Pilot Study: Effect of Battlefield Acupuncture Needle Selection on Symptom Relief and Patient Tolerance in the Treatment of Pain

NCT04464954

Feb 16, 2021

EIRB Protocol Template (Version 1.6)

1.0 General Information

***Please enter the full title of your study:**

Pilot Study: Effect of Battlefield Acupuncture Needle Selection on Symptom Relief and Patient Tolerance in the Treatment of Pain

***Please enter the Protocol Number you would like to use to reference the protocol:**

FWH20200117H
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**USAF** - 99 MDG/MOFMC

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Crawford, Paul F

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Crawford, Kristy J, BSN
Site Investigator
Crawford, Kristy J, BSN

Associate Investigator
Moss, David
Associate Investigator
Moss, Jennie B
Associate Investigator
Tate, Rachel A
Associate Investigator

B) Research Support Staff

Bogdanovich, Tracy Lee
Research Coordinator
Clark, Jill Marie, MBA/HCM
Research Coordinator
Crawford, Amanda J
Research Coordinator
Crawford, Kristy J, BSN
Research Coordinator
Estrada, Jonica
Research Coordinator
Haney, Thomas A
Research Coordinator
Huffman, Sandra G
Research Coordinator
Moss, Jennie B
Research Coordinator
Shaffer, Daniel WILLIAM
Research Coordinator
Tate, Rachel A
Research Coordinator

3.3 *Please add a Protocol Contact:

Clark, Jill Marie, MBA/HCM
Crawford, Paul F
Huffman, Sandra G

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

4.2 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

(•) Yes ( ) No

4.3 What type of research is this?

- [ ] Biomedical Research
- [ ] Clinical trial (FDA regulated)
- [ ] Behavioral Research
- [ ] Educational Research
- [ ] Psychosocial Research
- [ ] Oral History
- [x] Other

Describe other:

Operational Testing and Evaluation

4.4 Are you conducting this project in pursuit of a personal degree?

( ) Yes (•) No

4.6 * Is this human subjects research? (As defined by 32 CFR 219)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

(•) Yes ( ) No

4.7 * Do you believe this human subjects research is exempt from IRB review?

( ) Yes (•) No

5.0 Personnel Details

5.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Burton, Samuel 2d Lt	(703) 600-9209	samuel.burton@usuhs.edu	USUHS

Role on Protocol:

Associate Investigator			

5.2 Will you have a Research Monitor for this study?

- ○ Yes
- ○ No
- ◉ N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
No records have been added		

Total amount of funding:

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

○ Yes ◉ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
Air Force	99MDG /Nellis AFB	Performance site	P60002	03/27/2021	:IAIR	WHASC IRB

						: Protocol Office

Other:

	Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site	
No records have been added							

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.4 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

○ Yes ○ No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Battlefield acupuncture, pain

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

The use of acupuncture has increased in popularity and scope in the United States over the last several decades with some 20 million Americans estimated to have tried acupuncture at least once and between 2000 and 2010 acupuncture visits tripled[1]. Though acupuncture is used to treat many ailments such as nausea, allergies, hot flashes, etc., it's most common use is for alleviation of pain. The way that acupuncture reduces pain is explained largely by "gate theory" first cited in western literature in 1965 by Dr. Ronald Melzack[2] "The gate control theory of pain … proposes that a mechanism in the dorsal horns of the spinal cord acts like a gate that inhibits or facilitates transmission from the body to the brain on the basis of the diameters of the active peripheral fibers, as well as the dynamic action of brain processes"[2] The pain theory was expanded further by neuroscientist Zang-Hee Cho in 1998 via functional MRI when he showed that the visual and auditory cortices of the brain were stimulated during acupuncture. He drew further conclusions concerning the activation of beta-endorphins through the endocrine and autonomic systems which gave objective data to support gate theory.[3] Although this and

other studies have shown promising insights into the physiological mechanisms behind acupuncture, there have been considerable doubts raised against acupuncture's place in treating pain.

In 2009, a meta-analysis synthesized data from 13 RCTs comparing acupuncture, sham-acupuncture, and no acupuncture in the treatment of pain. The authors concluded that a small analgesic effect was found when comparing acupuncture and sham acupuncture to no acupuncture, however, it was unclear if this effect was clinically significant. They state in their conclusion that, " Whether needling at acupuncture points, or at any site, reduces pain independently of the psychological impact of the treatment ritual is unclear.[4] However, in 2018 a meta-analysis using 39 trials and over 20,000 patients compared pain and function outcomes of acupuncture, sham-acupuncture and no acupuncture. They found a 0.5 SD difference between acupuncture and no acupuncture and 0.2 SD difference with sham acupuncture which were both significant at $P<0.001$ in the short term and even at one year 15% improvement[5]. Another meta-analysis of 59 trials, but only 4980 patients validated its use in treating musculoskeletal pain specifically[6]. In 2018, the academy of family physicians (AAFP) cited several other studies that further supported the effective nature of acupuncture for chronic pain making acupuncture practice for pain that more mainstream[7] and in 2019, Medicaid began coverage acupuncture for the treatment of lower back pain in conjunction with NIH trials due to the mounting evidence and a desire to combat the opioid epidemic.[8] Other government departments have implemented acupuncture for similar reasons.
Acupuncture, among other pain management modalities, was studied at length by a task force in 2009 and 2010 with representation from Army, Navy, Air Force and the Veterans Affairs (VA). They ultimately made 109 recommendations for pain management that included the integration of acupuncture[9]. The Department of Defense (DOD) began employing acupuncture to treat a wide array of conditions such as post-traumatic stress disorder, traumatic brain injury, polytrauma, and musculoskeletal pain at dozens of MTFs[10]. Funding for training and education was provided from a joint incentive fund (JIF) including $5.4 million that was shared between the DOD and the VA and ultimately led to standard teaching of battlefield acupuncture (BFA)[11]. BFA is a subcategory of auricular/ear acupuncture that gained its name because of the rapid way and in the austere environment in which it could be applied. USAF Col (Ret) Richard Niemtzow originally introduced and advocated for BFA as an efficient, cost-effective means to treating acute pain on the battlefield while still allowing active duty military members to return to duty with limited interference on capability[12]. Several pilot studies and case studies in the military have strengthened advocacy for and expanded application of BFA in the acute treatment of MSK among many other ailments[13]. In one focused trial at Nellis AFB, 172 patients were observed over the course of one year for treatment of chronic pain and they found a 45% reduction in opioid use and comparable reductions in muscle relaxants and NSAID use. Furthermore, they reported improved pain control and functionality[14].

Training providers on how to perform BFA is streamlined in the DOD. Where it used to be a course reserved for physicians, it is now taught to nurse practitioners, physical therapists, medical technicians and special forces providers[10] and can be completed in 4 hours for Level 1 and 8 hours for Level 2 training [16]. BFA training was originally centralized at Andrews AFB under Dr. Niemtzow at the center of acupuncture and integrative medicine (AIM). Although it is now taught at many sites in the DOD and VA by hundreds of instructors, the approach remains the same and includes a stepwise progression of needles into five different points in the ear: Cingulate Gyrus on one ear then the other followed sequentially by the Thalamus, Omega 2, point zero and Shen Men. After each needle the patient's pain is reassessed. If analgesic effect is reached, there is no need to continue with the subsequent needles.[15] Th e common needles in DOD practice are found in the chart below provided in a recent procedure instruction by the Defense Health Agency (DHA) in February 20, 2020[16]:

Needle J-type No2 (.18) x 15 mm
Needle L-type No3 (.20) x 30mm
Needle L-type No5 (.25) x 40mm
Needles L-type No5 (.25) x 60mm
ASP Auricular Semi-Permanent needles, Gold
ASP Auricular Semi-Permanent needles, Stainless Steel
Pyonex Press Needles by Seirin Yellow, 0.2 x 0.6 mm
Pyonex Press Needles0.2 x 0.9 mm

In the same report the DHA codified BFA and other forms of acupuncture and the common clinical settings in which it can be administered. Despite the wide acceptance of BFA in the DHA and the

VA and the recently published procedural instruction there is no research that compares the commonly used needles against one another in terms of patient preference and treatment outcome. The Las Vegas VA Medical Center has chosen to use pyonex needles exclusively because of improved patient compliance whereas the DOD seems to prefer the ASP needles for ease of administering, but neither practice is well substantiated by research. This pilot study will seek to answer the question of if there is any significant difference between BFA needles and if so which has best overall results when considering both symptom relief and patient tolerance of treatment.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions/hypotheses

Aim

The aim of this pilot study is to conduct an unblinded pilot randomized clinical study on the effectiveness and tolerability of auricular semi-permanent (ASP) vs intradermal (long), and pyonex needles in Battlefield Acupuncture (BFA) for the treatment of pain.

Goals

1) Begin to identify which of 3 needles is most efficacious for BFA treatment of pain; 2) Identify patient experiences and tolerance of three commonly used acupuncture needles at Mike O'Callaghan Military Medical Center at Nellis Air Force Base. This study will compare 30 patients (10 per needling group) and will serve as a pilot study for a potential larger randomized control trial (RCT) across multiple MTFs in the Defense Health Agency (DHA) to establish better BFA care practices. We will be recruiting a total of 39 subjects, which is inclusive of a 30% drop out rate to accommodate those that may be lost to the study or have missing data to achieve a final total of 30 subjects.

Hypothesis

1) There is a difference in BFA effectiveness and tolerance between ASP, long, and pyonex needles for the treatment of acute MSK pain. 2) Pyonex needles are the most effective and tolerated acupuncture needle for the BFA treatment of pain.

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

Randomized clinical trial comparing ASP, long, and pyonex needles by recruiting and treating 13 patients per group with the goal of analyzing at least 10 patients' questionnaires per group comparatively for effect and tolerance of different BFA needles.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active Duty members and DoD beneficiaries, 18 years or older, meeting the inclusion/exclusion criteria will be recruited.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

BFA use and application is widespread. Needle phobia prevents many patients from seeking care, and prior experience with painful ASP needles prevents patients from returning for a second treatment. If we determine that other, less painful needles are as effective and better tolerated as ASP needles, then the uptake of acupuncture in the DoD will increase.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Active duty members and DoD beneficiaries, age 18 years or older, meeting the inclusion/exclusion criteria will be offered an opportunity to participate. They will be recruited from the clinics located at 99MDG (Nellis AFB). All of the below items are research-related unless marked as 'standard of care':

Screening visit:
-Obtain and document signed Informed Consent document and HIPAA Authorization
-Review past medical history to verify the inclusion/exclusion criteria
-Collect date of birth, age, gender, contact information, DoD ID number, name of standard of care medications (over-the-counter and prescription)
-Women of child bearing potential will be reminded that they only reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, intrauterine device (IUD), or sperm-killing products are not totally effective in preventing pregnancy. They will be asked to alert study staff if they become pregnant or feel that they might be pregnant.

Randomization: Subjects will be randomized using a random number generator using simple randomization into 1 of 3 research treatment groups, with approximately 13 subjects in each arm:
Group 1: Auricular semi-permanent (ASP gold) needles
Group 2: Intradermal (long) needles using J-type No. 1 (.16) x 15mm
Group 3: Pyonex Pink 1.5mm (0.2 x 1.5mm)

Treatment Visit (Day 0) (may be the same day as screening visit):
-Subjects will complete the Defense and Veterans Pain Rating Scale (DVPRS) and DVPRS Supplemental Questionnaire before treatment.
-Subjects will be prescribed naproxen 220 mg BID (twice a day) #15 as standard of care treatment for pain (unless they refuse or have a contraindication for use)
-Subjects will be given treatment according to their randomization group following the Acupuncture Procedure[15] below: Step 1: Either the left or right ear is chosen for the placement of the needles per provider or patient preference. Step 2: Needles will be placed in the following points on the chosen ear: Cingulate Gyrus, Thalmus, Omega 2, Point Zero, and Shen Men. Step 3: If the patients desires further pain reduction, acupuncture needles will be placed in the same points in the opposite ear. The maximum number of needles in each ear is 5.

Post-Treatment (10-15 minutes Post Treatment) In-person:
-Subjects will complete the DVPRS and DVPRS Supplemental Questionnaire.
-Subjects will complete the Needle Tolerance Questionnaire.

Contact 1 (24 hours Post Treatment +/- 4 hours) In-person, via telephone, Survey Monkey or Google Docs:
-Subjects will complete the DVPRS and DVPRS Supplemental Questionnaire.
-Subjects will complete the Needle Tolerance Questionnaire.

Contact 2 (7 days Post Treatment +/- 2 days) In-person, via telephone, Survey Monkey or Google Docs:
-Subjects will complete the DVPRS and DVPRS Supplemental Questionnaire.
-Subjects will complete the Needle Tolerance Questionnaire.

Acupuncture Needles:
Auricular semi-permanent (ASP gold) needles: will be remain in your ears for 2-8 days and allowed to fall out on their own.

Intradermal (long) needles using J-type No. 1 (.16) x 15mm: remain in place for 15-30 minutes and are removed by a member of the study staff.

Pyonex needles (Pyonex Pink 1.5mm (0.2 x 1.5mm): that will be remain in your ears for 2-21 days and allowed to fall out on their own.

This study received DoD Survey License Exemption (#14)-Exempt #0033.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

We will measure pain utilizing the DVPRS just before BFA therapy, 10-15 minutes after, 24 hours and 7 days post-therapy. Needle Tolerance questionnaire will be administered after DVPRS 10-15 minutes after, 24 hours and 7 days post-therapy.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

Outcome Measures: There are two outcome measures. The effectiveness outcome measure is the Defense and Veterans Pain Rating Scale (DVPRS). The DVPRS [1,2] consists of an 11-point numerical rating scale with 0 indicating no pain and 10 indicating severe pain. It has been confirmed for reliability and validity in measuring both acute and chronic pain, and is currently the standard for pain measurement throughout DoD and VA health systems. The DVPRS demonstrates linear scale qualities allowing parametric methods to be used. There will be four repeated measurements of the DVRPS: pre-acupuncture, post-acupuncture, 24 hours and one week post-therapy. The needle tolerance outcome will be measured using an in-house developed questionnaire. It employs 5-point ordinal scales to evaluate 12 post-therapy experiences or perception encompassing adverse outcomes, inconveniences, and satisfaction. There will be three repeated measurements: post-acupuncture, 24 hours and 1 week post-therapy.

Missing Data and Outliers: Outliers will be checked for clerical error. If improperly recorded, the data will be corrected, and, if found to be properly recorded, will be retained. Medians, means and ranges will be calculated and assessed to accommodate extreme observations. Subjects with missing data will be excluded from analysis and the estimated sample size seen below adjusted for this eventuality. Furthermore, an analysis of sample characteristics of retained and dropped subjects will be performed to determine whether bias has been introduced due to exclusion.

Sub-group Analysis: Analysis will center on differences between the three needle groups. The three treatment groups will allow inferences to be made as to whether each group is statistically different from one another. Medication is a potential confounder, but will be addressed by standardizing the dosage of analgesics used by all subjects rather than as a variable in a general linear model with the needle group variable.

Null Hypotheses:

H01 — there is no difference in means of the DVPRS between needle groups; and

H02 — there is no difference in means of the DVPRS between repeated measures; and

H03 — there is no difference in the distribution of the tolerance ordinal scales between needle groups.

1. Polomano RC, Galloway KT, Kent ML, Brandon-Edwards H, Kwon KN, Morales C, Buckenmaier C' 3rd. Psychometric Testing of the Defense and Veterans Pain Rating Scale (DVPRS): A New Pain Scale for Military Population. Pain Med. 2016 Aug;17(8):1505-19.
2. Nassif TH, Hull A, Holliday SB, Sullivan P, Sandbrink F. Concurrent Validity of the Defense and Veterans Pain Rating Scale in VA Outpatients. Pain Med. 2015 Nov;16(11):2152-61.

11.2 Sample Size:

A priori power analysis was performed using the DVPRS variable as described below. The analysis indicates a minimum of 10 subjects in each needle group, for a total sample size of 30, will have a power of 0.44 to detect the minimal clinically important difference at alpha = 0.14. We will be recruiting a total of 39 subjects, which is inclusive of a 30% drop out rate to accommodate those that may be lost to the study or have missing data to achieve a final total of 30 subjects.

11.3 Total number of subjects requested (including records and specimens):

39

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

Randomization: Subjects will be randomized using a random number generator using simple randomization into 1 of 3 research treatment groups, with approximately 13 subjects in each arm:
Group 1: Auricular semi-permanent (ASP gold) needles
Group 2: Intradermal (long) needles using J-type No. 2 (.18)x 15mm
Group 3: Pyonex Pink 1.5mm (0.2 x 1.5mm)

11.5 Please provide a justification for your sample size

The study is organized as a mixed effects, randomized design with repeated measures. Subject, gender and age are random effects as subjects are presumed to be a random representation of the population of adult male and female patients seeking treatment for this ailment and obtaining similar care at this and other Air Force medical treatment facilities. Time of repeated measure is a fixed effect as the pre- and post-therapy times cannot be generalized to other times. Needle group is a fixed effect as the needle employed cannot be generalized to other needles and conditions.

A priori power was assessed using G*Power Version 3.1.9.3 using the DVPRS for effect size. [4] DVPRS mean (SD) pain intensity for a broad sample consisting of inpatients and outpatients suffering from acute and chronic pain has been found to be 4.4 (2.4). The minimal clinically important difference of an 11-point pain scale in patients as will be included in this study has been determined to be a 25% percent change in the score. [5] This difference, mean and SD were used for the DVPRS effect size.

A priori power analysis of the DVPRS variable using the statistical method described below indicates 10 subjects in each research group, for a total sample size of 30, will have a power of 0.44 to detect the minimal clinically important difference at alpha = 0.14.

[4] Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods. 2007; 39 (2): 175-191.

[5] Sloman R, Wruble AW, Rosen G, Rom M. (2006). "Determination of clinically meaningful levels of pain reduction in patients experiencing acute postoperative pain." Pain Manag Nurs 7(4): 153-158.

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

Sample and needle group means, standard deviations, medians, interquartile ranges (IQR) and ranges will be calculated for interval variables. Frequency distributions will be produced for nominal and ordinal variables.

The null hypotheses H01 and H02 for the DVPRS outcome measure will be tested by a mixed effects repeated measures analysis of variance (rANOVA). In the event a null hypothesis is rejected, contrasts will be used to investigate effects and differences between and within research and time groups. Null hypotheses H03 will be tested with Chi Squared or Fisher's Exact tests. The significance level of multiple comparison tests will be corrected to $\alpha = .05$ by the Holm method. [6]

Mr. Danny Sharon, Senior Research Biostatistician Subject Matter Expert for Clinical Research Management under contracts OMNI 0004 3-82 and OMNI 0005 3-126, is the statistical consultant supporting this study. Statistical analysis will be performed with R Version 3.5.1. [7]

[6] Holm, S. 1979. A simple sequential rejective multiple test procedure. Scand. J. Statistics, 6: 65-70.
[7] R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. 2016 URL **http://www.R-project.org/**.

12.0 Participant Information

12.1 Subject Population:

Active Duty members and DoD beneficiaries, 18 years or older, meeting the inclusion/exclusion criteria will be recruited.

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [x] 65-74
- [x] 75+

12.3 Gender:

- [x] Male
- [x] Female
- [ ] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [ ] Active Duty Military Personnel

- ☐ Wounded Warriors
- ☐ Economically Disadvantaged Persons
- ☐ Educationally Disadvantaged Persons
- ☐ Physically Challenged (Physical challenges include visual and/or auditory impairment)
- ☐ Persons with Impaired Decisional Capacity
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, and Neonates
- ☐ Non-English Speakers
- ☐ International Research involving Foreign Nationals - Headquarters Review is necessary

12.5 Inclusion Criteria:

Order Number	Criteria
1	Inclusion Criteria: (adapted[17]) -Active duty and DoD Beneficiaries aged 18 years or older -Pain

12.6 Exclusion Criteria:

Order Number	Criteria
1	Exclusion Criteria: (adapted[17]) -Contra-indication to needle use including known bleeding disorder and psychogenic issues related to needle use (e.g., needle-phobia) -Allergy to metal or neutropenia -Women who are pregnant, may be pregnant, or attempting to become pregnant

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

All potentially eligible patients will be offered an opportunity to participate. Primary Care Manager (PCM) referrals, with the patient's oral or written authorization, and posted advertisements will be utilized for recruiting subjects to the study. Some patients may be patients of the PI or AI; however, they will have another study staff recruit their patients to prevent any misconception of coercion or undue influence. When a potential subject is identified by the treating PCM, the patient will either be provided a contact number to the Research Staff, the Research Staff will be given the potential subjects' contact information by the PCM, or the Research Staff will speak with the patients directly.

13.2 Compensation for Participation:

Subjects will not be paid for their participation.

13.3

Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

Pre-Eligibility review: Subjects who responded to advertisements or have given their permission to be contacted will be approached by a study staff member to discuss the subjects' interest in the research study and to receive a pre-eligibility screening for study participation. The attached "Pre-Eligibility Review Script" will be used and response will be recorded. If the subject is interested in participating in the study, the study staff member will schedule a screening visit while the subject waits on the phone or in-person, in order to confirm the schedule appointment with the subject. Following the pre-screening procedure, the script will be shredded.

13.4 Consent Process:

Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

Informed Consent and HIPAA authorization will be sought in advance of any screening and study-related procedures from each prospective study subject and appropriately documented in accordance with 32 CFR 219.117. Potential candidates will be notified about the study either through posted advertisements or by their healthcare provider and will be given the opportunity to consent by one of the referred study coordinators. The study coordinator will provide a written copy of the Informed Consent Document (ICD). The subject may decline to consent without prejudice. At the subjects' discretion, they may take the ICD home to discuss further with family members or another physician prior to making a decision. If they decide they are interested in participating in the study, they can contact the research department. If the subject consents, a copy of the signed ICD and HIPAA Authorization Document will be given to the subject. No vulnerable populations are included in this research study. Subjects who cannot provide Informed Consent will not be allowed to participate. No Legally Authorized Representatives (LAR) will be utilized. Each subject will be asked to place their de-identified research data into the "Nellis Acupuncture Data Repository" (FWH20140048H) for future research. If the subject does not give their authorization, then the de-identified research data will be destroyed no later than at 3 years after closure of the study. HIPAA forms will be maintained in hardcopy format for a minimum of 6 years.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

If a participant first agrees to participate and then changes their mind, they are free to withdraw consent and discontinue participation at any time. Their decision will not affect their ability to receive medical care and will not be penalized or lose any benefits to which they would otherwise be entitled. There are no risks from withdrawing. They will be advised in the Informed Consent process that if they decide to withdraw from the study early, we will ask them to discuss their decision with the study staff. The researcher may withdraw them from the study prior to the study's end without their consent for one or more of the following reasons: Failure to follow the instructions of the researchers and study staff. The

researcher decides that continuing their participation is not in their best interests. The study is cancelled. Other administrative reasons. Unanticipated circumstances. They become Pregnant. If they lose their status as a military health care beneficiary, they can no longer be included in the study.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

The potential risks to participate in this study are minimal. There is a risk of accidental breach of confidentiality. Other risks associated with participating in this research study include:

ACUPUNCTURE:
LIKELY: *Likely and not serious:*
-Pain
-Bleeding
-Flare of signs and symptoms

LESS LIKELY: *Less Likely and not serious:*
-Infection

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

Safeguards are in place for protecting subjects and their health data. The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room. Subjects do not have to participate or answer any question that they do not want to complete. If at any time the patient reports a side effect, they will be referred to one of the Investigators for care.

Women of child bearing potential will be reminded that they only reliable methods of birth control are total abstinence or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, intrauterine device (IUD), or sperm-killing products are not totally effective in preventing pregnancy. They will be asked to alert study staff if they become pregnant or feel that they might be pregnant.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e.g., child or spouse abuse

Safeguards for Protecting Information: The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room with restricted access. All identifiable research data including patient demographics will be kept in an electronic database separate from the coded research data, which will be encrypted, double password protected and the access will be restricted. Based on AFI 33-332, "The Air Force Privacy and Civil Liberties Program" and the National Institute of Standards and Technology Special Publication (NIST SP 800-88) which outlines the approved methods to destroy PII: The research data will be coded and any links to identifiable data (i.e., Master Key) will be destroyed as soon as all data mergers have occurred or no later than at the closure of the study. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. At the conclusion of the study, the data will be de-identified prior to review and analysis. Paper data, including completed consent forms: The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room with restricted access.
Electronic data: Medical records will be annotated with ICD-10 code Z00.6 to reflect the subjects' participation in a research study, in which they are receiving a research-related treatment intervention. All research data that includes the Master Key of identifiable patient demographics and PHI/PII will be kept in an electronic database, separate from the coded research data, which will be encrypted, password protected and the access will be restricted.
Long-term storage (following completion of the study and inactivation of IRB approval): The research data will be coded and any links to identifiable data will be destroyed (in approved shredding bin) as soon as possible or no later than at the closure of the study, with the exception of those study subjects that consent to place their de-identified research data into the "Nellis Acupuncture Data Repository" (FWH20140048H) for future research. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. All de-identified research data will be maintained for 3 years following study closure. HIPAA forms will be maintained in hardcopy format for a minimum of 6 years. Following research study closure, the Long Term Storage Plan will be followed.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Subjects may experience an improvement in pain; however, this is not a guarantee.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Records of participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. The Informed Consent gives permission for information gained from participants in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. They will not be personally identified; all information will be presented as anonymous data. We will annotate their medical record to reflect their participation in a research study for each visit because this study involves an intervention that is for research purposes only. A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of the research record. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between identity and the research information will be destroyed which means research information about the participant will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected for this study will not be used for any additional research activity beyond what was approved in the signed consent. In the unlikely event that a loss of confidentiality occurs, the study staff will advise the subjects to contact their local privacy office for

assistance. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

If significant new findings develop during the course of this study that may relate to subjects' decision to continue to participate in the study, they will be informed.

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- ○ DSMP
- ○ DSMB
- ○ Both
- ◉ Not Applicable

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

Events will be reported in accordance with 59MDW IRB policies and procedures.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

○ Yes ◉ No

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- ☐ Drugs
- ☐ Dietary Supplements
- ☐ Biologics
- ☐ Devices
- ☑ N/A

18.5 Sponsor (organization/institution/company):

☑ N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- ◉ Registration is not required
- ○ Registration pending
- ○ Registration complete

20.0 References and Glossary

20.1 References:

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[6] Yuan QL, Wang P, Liu L, et al. Acupuncture for musculoskeletal pain: A meta-analysis and meta-regression of sham-controlled randomized clinical trials. Sci Rep. 2016;6:30675. Published 2016 Jul 29. doi:10.1038/srep30675

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[11]Defense and Veterans Center for Integrative Pain Management.(2016). Retrieved from **http://www.dvcipm.org/**.

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[16]DHA-PI 6025.33, Acupuncture Practice in Military Medical Treatment Facilities February 20, 2020. Retrieved from pdf.

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20.2 Abbreviations and Acronyms:

Battlefield Acupuncture (BFA), Defense and Veterans Pain Rating Scale (DVPRS)