4/24/2019
Acupuncture for Plantar Fasciosis in the Primary Care Setting
NCT03246087

59th Medical Wing Institutional Review Board
PROTOCOL FOR NON-EXEMPT RESEARCH INVOLVING HUMAN SUBJECTS Title: Acupuncture for Plantar Fasciosis in the Primary Care Setting: A randomized control trial.
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The research relevance of this protocol focuses on:
Diagnosis
Treatment
Medical Utilization/Managed Care
Prevention
Medical Readiness
Other:
1. LOCATION AND SPONSOR Collaborating Facilities: None AF Sites Seeking Regional IRB:
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2. RESEARCH PLAN Purpose of Study:
To determine if the addition of acupuncture to a standard of care prescribed exercise program is more effective at improving pain and function in adult patients with plantar fasciosis. Hypotheses, Research Questions, or Objectives:
We want to investigate whether a specific acupuncture protocol, when added to the standard of care treatment, can improve pain and function in adults with plantar fasciosis.

We hypothesize that there will be a significant improvement in both pain and functional outcomes, both acutely and over time, in the experimental group compared to the control group. We will measure foot pain immediately prior to treatment (baseline), immediately after the initial treatment and at 2 weeks, 4 weeks, 6 weeks, and 12 weeks. The Foot Function Index Revised short form will be used during the same intervals to evaluate foot function. At 3 months, patients in the non-acupuncture group will cross-over into the acupuncture group if still experiencing pain. Significance:
Acupuncture, combined with a standard of care prescribed exercise program, is superior to a standard of care prescribed exercise program alone in military beneficiaries would result in less: lost duty days, profiles, and physical fitness testing exemptions in our active duty population, as well as an improved quality of life for all patients. Military Relevance:
Plantar fasciosis has a lifetime prevalence of 10% in the general population and can have a significant impact on quality of life.2,4 Overuse injuries including plantar fasciosis are commonplace in the military with reports being as high as 22% personnel experiencing overuse injuries in a deployed army unit.11
A recent combat training article showed that lower extremity overuse injuries accounted for over 70% of attrition rates during US Army combat training.8 Another study showed that of all chronic lower extremity injuries in military recruits, plantar fasciosis had the highest incidence.9 Current reports show an incidence of 10.5 cases of plantar fasciosis per 1000 patient years in the military. This indicates that 1 in 100 members will develop plantar fasciosis each year and a significant portion of these members will seek care in the primary care clinic.11 In the active duty population these individuals are placed on fitness restrictions which usually last 6 to 12 months leading to a significant impact on mission readiness.

Various levels of acupuncture training have been taught to several hundred military physicians. A barrier to more widespread implementation has been the lack of scientifically rigorous clinical trials to prove its efficacy in spite of anecdotal reports purporting its value in treating plantar fasciosis. Most conventional treatment trials incorporate vigorous treatment protocols that are time consuming and are not a reasonable treatment option to perform in a primary care setting. The goal of this trial is to develop a treatment protocol that can easily be performed in the primary care setting and will establish the efficacy of acupuncture for treating plantar fasciosis and develop a technique that a non-acupuncturist can easily learn. Learning whether or not acupuncture is an effective treatment for plantar fasciosis in military beneficiaries could result in fewer lost duty days, decreased profiles and physical fitness testing exemptions, and improved quality of life.
Background and Review of Literature:
Plantar fasciosis is characterized by calcaneal heel pain that is most severe with initial steps in the morning or after a prolonged period of rest. Palpation of the medial calcaneal tubercle, the site of the plantar fascia origin, will elicit the pain.2,4,7 Plantar fasciosis is

usually a self-limiting condition that resolves in 6 to 12 months without interventions. 2,4,7,11 However, there can be a significant impact on quality of life and physical function during a period of prolonged symptoms.

Management of plantar fasciosis focuses on stretching and strengthening of the associated structures involved to include the plantar fascia and gastroc-soleus complex. Orthotics are currently utilized to improve support and prevent over pronation of the foot when walking. 2,4 The evidence to support these modalities are limited given that most of these are performed in conjunction with other treatment modalities and there is no clear evidence to support one treatment modality over the other. 14 The goals of treatment are decreased pain and improved function.

The Foot Function Index-Revised short form is a validated assessment tool utilized in lower extremity tendinopathies and has been validated in the use of plantar fasciitis. It is a 34 item questionnaire with each question being scored from 1-4, with the highest possible score being 136 and the lowest being 34. The Foot Function Index-Revised form assesses pain and function during activities of daily living. The mean minimal difference associated with a significant patient oriented outcome is a decrease of 12 points in pain on the pain section of the questionnaire, a decrease of 7 in the function section of the questionnaire, or an overall decrease of 7 points on the Foot Function Index-Revised short form.6

Acupuncture is a nonpharmacologic treatment approach that has been proven to reduce pain acutely in plantar fasciitis. 1,3,12,15 However, the studies utilized daily therapies lasting 30 minutes, which make these treatments less likely to be performed in the primary care setting. 5,14, 15 Some of the methods used have poor or insufficient evidence to support the specific acupuncture points that were used in treatment. 3 This represents a significant research and knowledge gap. We propose to fill this gap by conducting a large, carefully designed, and randomized controlled trial that directly compares the efficacy of the addition of acupuncture to a standard of care prescribed home exercise program.

The needles being used are Hwato 0.3x100mm stainless steel needles which are approved by the FDA for use in acupuncture and will be used in accordance with their FDA approved labeling. As part of this study, the acupuncture needles themselves are not the object of the investigation, the process of acupuncture and the effect it has is what we are studying. The needles are merely the avenue we use to perform the acupuncture. According to 21 CFR 880.5580, an acupuncture needle is a device intended to pierce the skin in the practice of acupuncture.13 There are no known restrictions on the use of the acupuncture needles that prevent them from being used by qualified practitioners of acupuncture as they deem appropriate. Bibliography:

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5. Kumnerddee, W, N Pattapong. "Efficacy of Electro-Acupuncture in Chronic Plantar Fasciitis: A Randomized Control Trial," The American Journal of Chinese Medicine. 2012: Vol. 40, No. 6, 1167-1176.
6. Landorf, K, J Radford, "Minimal important difference: Values for the Foot Health Status Questionnaire, Foot Function Index and Visual Analogue Scale," The Foot. Mar 2008 18(1):15-19.
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14. Woitzik, Erin, C Jacobs, J Wong, et al. "The effectiveness of exercise on recovery and clinical outcomes of soft tissue injuries of the leg, ankle, and foot: A systematice review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration," Manual Therapy. 20 (2015);633-645.
Zhang, S, T Yip, and Q Li, "Acupuncture Treatmet for Plantar Fasciitis: A Randomized Controlled Trial with Six Months Follow-Up," Evid Based Complement Alternat Med. Epub 20011 Feb 15.

3. RESEARCH DESIGN AND METHODS

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 in Armed Forces Health Longitudinal Technology Application (AHLTA) to verify the inclusion/exclusion criteria including previous encounter, vital signs review, medication list, co-morbidities, demographics, and problems list.
• Record: Date of birth, age, gender, race, ethnicity, last 4 of social security number, name of standard of care medications (over-the-counter and prescription), current email address (to be used for scheduling), height (in inches), weight (in pounds), history of prior foot injury, and note any prior acupuncture received.
• We will ask what the subjects expectations are regarding acupuncture's effectiveness for plantar fasciitis.
• If the subject is an active duty member, we will ask:
o Have you or are you currently on a fitness restriction for plantar fasciitis.
o If so, what are the dates of the restriction.
• There are several standard of care treatments for plantar fasciitis which include physical therapy and a standard of care prescribed home exercise program. We will standardize what patients in this study are receiving by having all subjects follow the standard of care prescribed home exercise program and discontinue any formal physical therapy when entering this study (regular physical activity such as exercise is allowed).
Visit 1-Day 1 (may be same day as screening visit):
• Subjects will be given a study diary to document the number of times they performed the standard of care prescribed home exercise program. Subjects will be advised to complete the stretching exercises daily and the strengthening exercises every other day.
• Administer the Foot Function Index-Revised short form (FFI-R short)
• Subjects will be randomized into one of two groups and the intervention will be performed:
o Group 1: Self-reported pain severity pre-intervention (0 for no pain to 10 being the worst pain) Acupuncturist will be given a copy of the Protocol for Needle Insertion. Acupuncture will be performed and the standard of care prescribed home exercise program will be reviewed. Research Coordinator will record the name of the investigator performing the acupuncture, the number of acupuncture needles placed, and the position placed. Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day. Self-reported pain severity post-intervention (0 for no pain to 10 being the worst pain)
o Group 2: Self-reported pain severity (0 for no pain to 10 being the worst pain) The standard of care prescribed home exercise program will be reviewed. Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.

Visit 2-Week 2:

• We will review subjects study diary and document the number of days the standard of care prescribed home exercise program was performed.
• Administer the Foot Function Index-Revised short form (FFI-R short)
• Group 1:
o Self-reported pain severity pre-intervention (0 for no pain to 10 being the worst pain)
o Acupuncturist will be given a copy of the Protocol for Needle Insertion.
o Acupuncture will be performed and the standard of care prescribed home exercise program will be reviewed.
o Research Coordinator will record the name of the investigator performing the acupuncture, the number of acupuncture needles placed, and the position placed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
o Self-reported pain severity post-intervention (0 for no pain to 10 being the worst pain)
• Group 2:
o Self-reported pain severity (0 for no pain to 10 being the worst pain)
o The standard of care prescribed home exercise program will be reviewed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
Visit 3-Week 4:
• We will review subjects study diary and document the number of days the standard of care prescribed home exercise program was performed.
• Administer the Foot Function Index-Revised short form (FFI-R short)
• Group 1:
o Self-reported pain severity pre-intervention (0 for no pain to 10 being the worst pain)
o Acupuncturist will be given a copy of the Protocol for Needle Insertion.
o Acupuncture will be performed and the standard of care prescribed home exercise program will be reviewed.
o Research Coordinator will record the name of the investigator performing the acupuncture, the number of acupuncture needles placed, and the position placed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
o Self-reported pain severity post-intervention (0 for no pain to 10 being the worst pain)
• Group 2:
o Self-reported pain severity (0 for no pain to 10 being the worst pain)
o The standard of care prescribed home exercise program will be reviewed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
Visit 4-Week 6:
• We will review subjects study diary and document the number of days the standard of care prescribed home exercise program was performed.
• Administer the Foot Function Index-Revised short form (FFI-R short)

• Group 1:
o Self-reported pain severity pre-intervention (0 for no pain to 10 being the worst pain)
o Acupuncturist will be given a copy of the Protocol for Needle Insertion.
o Acupuncture will be performed and the standard of care prescribed home exercise program will be reviewed.
o Research Coordinator will record the name of the investigator performing the acupuncture, the number of acupuncture needles placed, and the position placed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
o Self-reported pain severity post-intervention (0 for no pain to 10 being the worst pain)
• Group 2:
o Self-reported pain severity (0 for no pain to 10 being the worst pain)
o The standard of care prescribed home exercise program will be reviewed.
o Subjects will be instructed to perform the stretching exercises daily and the strengthening exercises every other day.
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Visit 5-Week 12:
• We will collect subjects study diary.
• Administer the Foot Function Index-Revised short form (FFI-R short)
• Group 1:
o Self-reported pain severity (0 for no pain to 10 being the worst pain)
o We will ask if their expectations were met or changed regarding acupuncture's effectiveness for plantar fasciitis.
• Group 2:
o Self-reported pain severity (0 for no pain to 10 being the worst pain)
* CROSSOVER: At Visit 5 (final visit), those in the non-acupuncture group still experiencing pain and symptoms will be rolled into the acupuncture treatment arm of the study as outlined above. If the acupuncture group is still having pain they will be referred back to their primary care manager for further evaluation.
Those subjects in Group 2 (non-acupuncture) that cannot make it to a follow up visit, may have their follow up visits via telephone.
Acupuncture:
This type of Acupuncture for this indication is routinely done as part of standard of care in our Family Medicine and acupuncture clinics in conjunction with a standard of care prescribed exercise program and as a stand-alone therapy. The Research Coordinator will record the name of the investigator performing the acupuncture and also the number of acupuncture needles placed for each treatment.
Acupuncture treatments will be utilizing the KB-2 points with manual manipulation accomplished by vigorously running the acupuncturists thumb nail up and down the handle until a perceived sensation change is noted in the patient’s foot. A single needle will

be inserted as stated above and if the sensation change is not noted throughout the entire plantar and dorsal surfaces of the foot a second needle will be inserted over the first needle. This needle will be manipulated in the same manner as the first needle. This can be repeated up to a third needle if the desired change in sensation is not noted. No more than 3 KB-2 needles will be placed per leg. The needles will be removed after the treatment is complete, which will last approximately 5-10 minutes (standard care).
Acupuncture treatments will be as defined: The KB-2 points (see figure 1 below) will be used as the treatment points. KB-2 are generally not defined specific points, but are referred to the placement of the needle into the lateral leg and advanced through the interosseous membrane. The initial KB-2 point will be placed in the lower 1/3 of the leg above the lateral malleolus. The second needle will be placed in the middle 1/3 only if pain is still present after insertion and stimulation of the first needle. The third needle will be placed in the upper 1/3 only if pain is still present after insertion and stimulation of the first 2 needles. This study will follow all FDA requirements for the safe use of these devices.
The acupuncture being performed in this study is a standard acupuncture technique for the treatment of plantar fasciitis. The physicians performing the treatment are trained in this acupuncture technique. As such, all physicians trained in this procedure will be able to perform the acupuncture for treatment of research subjects. The Food and Drug Administration (FDA) regulates acupuncture needles as a class II medical device, because they are intended for use in the cure, mitigation, treatment, or prevention of disease in man or are intended to affect the structure or function of the body of man. The FDA regulates the acupuncture needles (see 21 CFR 880.5580). The needles being used are Hwato 0.30X100mm Acupuncture needles (see figures 2-3 above), which are exempt from premarket notification by the FDA for use in acupuncture and will be used in accordance with their FDA approved labeling.
Home Therapy:
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No acupuncture will be performed on this group for treatment of plantar fasciosis. This group will only receive the standard of care prescribed home exercise regimen at the initial visit and have the exercises demonstrated to them. These subjects will follow-up at 2 weeks and 4 weeks and education and demonstration will be performed again with these patients at subsequent visits. a. Interventions and Observations:
We will measure subject's pain level and administer the FFI-R short at the first visit, 2 weeks, 4 weeks, 6 weeks, and 12 weeks. Acupuncture treatments will be placed in the manner as described above. The number of needles will be recorded. b. Setting:
Male and female (DoD beneficiaries). Age 18 years or older, who are diagnosed with plantar fasciosis and enrolled to the Scott AFB O'Fallon Family Medicine Residency Clinic located at 3 St. Elizabeth's Blvd, Suite 4000, O'Fallon, IL and Nellis AFB MTF. c. Date(s):
May 2017 through May 2020 d. Subjects:

Male and female (DoD beneficiaries). Age 18 years or older, have been diagnosed with plantar fasciosis. No other special populations (e.g., children, military basic trainees, prisoners, detainees) will be recruited. e. Inclusion/Exclusion Criteria:
Inclusion Criteria
Inclusion:
• Male and female DoD beneficiaries, age 18 years or older, who have been diagnosed with plantar fasciitis/fasciosis (in one or both of their feet) OR Patients meeting criteria of pain in the bottom of the foot/heel with first steps in the morning & tender to palpation over the medial calcaneal tubercle (where the plantar fascia inserts). Those with acute and chronic diagnoses will be included.
Exclusion Criteria
• Pregnant
• Any of the following in the foot being included into the study:
o Active cellulitis of lower extremity
o Prior surgery for plantar fasciitis
o Steroid injections in the last 12 weeks for plantar fasciitis; if received in last 12 weeks subjects will be offered to be involved in the study after they have completed a 12 week wash out period.
o If they have every had any prior acupuncture for plantar fasciitis using the defined KB-2 points Any regenerative therapy to include proliferation therapy or platelet rich plasma therapy in the last 12 weeks for plantar fasciitis; if received in last 12 weeks subject will be offered to be involved in the study after they have completed a 12 week wash out period.
o Botox injections for plantar fasciitis injections in the last 12 weeks for plantar fasciitis; if received in last 12 weeks subject will be offered to be involved in the study after they have completed a 12 week wash out period.
• Use of anticoagulants
f. Source of Research Material: Will you be using private information in this study?
No – Only using publically available information Yes – If Yes, protected health information (PHI) held by a covered entity other types of private information
Describe: research information (non-PHI) that is not publically available (i.e., student records)
Describe: Use of identifiers with private information
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Identifiers to be Used? Column A Looked at by research team Column B Recorded on enrollment log, subject list, or key list Column C Recorded on data collection tool (survey, spreadsheet, etc.) Column D Recorded on specimen containers Column E Shared w/ others not on research team Column F Stored after study ended NONE STOP STOP STOP STOP
Names
Study codes linked to individuals' identities using a key only accessible by the researcher
Addresses

Dates (except year)
Ages over 89
Phone/Fax Numbers
E-mails
- SSNs
- Scrambled SSNs
- last four of SSN
Specify:spo nsor last 4
Specify:
Specify:
Specify:
Specify:
Specify:
Numbers:
- Medical record #
- Account #
- Certificate/license #
- Health plan beneficiary #
- Vehicle identifier/serial #
- License plate #
- Device identifier/serial #
Specify:
Specify:
Specify:
Specify:
Specify:
Specify:
Web URLs or IP addresses
- Biometric Identifiers, including finger/voice prints
- Full-face photo images and comparable images
Specify:
Specify:
Specify:
Specify:
Specify:
Specify:
Any other pre-existing unique identifying number, characteristic, or code
Coding Plan? Describe the method that will be used to create and assign unique study codes to data.
The unique study code will be assigned in a sequential order beginning with 001 and ending with 100. The code will be placed in a Master Key of identifiable PHI/PII for each

subject at each collaborating site Describe the method that will be used to create and assign unique study codes to specimens.
N/A, not collecting specimens What is the format of the key?
Paper Electronic
Who will have access to the
Research Coordinators
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key?
Where will the key be stored and how will it be protected?
Location(s): Each collaborating site will maintain a Master Key of identifiable PHI/PII that will be kept in an electronic database, which will be encrypted, password protected and the access will be restricted to the Research Coordinator. The Master Key will be electronically stored separately from the coded de-identified research data. The Master Key will not be stored on any non-government or personal computers or laptops. At the conclusion of the study, the data from each site will be de-identified prior to review and analysis.
Confidentiality measures: The coded research data will be kept in a locked cabinet in a locked office and only the research department has the key. The coded research data will be retained until the conclusion of the research study. Once a Final Report has been approved by the IRB, all the paper records will be de-identified and any key linking the subject to their records will be destroyed, 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) for the approved methods to destroy PII. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. Complete the table.
Source of Research Material per Participant (Procedures) # Routine Care # Research Driven # Total Procedures
Self-Reported Pain Severity
0
7
7
Foot Function Index-Revised short form (FFI-R short)
0
4
4 g. Instrumentation: N/A
4. HUMAN SUBJECT PROTECTION Recruitment and Consent Processes:
All potentially eligible patients will be offered an opportunity to participate. Primary Care Manager (PCM) referrals 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 the 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 patient directly.
Consent Processes:
Informed Consent and HIPAA authorization will be sought in advance from each prospective 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 care 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 subject's discretion, they may take the ICD home to discuss further prior to making a decision. If the subject consents, a copy of the ICD 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 study-related PHI/PII into the "Nellis Acupuncture Research Data Repository (FWH20140048H) for future research. If the subject does not give their authorization, then all PHI/PII will be destroyed no later than at the closure of the study.
Recruiting Service Members
Will you be recruiting service members in a group setting?
Yes
No
Participation Compensation:
Subjects will not be paid for participation in this study.
Assent Process: N/A
Benefits:
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Subjects may experience an improvement in pain and physical function in both the treatment and control groups, however, this is not a guarantee.
Risks:
The potential risks to participate in this study are minimal. The risks of acupuncture associated with participating in this research study include:
LIKELY: Likely and not serious:
• Pain
• Bleeding
LESS LIKELY: Less Likely and not serious:
• Infection
• Muscle cramp/spasm
Costs: N/A
Safeguards for Protecting Information:

The research consents will be stored in a locked cabinet in a locked room. Medical records will be annotated with ICD- 10 code Z00.6 to reflect the subject's participation in a research study. All research data including patient demographics will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The research data will be coded and any links to identifiable data will be destroyed as soon as the Final Report Approval has been obtained from the IRB with the exception of those that consent to place their study-related PHI/PII into the "Nellis Acupuncture Research 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. At the conclusion of the study, the data from each site will be de-identified prior to review and analysis. Data and Specimen Storage Plan

Not applicable, coded or identifiable information will not be collected.

How will coded or identifiable data/specimens be stored?

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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 to reflect the subject's participation in a research study. All coded, de-identified research data will be electronically stored separately from the Master Key of identifiable patient demographics and PHI/PII.

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, 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) for the approved methods to destroy PII, 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 Research 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.

Safeguards for Protecting Subjects Relative to Reasonably Expected Risks:

The principal investigator will be responsible for the protocol safety monitoring. The PI will make study documents (e.g., consent forms, data pulls) and pertinent hospital or clinical records readily available for inspection by the local IRB and over sight staff for confirmation of the study data.

These risks will be minimized by cleaning the acupuncture site with an alcohol swab prior to placement. If at any time the patient reports a side effect, they will be referred to one of the Investigators for care.
Categories of subjects-None
Clinical Care:
All subjects will receive standard of care regardless of inclusion into this study. If at any time a subject experiences any injury or adverse effects, appropriate clinical care will be given or subject will be referred to appropriate provider.
Injury Compensation: N/A
Data Safety
N/A – none of the Msitounaittioonrisnglisted above ap
ply
5. ALTERNATIVES Alternatives:
Acupuncture for plantar fasciitis is done in the Family Medicine Residency as part of standard of care. Subjects may choose to get this type of acupuncture without participating in this study.
6. DATA ANALYSIS Data Analysis:
Outcome Measures:
Primary outcomes: The primary outcome measures are the 11-point numerical pain rating score (NPRS-11) and the FFI-R short form scores as described above. The FFI-R scores are interval variables and can be assessed with parametric methods. Parametric methods can be used with the Visual Analog Score (VAS) if less than 16% of subjects rank pain as 0 or 10, and the NPRS-11 and VAS have been found to be equivalent in being able to detect differences in treatment. (16, 17) Therefore, parametric methods may also be used for the NPRS-11.
Due to the manner in which data will be collected, data analysis will be conducted in two parts. The first analysis, a repeated measures mixed effects design with a control group, will be of the outcome measures taken from patients randomly assigned to the acupuncture and non-acupuncture groups at the first visit, 2 weeks, 4 weeks, and 3 months. The second analysis, a regression point displacement design (RPDD), will be of the patients initially randomly assigned to the non-acupuncture group and then crossover into the acupuncture group at visit 5.
16. Breivik EK, Björnsson GA, Skovlund E. A comparison of pain rating scales by sampling from clinical trial data. Clin J Pain. 2000 Mar;16(1):22-28.
17. Ludington E, Dexter F. Statistical Analysis of Total labor Pain Using the Visual Analog Scale and Application to Studies of Analgesic Effectiveness During Childbirth. Anesth Analg 1998;87:723-727.
Sample Size Estimation/Power Analysis:

A priori power for a repeated measures ANOVA, mixed effects design, was assessed using G*Power Version 3.1.9.2.
(18) Effect size was based on the NPRS-11 detecting a 1SD difference within groups having a 1SD difference for 4 repeated measures. The results indicate that as few as 5 subjects per treatment group, or 10 total subjects, will have a power of 0.92 to detect a difference of 1SD for the NPRS- 11 at alpha = 0.019. However, post-hoc tests of differences among groups and time periods would require a sample size of 13 subjects per group, 26 total subjects, to achieve a power of 0.81 at alpha = 0.048.
However, sample size must also be based on the RPDD analysis. Effect size is determined by the variance explained by the intervention variable, acupuncture, and the residual variance. Power is based on the alternate hypothesis that the intervention coefficient in the regression model is greater than 0. A priori, both of these variances are unknown for this study. Therefore, power and sample size are based on an assumed small effect size of 0.15. Given there are two predictors, time of repeated measure (fixed effect) and non-acupuncture or acupuncture intervention (covariate), a sample size of 43 subjects in the non-acupuncture to acupuncture sequence will have a power of 0.803 to test this hypothesis at alpha = 0.05. If the number of subjects for the non-acupuncture to acupuncture cohort is kept to 13 in conformance with the first part of the analysis, we will have a power of 0.78 to detect a large effect size of 0.50 at an alpha = 0.055.
18. 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.
Statistical Analysis:
Sample means and standard errors of measurement will be calculated for normally distributed interval variables and medians and interquartile ranges (IQR) for non-normally distributed interval variables. Frequency distributions of nominal and ordinal variables will be calculated. For the first analysis, to test the null hypothesis that there are no differences in outcome measure means between the acupuncture and non-acupuncture groups controlling for within- subject variation and to examine interaction effects, we will employ a mixed effects, repeated measures ANOVA linear model with the data collected for both groups in the first 4 visits. For the second analysis, to test the null hypothesis that the intervention coefficient in the regression model is equal to 0, we will employ a repeated measures ANCOVA linear model with the data collected for the non-acupuncture and acupuncture in 5 visits. Multiple comparison tests to investigate post hoc effects, will be corrected by either the Bonferroni or Holm methods to maintain the alpha level of significance at p=0.05. (19,20) Mr. Danny Sharon, Senior Research Biostatistician Subject Matter Expert for Clinical Research Management under contract W911QY-11-D-0065, is the statistical consultant support for this study.
Statistical analysis will be performed with R Version 3.3.2. (21)
19. Abdi H. Bonferroni and Šidák corrections for multiple comparisons. In N.J. Salkind (ed.). Encyclopedia of Measurement and Statistics. 2007; Thousand Oaks, CA: Sage.

20. Holm, S. 1979. A simple sequential rejective multiple test procedure. Scand. J. Statistics, 6: 65-70.
21. R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing,Vienna, Austria. URL http://www.R-project.org/.
Number of Subjects: # Planned to Enroll # Enrolled # Planned to Complete Study TOTAL
Number of Subjects at Nellis AFB
50
0
44
50 Number of Subjects at Scott AF
50
0
44
50
*If one site recruits more than the other, then they will be able to continue recruitment until the accrual ceiling has been reached.
7. STUDY DURATION Duration of Study:
Approximate duration of the study: 3 years
8. LOCAL AND EXTERNAL SUPPORT SERVICES
Version: 6 February 2017 Revised by PR 2019 11
59th Medical Wing Institutional Review Board
research team and will be administering intervention(s).
personnel required
9. INTRAMURAL (GME) AND EXTRAMURAL FUNDING SUPPORT Intramural (GME) and Extramural Funding Support: O&M Intramural grant funding from SG5i was approved for $17,000.
10. DRUGS, BIOLOGICS, DIETARY SUPPLEMENTS, AND MEDICAL DEVICES Does the study plan dictate the use of any of the following?
A drug
Yes
No
A biologic
Yes
No
A compound intended to affect structure or any function of the body
Yes
No Local and External Support Services: None Describe the plan for training personnel who are not part of the
Not applicable – no training of non-study
A dietary supplement or substance generally recognized as safe that will be used to diagnose, cure, mitigate, treat, or prevent disease

Yes
No
A medical device
Yes
No
10A. List all drugs covered by an Investigational New Drug (IND) from the FDA (approved or submitted)
N/A, an IND has not been submitted to or approved by the FDA 10B. List all FDA approved drugs being used in accordance with FDA approved labeling
Name of Drug
Dose(s) directed by protocol
Route(s) of administration
N/A, no FDA approved drugs being used according to the labeling 10C. List all FDA approved drugs used for an unapproved use ("off-label")
N/A, no FDA approved drugs being used "off-label" 10D. List all biologics, compounds and dietary supplements
N/A, no biologics, compounds and dietary supplements 10E. List all devices covered by an Investigational Device Exemption (IDE) from the FDA (approved or submitted)
N/A, an IDE has not been submitted to or approved by the FDA 10F. List all FDA approved devices used for an unapproved use ("off-label")
N/A, no FDA approved devices being used "off-label" 10G. List all unapproved devices.
N/A, no unapproved devices 10H. Device Storage Location(s):
Is this research an "applicable clinical trial" which must be registered on ClinicalTrials.gov?
Yes, Local Investigator is responsible for registering the trial. NCT02929589
Use of a placebo in place of standard therapy:
Is a placebo being used in place of standard therapy?
No
Yes
11. MEDICAL RESEARCH AREA
Version: 6 February 2017 Revised by PR 2019 12
Analytical Chemistry
Anatomy
Anesthesiology
Biochemistry
Cardiovascular Surgery
Cardiology
Cell Biology
Dentistry

12. ATTACHMENTS

1. Form A, Signature Sheet
2. Form A-2, Study Personnel Listing
3. Form D, Informed Consent Document
4. H15 Template, HIPAA Authorization Document
5. Plantar Fasciopathy Training Protocol
6. Application Checklist
7. Revised Foot Function Index (FFRI-R)
8. Advertisement
9. Study Diary
10. Protocol for needle insertion

Dermatology
Dietetics
Electrophysiology
Endocrinology
Emergency medicine
Gastroenterology
General Surgery
Hematology
Histology
Immunology/Allergy
Infectious Disease
Microbiology
Molecular Biology
Neonatology
Neurology
Neurosurgery
Nursing
OB/GYN
Occupational Medicine
Occupational Therapy
Oncology
Ophthalmology
Oral/Maxillofacial Surgery
Orthopedics
Pathology
Pediatrics
Pharmacology
Physical Therapy
Mental Health
Radiology/Imaging
Urology

Wellness
Other:
Family Medicine Residency