamic-pituitary-adrenal (HPA) axis.⁴ By blocking the chronic stimulation of the HPA, acupuncture may reduce the physiologic effects of acute stress.⁴ Findings from previous research provide evidence that by maintaining homeostasis in one's stress response process,

^{*}Department Head, Mental Health, Naval Hospital, Camp Pendleton, CA, PSC 482 BOX 2903, FPO, AP 96362.

[†]James H. Quillen, VA Medical Center, 130 Burning Oaks Dr., Sevierville, TN 37876.

[‡]Vanderbilt University School of Nursing, 461 21st Avenue South, Nashville, TN 37240.

[§] Vanderbilt University School of Medicine, Vanderbilt University School of Nursing, 461 21st Avenue South, Nashville, TN 37240.

Vanderbilt University School of Nursing, 461 21st Avenue South, Nashville, TN 37240.

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acupuncture could prevent allostatic load (i.e., the physiologic consequence of perceived stress from adverse psychosocial or physical events based on one's psychological risk factors and operation of the stress hormone system⁶). Five known studies have been conducted in the Military Treatment Facilities (MTFs) which investigate the effect of acupuncture for the treatment of posttraumatic stress disorder (PTSD), traumatic brain injury-related headaches, and sleep disturbances.^{3,7–10} Findings from a randomized control trial conducted at Walter Reed National Medical Military Center (WRNMC) showed that a Traditional Chinese Acupuncture (TCA) improved PTSD symptoms, depression, and pain compared with usual care.³ Another study at WRNMC showed that auricular acupuncture (AA) and TCA improved headaches and global pain compared with usual care.9 Thus, service members reported overall satisfaction with acupuncture and that AA improved sleep, relaxation, and pain.¹¹

While acupuncture styles such as TCA and AA show promising results, they have their challenges.^{3,11} TCA uses of a complex array of diagnostics and acupuncture points, relies on the practitioner's subjective assessment of the patient, and requires a great deal of time from both practitioner and service member. Although the use of ASP or Aiguille Semi-Permanente needles (i.e., semi-permanent needles used in AA) is considered brief and pragmatic, their insertion may be reported as painful by the patient. Meanwhile, some service members hesitate to receive ASPs, while wearing the military uniform, because the needles are visible on their ears. To mitigate these challenges, we propose a standardized stress acupuncture (SSA) approach to acupuncture treatment. SSA offers a pragmatic approach to acupuncture treatment in busy MTFs or operational environments. SSA is a standardized form of TCA acupuncture that includes acupuncture points shown to be effective in clinical practice in military personnel with stress (i.e., Koffman Cocktail consisting of six acupuncture points). 12,13 To this date, there is scarcity in research that investigates the feasibility and acceptability of this intervention in a military sample.

The overall goal of this study was to evaluate the feasibility and acceptability of SSA for perceived stress in service members. The aims of this study were as follows: (1) determine the feasibility of recruitment in service members to receive SSA treatment for perceived stress, (2) determine feasibility of implementation of study procedures, 14 (3) determine the acceptability of SSA treatment in a sample of military personnel with perceived stress, and (4) assess perceived stress and general health before and after SSA in the sample of patients who are receiving an SSA protocol. The expected outcomes for the above aims were the following: (1) participants will agree to receive SSA treatment for their perceived stress, (2) field notes and lessons learned will be recorded in preparation for a clinical trial with increased methodological rigor, (3) participants will report SSA to be acceptable as a treatment for perceived stress, and (4) that participants will report improved PSS and SF-36 scores at the completion of acupuncture treatment compared with baseline scores.

METHODS

Procedures

This was a single-arm, single-center pilot and feasibility study in Naval Hospital Camp Pendleton's (NHCP) Branch Health Clinic (BHC) Yuma, Arizona. Naval Medical Center San Diego (NMCSD) and Vanderbilt University granted IRB approval for this study. Participants were recruited from the Marine Corps Air Station (MCAS) Yuma from January 15 to February 2, 2018. Participants were screened for eligibility via telephone or in-person at a private office in the mental health department, and informed consent was obtained prior to the beginning of the study. 15 Active duty service members were considered eligible if they were: (1) 18 to 65 years of age, (2) Self-report of perceived stress for > 1 months, (3) A score of \geq 16 on the PSS, ^{15,16} (4) Stable on psychiatric and other medications for ≥ 3 months, and (5) Able to sign an informed consent. Exclusion criteria were: (1) Recent surgery within one month, (2) Alcohol abuse or dependence diagnosis within one month and active substance use/abuse/dependency treatment within one month, (3) Pregnancy, ¹⁷ and (4) History of acupuncture treatment in the past month.

Intervention

Service members who completed the study received acupuncture for a total of four weeks. Because this was a feasibility study, participants were not randomized and there was no control group for comparison. The research team consisted of the acupuncturist, psychologist, and psychiatric technician who were trained on the following research activities: recruitment, screening of eligible participants, proper procedures about reporting of adverse events and psychological distress, informed consent process, follow-up tracking procedures, and administration of surveys and questionnaires. The acupuncturist was a licensed, privileged Psychiatric Mental Health Practitioner (PMHNP) and trained acupuncturist with \geq seven years of experience in acupuncture therapy in the military setting. In addition, a licensed acupuncturist (i.e., LAc) was involved in the study as a peer reviewer and consultant as needed. Participants who completed the study received a six-point SSA treatment once a week for four weeks. The SSA consisted of GV-20, GV-24.5 (Yin Tang), bilateral LI-4, and bilateral LR-3 (see Figure S1). The sterile, disposable needles used were: SEIRIN[®] J-Type Sj.20×30 for GV-20 and GV-24.5SEIRIN[®] L-Type Lc.20×40 for LI-4 and LR-3. Needles in GV-20 and GV-24.5 were inserted subcutaneously in the depth of 0.3–0.5 inch and were not manipulated after insertion.¹⁸ Needles in LI-4 and LR-3 were inserted perpendicularly in the depth of 0.5-0.8 and 0.3-0.5 inch, respectively, and were manipulated to elicit the sensation of de qi. 17 The needles were left in place for 30 minutes per acupuncture session.

Treatment Fidelity

To assess adherence to the acupuncture protocol, a peer reviewer (i.e., licensed acupuncturist at NHCP) assessed the acupuncturist's delivery of the intervention. The gold standard in assessing that the intervention was delivered according to a priori criteria is to use either audiotaping or videotaping. Six SSA sessions were videotaped for this study. The details of videotaping were included in the informed consent signed by each participant. The peer reviewer provided necessary feedback to the practitioner in which the acupuncturist received 100% adherence on all six videos.

Measurements

Demographic data were obtained at the beginning of the study using a self-report questionnaire. If a session required completion of the paper questionnaires, participants completed those upon check-in. Prior to the first acupuncture treatment, those questionnaires included the demographic form, Acupuncture Expectancy Scale (AES), PSS, and SF-36 survey; the AES, PSS, and SF-36 were completed again after their last treatment in the study (week 4). Blood pressure (BP) of the right arm and heart rate (HR) measurements were obtained before each treatment, about five minutes after the participant's arrival to the mental health clinic.²⁰

Acupuncture Expectancy Scale (AES)

The AES is a 4-item questionnaire that measures the participants' expected responses to acupuncture. In an initial validation, the instrument's score had a Cronbach's α of $0.82.^{21}$ The AES has been found to be reliable, valid, and has acceptable sensitivity to change during treatment starting at week 4 of treatment with increasing statistically significant changes with more acupuncture treatments. The reliabilities of the scores for the two times of assessment in this study were both 0.90 (Cronbach's alpha).

Perceived Stress Scale (PSS)

The PSS is a 10-item scale that has been used to evaluate perceived stress experience in adults.²³ In a normative sample, the Cronbach's α for the scores ranged from 0.84 to 0.86.²³ The PSS has acceptable sensitivity to change in group scores starting at week 6 of acupuncture treatment.¹⁵ The reliabilities of the scores in this study were 0.72 (baseline) and 0.91 (post).

Short Form (SF) Health Survey

The SF-36 is a 36-item scale that measures the multidimensional concept of health including perceptions about general health, physical health, mental health, and social functioning.²⁴ The scores in prior work had internal consistencies ranging from 0.52 to 0.89.²⁵ This measure has moderate sensitivity in detecting changes in group scores using all SF-36 subscales.²⁶ The reliabilities of the baseline scores in this study ranged from 0.66 (General Health) to 0.93 (Physical Health); reliabilities of the scores at the end of the study ranged from 0.41 (Social Functioning) to 0.96 (Role Limitations due to Emotional Problems).

Data Analyses

The PI and another research team member exported deidentified study data individually from Microsoft Excel® into IBM SPSS Statistics software for analyses. The primary goals of the analyses were feasibility summaries and effect sizes; however, any tests of statistical significance maintained an alpha of 0.05 (p < 0.05). The research team (i.e., primary investigator, research mentor, and research assistant) delineated field notes and lessons learned in the implementation of this study through textual summaries. Descriptive statistics were used to summarize all study scores at baseline and at the end of study. Change values for each measure (end of study minus baseline) were generated and summarized using descriptive statistics and graphics. Wilcoxon Signed-Ranks test were used to evaluate the statistical significance of the simple change in each measure. Given measurement error inherent in psychosocial measures, reliable change indices (RCI) that took into account reliability of measurement were also generated for each study measure.^{27,28}

RESULTS

Feasibility

Recruitment

The recruitment for this study occurred over a three-week time period, after which, the research team removed advertisements to the study. Given the size of the BHC and the remote location of the MCAS, our goal for the sample size of this feasibility study was 15 participants. Table I summarizes the demographic and military characteristics of the participants completing the study. There were no statistically significant differences in demographic or military characteristics between the participants who completed the study and those who did not (p > 0.05).

Study Procedures

Training of study staff was conducted by the PI at the beginning of the study and then again weekly for four weeks and as needed throughout the study. Establishment of eligibility generally was conducted via telephone. The scripted screening process was effective and efficient for this study. The research team screened 34 service members within a three-week time frame. Twenty-two service members were eligible for the study and 16 completed the four-week intervention which makes the attrition rate 27% (see Figure S2). This rate is comparable to other acupuncture studies conducted in service members.^{7,29}

Acceptability

Acupuncture Expectation (AES)

Summaries of the AES scores at baseline, end-of-study, as well as changes in those scores are shown in Table II. Expectation scores at baseline were in the middle of the possible

TABLE I. Demographic Characteristics of the Sample

Demographic Characteristics	Total ($N = 16$
Age (Years) (Mean, SD)	29.6 (9)
Gender	
Female $(n, \%)$	4 (25)
Male (<i>n</i> , %)	12 (75)
Other $(n, \%)$	0 (0)
Race	
Asian or Other Pacific Islander $(n, \%)$	0 (0)
Black or African American, Non-Hispanic (n, %)	1 (6.3)
Caucasian, Non-Hispanic (n, %)	12 (75)
Hispanic $(n, \%)$	2 (12.5)
Other $(n, \%)$	1 (6.3)
Education Level	
High School $(n, \%)$	5 (31.3)
Some College, No Degree (<i>n</i> , %)	5 (31.3)
Bachelor's Degree $(n, \%)$	2 (12.5)
Master's Degree $(n, \%)$	3 (18.8)
Doctorate Degree $(n, \%)$	1 (6.3)
Marital Status	
Single $(n, \%)$	4 (25)
Married $(n, \%)$	12 (75)
Military Characteristics	
Enlisted $(n, \%)$	11 (68.8)
Officer $(n, \%)$	5 (31.3)
Branch of Service	0 (0)
Army $(n, \%)$	10 (62.5)
Marines (n, %)	6 (37.5)
Navy $(n, \%)$	4.7 (3.0–17.5
Years of Service (Median, IQR)	6 (37.5)
Deployed $(n, \%)$	
Clinical Characteristics	
Use Tobacco (n, %)	4 (25)
Use Alcohol (n, %)	11 (68.8)

range of scores. The median change in those scores was 1.8 points (min = -1.0, max = 1.8) and were not clinically or statistically significant (Cohen's d = 0.05, see Table II).

Preliminary Efficacy

Perceived Stress (PSS)

Perceived stress at baseline was in the middle of the possible range of scores (Median = 20.5, min = 16, max = 32). Median change in those scores was -6.5 points and was statistically significant (IQR = -10, -3, p = 0.001, Cohen's d = 1.03). Sixty-three percent (n = 10 of 16) demonstrated a clinically meaningful decrease in perceived stress over the course of the study) (see Table II).

Health

Summaries of the findings from the SF-36 measure are shown in Table III. Statistically and clinically significant increases in energy and social functioning as assessed by the SF-36 Energy/Fatigue and Social Functioning subscales were observed (p < 0.05). Median increase in Energy/Fatigue scores from baseline was 17.5 (maximum decrease = -30, maximum increase = 65, p = 0.009, Cohen's d = 0.78) with 50% (n = 8 of 16) demonstrating a reliable increase in scores from baseline.

Median increase in Social Functioning scores from baseline was 25.0 (maximum decrease = -38, maximum increase = 75, p = 0.018, Cohen's d = 0.72) with 56% (n = 9 of 16) demonstrating a reliable increase in scores from baseline. There was a statistically significant increase in the SF-36 Emotional Well-Being scores (median change = 10, maximum decrease = -8, maximum increase = 48, p = 0.004, Cohen's d = 0.77) yet only 25% of the participants (n = 4 of 16) demonstrated a clinically reliable increase in scores. No other statistically or clinically meaningful changes in the SF-36 scores were observed (p > 0.05, Cohen's d = 0.04 to 0.52, see Table III).

Blood Pressure/Heart Rate

There were no significant changes from baseline in the systolic and diastolic blood pressure readings, and heart rate measures (p > 0.05, Cohen's d = 0.01–0.19, see Table IV).

DISCUSSION

This study was the first study to determine the feasibility and acceptability of SSA in service members with perceived stress using the perceived stress scale. This was also the first study to determine the feasibility of recruitment for conducting SSA and treatment fidelity procedures using the gold standard. ¹⁹ The investigators of this study were also the first to assess the influence of acupuncture expectation in the acceptability of acupuncture in service members.

The results of this study showed that the feasibility of recruitment among active duty service members was acceptable. Many service members voluntarily asked to participate in the study to receive acupuncture treatments. Because this was a feasibility study conducted over a short period of time, the goal was to recruit only 15 people in the study. Considering previous barriers about seeking mental health treatments in service members, such as perceived stigma, subjects in this study were readily available to receive acupuncture for perceived stress.³⁰ The success of recruitment in this study may be attributed to engaging the leaders of the Marine Corps units in the recruitment process. Sending the flyer via email to the leaders who then sent the flyer to prospective participants may have been a major influence in our recruitment. This recruitment strategy is consistent with previous report that the support of leadership is an important influencer in how active duty service members seek help for their symptoms.30

This study demonstrated that the following study procedures were feasible: inclusion and exclusion criteria, eligibility process, informed consent procedures, and treatment fidelity methods. The high attrition rate in this study was associated with occupational and personal demands versus diminished interest in receiving the intervention. The acceptability in service members to receive acupuncture treatment was high as evidenced by service members continuing to inquire about the study even after the conclusion of recruitment time frame. An interesting result from this study was that participant expectations from the acupuncture treatment did not improve

TABLE II. Summaries of the Acupuncture Expectancy Scale (AES) and Perceived Stress Scale (PSS) and Measure Scores (N = 16)

					Reliable Change			
Measure	Baseline Median (IQR)	4-Week Median (IQR)	Change Median (IQR)	<i>p</i> -value	Decrease n (%)	No Change n	Increase n (%)	Effect Size (Cohen's d)
AES PSS	12.0 (8.3, 13.8) 20.5 (18.0, 0.0)	12.0 (8.0, 14.0) 13.0 (10.0, 20.3)	0.0 (-1.0, 1.8) -6.5 (-10.0, -3.0)	0.789 0.001	3 (18.8) 10 (62.5)	10 (62.5) 6 (37.5)	3 (18.8) 0 (0.0)	0.05 1.03

Note: Reliable changes take into account the reliability of the measure at baseline. Lower reliability of the measure will require a greater amount of change to be considered clinically meaningful than a measure with higher reliability.

TABLE III. Treatment Results on the SF-36 Measure (N = 16)

					Reliable Change			
Measure	Baseline Median (IQR)	4-Week Median (IQR)	Change Median (IQR)	<i>p</i> -Value	Decrease n (%)	No Change $n (\%)$	Increase n (%)	Effect Size (Cohen's d)
Energy/Fatigue	25.0 (20.0, 50.0)	47.5 (36.23, 68.8)	17.5 (5.0, 28.8)	0.009	1 (6.3)	7 (43.8)	8 (50.0)	0.78
Pain	58.8 (45.0, 90.0)	77.5 (67.5, 77.5)	5.0 (0.00, 35.6)	0.052	0(0.0)	12 (75.0)	4 (25.0)	0.50
General Health	67.5 (56.3, 78.8)	75.0 (57.5, 80.0)	5.0(-3.8.10.0)	0.105	0(0.0)	15 (93.8)	1 (6.3)	0.33
Social Functioning	68.8 (28.1, 93.8)	87.5 (28.1, 93.8)	25.0 (-9.4, 50.0)	0.018	1 (6.3)	6 (37.5)	9 (56.3)	0.72
Emotional Well-Being	62.0 (44.0, 68.0)	74.0 (61.0, 86.0)	10.0(-1.00, 19.0)	0.004	0(0.0)	12 (75.0)	4 (25.0)	0.77
Limitations Due to Emotions	66.7 (33.3, 100.0)	100.0 (75.0, 100.0)	16.7 (0.00, 66.7)	0.176	0 (0.0)	12 (75.0)	4 (25.0)	0.52
Physical Functioning	92.5 (80.0, 100.0)	95.0 (85.0, 100.0)	0.0(-3.8, 5.0)	0.223	0 (0.0)	15 (93.8)	1 (6.3)	0.22
Limitations Due to Physical Health	100.0 (31.3, 100.0)	100.0 (56.3, 100.0)	0.0 (-18.8, 0.0)	0.931	4 (25.0)	9 (56.3)	3 (18.8)	0.04

Note: Reliable changes take into account the reliability of the measure at baseline. Lower reliability of the measure will require a greater amount of change to be considered clinically meaningful than a measure with higher reliability.

TABLE IV. Treatment Results on the Blood Pressure (BP) and Heart Rate (HR) Measures (N = 16)

Measure	Baseline Median (IQR)	4-Week Median (IQR)	Change Median (IQR)	<i>p</i> -value	Effect Size (Cohen's d)
Systolic BP	127.0 (117, 138)	130.5 (123, 141)	-0.50(-5.11)	0.426	0.19
Diastolic BP	76.5 (68, 82)	76.0 (64, 86)	-1.50(-9,6)	0.605	0.09
HR	67.5 (61, 76)	65.0 (62, 73)	3.5 (-11, 9)	0.623	0.01

after four weekly treatments based on AES scores. Despite this lack of change in participants' expectations, their perceived stress scores have improved at the end of the study. Before this study, it was unknown if SSA will improve one's perceived stress in service members. The authors met the expected outcome that a four-week SSA will improve the participants' PSS scores.

LIMITATIONS

Given that this is a feasibility study with only one group, there were several limitations that must be considered while interpreting our findings: the sample size was small, and the lack of comparison group to control for other confounding variables may have influenced the results. The service members stationed in the air wing community may also be different compared with those in the infantry divisions or other support groups. Further studies with rigorous designs and methods, including having a control group and a larger sample size, are needed to make the results more generalizable to other

groups. Another limitation of this study was the lack of a qualitative approach in investigating the acceptability of the intervention for perceived stress, general health, and acupuncture expectation. Future studies that provide subjective findings may delineate the person's perception of acupuncture based on the participant's own perspectives. Finally, because this study was conducted within a short period, the duration of the participants' relief from stress, post-protocol, remains unknown. Longitudinal studies that investigate the duration of improvement are needed.

CONCLUSIONS

The SSA used in this study is pragmatic and required minimal effort for both the practitioner and patient. Future research that investigate SSA for perceived stress, chronic stress, emotional and physical health, and pain, in comparison with other treatment modalities, may be considered by investigators. Future studies with methodological rigor are needed to solidify the findings from this study.

SUPPLEMENTARY MATERIAL

Supplementary material is available at Military Medicine online.

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INSTITUTIONAL APPROVAL FOR THE STUDY

This protocol titled, "Feasibility and acceptability of a brief acupuncture intervention for service members with perceived stress" was reviewed and recommended for approval on 28 December 2017 by the Naval Medical Center San Diego (NMCSD) Institutional Review Board, DOD Assurance number DOD-N40005. The research was conducted in compliance with all relevant federal regulations, Department of Defense directives, Department of the Navy instructions, and state and local laws for the protection of human research subjects.

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