

COVER PAGE

STUDY TITLE: SELF-ADMINISTRATION OF AURICULAR  
ACUPUNCTURE PILOT PROJECT

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DATE OF DOCUMENT APPROVAL: 30 SEP 2019

## Self-Administration of Auricular Acupuncture Pilot Project IRB Proposal

### I. OBJECTIVES/SPECIFIC AIMS:

- a. The primary aim of this pilot project is to assess the safety and feasibility of a program that formally trains veterans to self-administer Battlefield Acupuncture (BFA) for pain relief. Safety is defined as no serious adverse events in any of the participants during six months of self-administration of BFA. Feasibility is defined as whether it is physically possible for greater than 90% of participants to self-administer BFA with or without assistive devices. This is primarily an innovation project to evaluate a method for self-administration of BFA.

The project will focus on veterans who have had a prior “good” response to BFA performed by a provider. A “good” response is one that lasts at least three days AND causes either a 3-point decrease in the pain score or allows the recipient to ambulate or perform other functional tasks easier as determined subjectively. However, the primary purpose of this project is not to detect a treatment effect, but to innovate a safe and convenient way for self-administration of BFA. If results are promising, the project will be submitted for consideration of rapid diffusion throughout VA and as an impetus towards more extensive, multi-center studies that are powered to detect other parameters such as long-term efficacy, progressive improvement in pain and function and reduction of oral medication use.

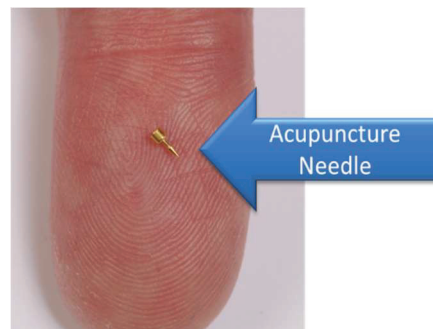
- b. *Key Predictions/Hypotheses:*

- i. Veterans trained by providers who routinely perform BFA will be able to self-administer BFA per pre-existing BFA protocol (defined later) without any serious adverse effects over a period of six months. At least 90% of participants will remain able and willing to consistently self-administer BFA without major difficulties for the study period, either with or without a prosthetic assistive device.
- ii. Self-administered auricular acupuncture (SAAA) will be subjectively non-inferior in terms of perceived efficacy to provider-administered auricular acupuncture (PAAA) i.e. BFA performed by a provider. The main measure of this will be that participants continue to want to self-administer BFA after the study.
- iii. 3D-printed ear molds will facilitate placement of the BFA needles. This will be tested by providing the prosthesis several months after the participants have

been self-administering BFA without the prosthesis.

## II. BACKGROUND/SIGNIFICANCE

- a. *Why this study?* The PI was unable to find any formal studies that looked at self-administration of auricular acupuncture or those that involve the use of a 3D-printed prosthesis to guide acupuncture needle insertion. The PI believes that formally allowing patients to self-treat with BFA is novel enough to warrant supervision by research regulatory bodies. This is both for safety purposes and to establish BFA self-treatment as legitimate for future research projects and clinical implementation. When administered by a provider, BFA is considered a procedure of “negligible” risk by VA and only requires verbal consent. However, the risk is not “minimal” from a research approval standpoint as it entails more potential harm than a review of records or a routine physical exam.
- b. *What is acupuncture?* Acupuncture is a system of medical treatment that is chiefly associated with but not exclusive to Traditional Chinese Medicine (TCM). TCM involves manipulation of purported energy channels (meridians) that connected and controlled many bodily functions. Vital “energy” or *qi* (pronounced “chee”) flowed along these channels and could be modulated by application of needles to various points along the channels. In Western medicine, acupuncture is becoming more widely used, especially for pain, for which it has been well studied. However, Western practitioners generally favor a more “Western” physiologic explanation for its pain relieving effects. A brief exploration of purported physiological mechanisms of action (MOA) is included below.
- c. *Origin of BFA:* BFA is an auricular, or ear, acupuncture (AA) protocol developed in 2001 by Air Force physician Col. Richard Niemtow. It is the result of an effort to find an efficient way to rapidly relieve pain that was not associated with the sedative effects of most narcotic analgesics. The points used in BFA appear to be drawn from several different schools of acupuncture.
- d. *What is BFA?* BFA is an AA protocol that uses special indwelling needles to cause pain relief. This protocol involves up to five points on each ear that are believed to be effective for pain control. “Indwelling” acupuncture needles are special acupuncture needles that are supposed to stay in for more than a short time to make the effect last longer. The BFA protocol allows the needles to remain for up to seven days but they usually fall out before that. The needles used in BFA are very small, short needles that are



designed to stay in the skin but not penetrate too deeply. To the right is a picture of an ASP Gold needle (the ones commonly used in BFA). Each needle comes in a sterile blister pack and comes with a sterile plastic applicator to facilitate insertion.

Pictured below is the needle with the applicator that comes in sterile packaging. The needle may be difficult to see depending on the color status and quality of paper if this document is printed.



- e. *Patient Education Sheet*: A non-local VA patient education sheet is attached after the reference section of this proposal. *This education sheet states that bleeding disorders and anti-coagulation are a contraindication to “acupuncture”*. This education sheet is not meant to be an authoritative literature for BFA, it is simply one that a specific VA facility put together and is a visual aid to allow reviewers to become more familiar with BFA. BFA can be safely done in patients on anti-coagulation with a minor increase in bleeding risk, which will be explained during the consent process.
- f. *Purported Mechanism(s) of Action*: The purported mechanism(s) of action of acupuncture in general include central modulation of pain via various structures in the central nervous system (CNS). These include the hypothalamus, thalamus, cingulate gyrus and cerebral cortex. Evidence for the involvement of these structures come from functional MRI (fMRI) studies showing that they are activated when the BFA needles are in place. Other mechanisms of acupuncture in general have evidence to support them, but they are not directly relevant to the chiefly clinical research proposal under consideration. These mechanisms will be briefly summarized in the following subsection.

g. *Relevant Literature Review*

- i. The PI is unable to find any existing articles pertaining to self-administration of auricular acupuncture for any condition or the use of 3D-printed prostheses to guide acupuncture needle insertion.
- ii. References are included at the end of the proposal and prior to the patient education sheet.
- iii. *Mechanisms of Action*: Purported mechanisms of action (MOA) for acupuncture are briefly summarized in this section. References for these MOAs are included in the secondary source *An Introduction to Western Medical Acupuncture*<sup>1</sup>, which is cited in the reference section and in turn includes more references. Extensive citations are not included because a detailed exploration of acupuncture MOAs is beyond the scope of this proposal for a small pilot project prior to a potentially larger and more academic study.
  1. Local Effects: Acupuncture stimulates A-delta fibers in skin and muscle. Stimulation of A-delta fibers in turn causes release of several neuropeptides that affect the surrounding tissue. The most important neuropeptides include calcitonin gene-related peptide (CGRP) and histamine. These substances are vasoactive and promote increased blood flow to the area.
  2. Segmental Analgesia: Stimulation of A-delta fibers lead to activation of intermediate cells in the dorsal horn of the spinal cord. These intermediate cells release enkephalin, which blocks the transmission of pain in the substantia gelatinosa, which is part of the pain transmission pathway.
  3. Extrasegmental Analgesia: Acupuncture causes the release of beta-endorphin in the brain. Serotonin and oxytocin are also involved in the body's response to acupuncture. Acupuncture also potentiates activity in the periaqueductal gray matter (PAG), which is the closest thing in the body to a "pain control center." The beta-endorphin release caused by the acupuncture affects the PAG, which causes general activation of the descending pain inhibitory system in the body. Activation of this system causes multi-level suppression of nociceptive activity in the dorsal horn.
  4. Central Regulatory Effects: Through unclear mechanisms, acupuncture is thought to positively affect the limbic system and the resultant affective states in response to pain.
- iv. Clinical Literature Review of AA and BFA in Different Contexts
  1. This subsection contains summary statements of various studies involving BFA/AA. It is not meant to be an extensive summary of the literature but to

provide evidence that AA has been used in several contexts with reasonably good results and thus should be considered for self-administration by trained patients.

2. BFA is used throughout VA and DoD for acute and chronic pain relief.
  3. Auricular acupressure was shown to significantly lower post-operative opioid use after total knee arthroplasty (TKA)<sup>9</sup>.
  4. Indwelling AA was shown to reduce pain medication (opioid) use after total hip arthroplasty (THA)<sup>6</sup>.
  5. BFA + standard care was shown to reduce low back pain (LBP) acutely in the emergency department (ED) setting compared to standard care alone<sup>11</sup>.
  6. Other articles are included in the “references” section for reviewers’ perusal.
- h. *Context of the Opioid Epidemic:* Given societal concerns about the opioid epidemic, it is critical to identify and disseminate effective pain control modalities to mitigate the lack of effective care for chronic pain as a barrier to addressing the opioid epidemic. This effort is further confounded by access issues to obtain BFA and other complementary and integrative health (CIH) modalities in a rural VA setting. These can include transportation difficulties and significant financial and temporal constraints for providers and patients. SAAA would reduce these difficulties by allowing patients to administer treatment to themselves. The PI hopes that SAAA will empower the veterans to be more actively engaged in their care, reduce dependence on others to manage their problems and reduce oral medication use.
- i. *Appropriateness as a self-administered treatment:* It can be argued that allowing patients to needle themselves with acupuncture needles without supervision will have some risk of harm associated with it. While these concerns are valid, these risks are certainly less than the risks associated with either self-administration of insulin, which can be lethal if done incorrectly, or the use of oral opioid medications for chronic pain, which can be lethal even if done correctly. These needles are very small and are designed specifically to prevent penetrating too deeply. BFA does not require advanced knowledge to utilize correctly.
- j. *Ultimate Goal:* The purpose of this pilot project is 1) to determine whether a brief education program can allow the safe self-administration of BFA and 2) whether 3D-printed ear prostheses with guide holes will allow easier application. “Safety” of the procedure is defined as no serious adverse events occur within six months

of self-administration by 30-40 participants. After project completion, the results will be presented to a higher level in the VA for rapid diffusion and further and hopefully multi-center studies that can examine efficacy and impact on pain medication use.

### **III. PRELIMINARY STUDIES**

No formal preliminary studies have been conducted prior to this proposed study, which is itself a pilot study. The PI was unable to find any scientific articles pertaining to self-administration of auricular acupuncture or the use of 3D-printed prostheses to guide acupuncture placement.

### **IV. INVESTIGATOR EXPERIENCE**

The PI is board-certified in Physical Medicine and Rehabilitation and has a graduate-level psychology background, which includes formal education in experimental design and statistical analysis in the context of experimental design. The PI also has substantial training in quality improvement methods from his residency program which includes but is not limited to root cause analysis, statistical analysis and coordination of multi-disciplinary efforts to accomplish organizational goals.

### **V. METHODOLOGY**

a. *Methods and Procedures*: An hour-long educational session will be given to veterans in a face-to-face visit. The veteran will demonstrate self-placement of the needles prior to leaving. At a separate visit, participants will have their ears scanned by a 3D-ultrasound scanner to provide a basis for ear prosthesis development. After several months of non-guided self-administration, bilateral 3D-printed ear prostheses will be given to the veteran. These ear molds will have guide holes to facilitate easy and precise insertion of the BFA via self-administration. The questions to be addressed will be those listed under the "Hypotheses" subsection of the "Objectives" section. There is currently a "Battlefield Acupuncture" note template that is used for routine clinical and research purposes at a national level. This template will be used in this project to record data and will be used to record data in CPRS as a "Battlefield Acupuncture note". This note will be considered a part of routine clinical care as it would if a provider had administered the BFA. This template already includes free response sections so that any difficulties experienced by participants can be recorded without altering the template. A print-out of this template will be

included at the end of this document.

- i. *Description of the BFA procedure:* BFA is a type of auricular (ear) acupuncture that involves the insertion of specialized indwelling acupuncture needles into sequential points in the ears. The needles are inserted with the aid of plastic applicators. There are five points on each ear. The standard needle is the ASP Gold needle, which is made of stainless steel coated in 24K gold and comes in sterile packaging. Ears are cleansed with alcohol swabs prior to needle insertion. In the BFA protocol, the first point needled is on the side of the body where the pain is most prominent. After a needle is inserted, the patient is instructed to ambulate for one to two minutes and see if the pain diminishes. If the pain has not reached the target of 0-1 out of 10, the next needle is inserted on the same point in the contralateral ear. After repeated ambulation, if pain has not reached target, the next point is needled. There are five points on each ear, or ten total points. Intermittent needling and ambulation continues until all ten needles have been inserted or the pain reaches 0-1/10.

The recommended frequency of BFA is that repeated needling of the same point be done not less than two weeks apart to avoid irritation of the ear. This is largely anecdotal but our protocol will adhere to this recommendation. In most people, the needles will remain in for two to four days before coming out on their own, but in some they will remain in much longer if they are not removed. BFA protocol advises that the needles do not remain in longer than 7 days. There is no easy way to ensure that needling will not be done more frequently other than dispensing a very limited amount of needles at a time, which essentially defeats the purpose of this project and will drive up costs to provide needles. Participants will be removed from the study if it is discovered they are using the needles in a manner that is inconsistent with the protocol.

- ii. *Self-administration method:* The participants will first learn to self-administer BFA without an ear mold and will follow the original BFA protocol. Later, veterans will also be given 3D-printed auricular prostheses (AP) with guide holes to facilitate BFA needle insertion. Veterans will then be able to try needle insertion with and without the AP to see which is easier. The following steps will be followed with the ear molds:
  1. Needles are not inserted into the same point more than once every two weeks to avoid skin irritation.
  2. Cleanse the ears and APs with the provided alcohol prep pads.



3. Place the AP over the ear as appropriate.
4. Verify that the guide holes are in the correct place using a hand-out or other visual aid that is provided. This will be done in a mirror and confirmed with a handout. Correct placement will also be verified at the time of AP dispensing by visual examination.
5. Verify that the AP is securely in place and will not easily slide off the correct site.
6. Insert the needle at the first point starting on the side of the body where the pain is worst.
7. Ambulate intermittently between insertions for one to two minutes.
8. Continue in sequence until all needles are inserted or pain is 0-1/10.

*iii. Educational program*

1. The providers participating in the study will spend an hour with each participant training them to insert the needles, first on a silicone ear, then on the participants themselves. These providers routinely perform BFA in clinical practice and are credentialed to do so. These providers are study staff and investigators.
2. Participants will demonstrate correct self-insertion in all five points in both ears prior to being given an 80-count box of BFA needles. These needles and their applicators are single-use and disposable.
3. Participants will also be given a silicone practice ear, an 80-count box of ASP Gold needles (the standard BFA needles), and simple written instructions to follow.
4. The use of needles by or on someone other than the participant will result in the participant's immediate dismissal from the study. This event will be reported to IRB immediately. It will be strongly emphasized to the participants that the needles are only for self-administration and only to be used on the participants themselves.

*iv. Auricular prosthesis development*

1. The purpose of the AP is to severely limit the possibility of incorrect or angulated needle insertion and increase participant confidence.
2. Several materials commonly used in 3D-printed prosthetics will be trialed for suitability.
3. If the APs are unwieldy or unhelpful, the participants will revert to use of unassisted self-insertion.

4. The APs will be given to participants after several months of non-guided administration. This will help assess how helpful they are because participants will be used to doing them without guidance of the AP.
  5. The participant's ears will be scanned with a 3D ultrasound scanner.
  6. The ear scan data will be uploaded into a VA secure computer and processed to be utilized by the 3D printing program.
  7. The AP will be printed.
  8. Fit of the AP will be verified at a subsequent visit to receive the AP.
  9. The ear scanning and fitting/giving of the AP is anticipated to take two visits total.
  10. BFA points will be manually marked on the AP, or the points may be identified through digital subtraction of the parts of the AP overlying the points prior to printing so the guide holes will be printed automatically.
  11. If manual marking of the guide holes is more feasible, a small caliber hole will be bored into the marked BFA points of the AP and the hole will be smoothed with fine sandpaper to remove jagged edges.
  12. The key aspect of guide hole development and use will be to keep them as tightly toleranced as possible. In other words, the guide holes will be barely large enough to allow insertion of the ASP Gold needle applicator. This will prevent angulation of the applicator, which is the primary factor in suboptimal placement and poor retention of the needle.
  13. The materials used to print the ear prostheses will consist of either silicone or another hypoallergenic material that is commonly used for 3D-printed prostheses.
- v. *Ear prosthesis cleaning and maintenance:* Prior to each use, the auricular prostheses will be cleansed with standard isopropyl alcohol prep pads, which will be provided to participants along with the BFA needles.
- b. *Data analysis and Data Monitoring:*
- i. Every two weeks participants will be called by study investigators during a scheduled telehealth or telephone encounter, and a standardized BFA note, which already exists as a national-level template, will be used to record their responses. The responses will be recorded directly into CPRS and these notes will be considered equivalent to those done in routine care.
  - ii. Advanced statistical analyses and comparisons are not necessary for this pilot project as the chief question is whether it can be done safely for six months by a significant number of participants (i.e. thirty to forty). We will

- attempt to recruit forty participants to allow for up to a 25% attrition rate, although we expect a high retention rate for this study.
- iii. The primary metric of this project is whether any significant adverse events occur (i.e. serious infection, imbedding of the needle past the skin) that can be clearly attributed to BFA self-insertion. If one occurs, local research committee will be consulted for further guidance on whether to continue the study. If none occur, this will be recorded at the end of the study.
  - iv. The secondary goal of this project is to determine whether APs are helpful in self-administration of BFA. If there are unforeseen problems with their use or they seem to be overtly unhelpful from the beginning, the use of APs will be dropped from the protocol. If there is significant difficulty with producing the APs, they will be discarded from the protocol.
  - v. Data will be made available to regulatory bodies upon request.
- c. *Data Storage and Confidentiality*: Data will be stored in CPRS in a note that is already used to document the BFA procedure. The only physical data will be the paper-based informed consent forms and other waivers used in IRB-approved research. There will also be a list of participants that only includes initials and last 4 of SSN. The documents will be stored in a locked room inside a locked cabinet in the pain clinic area. All data to be used in analyses will be totally de-identified by disassociating them from any possible identifiers. Only authorized study staff will have access to them. No identifying data will be released except upon legitimate request to authorized agencies or regulatory personnel in compliance with federal law and VA policy.
- d. *Setting*: The setting in which the study will be conducted includes the Chillicothe VAMC main campus. Veterans will be recruited from both the main campus only by BFA providers who are study staff/investigators. Veterans will receive explicit training in self-administration of BFA by providers who are credentialed to perform it and who do it regularly.
- e. *Laboratory methods and facilities*: No laboratory tests are anticipated for this study.
- f. *Estimated Time to Complete the study*: 12 months total, six months for each participant

## **VI. HUMAN SUBJECTS**

- a. Description of human participants follows

- b. *Sample Size*: 30-40 participants from Chillicothe VAMC facility and its community-based outpatient clinics (CBOCs)
- c. *Inclusion Criteria*: All veterans with chronic pain who subjectively responded (as defined earlier) to provider-administered BFA who wish to participate and have no significant or absolute contraindications can be included. Veterans must be able to demonstrate to the investigator(s) during the training session that they can successfully self-administer once for continued participation. Those on blood thinners will be allowed to participate if they acknowledge that there is an increased risk of bleeding. In general, use of anticoagulant or anti-platelet medication is not a contraindication to BFA.
- d. Exclusion criteria include those who do not wish to participate and those who have significant contraindications to AA or indwelling acupuncture. These include: being immunocompromised, congenital or acquired defects in the tympanic membrane, pregnancy, severe cognitive impairment, inability to perform BFA on themselves. Medical anti-coagulation is not an automatic exclusion as many patients on these medications will not have any issues with bleeding with BFA. Those who have history of severe vasovagal/syncopal or other adverse response to skin puncture will also be excluded. Those with artificial heart valves or those with a history of heart valve infection are excluded because of risk of endocarditis. Pregnant patients will be excluded from this study to eliminate the possibility of harm to pregnant patients and developing children. **Medical conditions that would exclude someone from using BFA include**: 1) those with replacement heart valves; 2) those with history of heart valve infection; 3) those who are pregnant; 4) those who have a pacemaker, defibrillator, or other similar electronic device; 5) those who are afraid of needles, 6) those who are scheduled for an MRI; 7) those with non-medication induced bleeding disorders.  
Participants will be removed from the study if it is discovered they are using the needles in a manner that is inconsistent with the protocol.
- e. *Intended gender/age range/etc.*: There will be no age or any other sort of restrictions on this group other than pregnancy. Women who are not attempting pregnancy or who are unable to become pregnant will not have any additional criteria to be included. Since it is not possible for pediatric patients to be military veterans, pediatric patients will not be included by default.
- f. *Source*: The source of study participants is the population of veterans at our facility with chronic pain who are willing to participate and who have received BFA at some point with subjectively positive response (as defined earlier). The primary source of the participants will be the current patients who receive recurring BFA treatment from Dr. James, Dr. Welch or Dr. Williamson.

- g. *Recruitment Plans*: Veterans who experience an ongoing subjectively positive response to BFA during standard care for pain will be asked by their BFA provider (who is an investigator in the study) if they wish to participate. Again, a “good” response is one that lasts at least three days AND causes either a 3-point decrease in the pain score or allows the recipient to ambulate or perform other functional tasks easier as determined subjectively. Regular recipients of BFA from participating investigator-providers will also be asked directly. Participants may also include those who have had good response to BFA in the past but are not receiving it recurrently who are under the care of one of the investigators.

## **VII. Risk/Benefit Assessment**

- a. *Level of Risk*: The level of risk is considered more than “minimal” from an IRB standpoint, as the potential for harm is greater than expected from a review of medical records or a routine physical exam. However, in the VA, BFA done by a provider is considered a procedure of “negligible” risk and only requires verbal consent. Overall, the PI and the VA would consider correctly administered BFA to be very low risk but not “minimal” risk according to 45 CFR 46.102(i). If this project demonstrates that self-administration of BFA is safe, it will allow much easier access to this therapy and hopefully will reduce oral pain medication usage. A large systematic review of various auricular acupoint therapies did not mention any serious adverse events when performed by a provider<sup>15</sup>.
- b. *Anticipated Benefit Justifies the Risk*: In the context of very low risk, even a modest benefit justifies performing a study that may improve care and improve access to non-opioid chronic pain relief. Based on preliminary clinical experience and literature review, the anticipated benefit far outweighs any risk, assuming the procedure is administered according to protocol.
- c. *Experiences/risks are similar to real life for participants*: Again, an analogous procedure could be diabetic self-testing, which is a widespread medical practice. The experience of self-administration of BFA is likely to be very similar to BFA administered by the provider.
- d. *Generalizable knowledge anticipated*:
- i. That BFA is reasonably safe to formally allow suitable patients to self-administer for pain relief.
  - ii. If this study is successful and a larger study is undertaken, further research could facilitate:
  - iii. Identification of the conditions that are most likely to respond to BFA.

- iv. To assess the occurrence or lack thereof of progressive improvement in pain level that is reportedly associated with repeated acupuncture administration.
  - v. That BFA can be self-administered safely, effectively and cost-effectively.
  - vi. That self-administered BFA can reduce the use of oral analgesics in an outpatient setting
- e. *Potential Risks or Discomforts*: When the skin is penetrated, there is always the chance of infection or bleeding. Those on anti-coagulation may have a slight increase in the risk of bleeding- however, BFA is done routinely on those on anticoagulation with no issues and this risk will be addressed in the informed consent. With appropriate cleansing of the ears with alcohol pads and screening of participants, the likelihood of an infection is extremely low. Diabetic blood sugar testing arguably has a similar, if not larger, risk because the actual intention is to cause bleeding. Self-administration of insulin is routinely done and is indisputably dangerous if done incorrectly. These procedures are routinely done by patients to themselves. Transient bleeding of a very small amount can occur; the harm associated with this is likely less than that of routine venipuncture or diabetic blood sugar testing. Another theoretical risk involved in BFA is damage to underlying structures. However, given that the needles do not penetrate more than 1-2 millimeters and that there are no significant vascular or neural structures underlying the target points, any risk of anatomic damage is largely theoretical and are likely to occur only if the protocol is not followed. Other rare adverse events that may occur include transient nausea or dizziness.

Indwelling acupuncture poses a small but serious risk to those with history of artificial heart valves or history of endocarditis; therefore, these patients will be excluded. Endocarditis with indwelling acupuncture has only been reported in those with previous history of heart valve pathology and is extremely rare<sup>12</sup>. The PI can only find one case reported of endocarditis in a patient with history of rheumatic fever. According to one study by Stellon<sup>13</sup>, brief acupuncture does not seem to increase the risk for endocarditis. See references section for relevant citations.

**VIII. PAYMENT:** Participants will not be remunerated for their participation. Veterans will receive the BFA needles and other relevant materials at no cost. If they incurred the pain condition during their active military service (i.e. service-connected condition), the VA covers all costs associated with the treatment of that condition.

- IX. SUBJECT COSTS:** Subject costs may include travel to VA facility and initial evaluation for non-service connected conditions. Again, if the veteran is service-connected for the pain condition, they will not have to pay anything. All materials and supplies will be covered by the study funding.
- X. CONSENT FORM:** Enclosed in separate document



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**BATTLEFIELD ACUPUNCTURE NATIONAL NOTE TEMPLATE EXAMPLE**

Follow up visit

Battlefield Acupuncture was the only treatment given.

Patient was evaluated and agreed to receive Battlefield Acupuncture Protocol (BFA) for the following pain condition(s):

Comment: low back

Pre BFA Pain Numeric Rating Scale of site with highest pain:

0-10

The patient was asked the following questions:

During the past 24 hours, how much has your pain interfered with your usual activity?

0-10

During the past 24 hours, how much has your pain interfered with your usual sleep?

0-10

During the past 24 hours, how much has the pain affected your usual mood?

0-10

During the past 24 hours, how much has pain contributed to your stress?

0-10

Oral informed consent obtained for BFA.

Procedure:

Time out was performed

Ear was prepped with alcohol

Needle type:

Semi-permanent ASP needles

The following points were placed:

All 10 points in both ears

Complications:

Patient tolerated well without any complications.

Post BFA Pain Numeric Rating Scale:

0-10

The patient was provided with the following post BFA instructions:

-Avoid alcohol, heavy or difficult to digest meals, exercise and sexual activity for six hours after today's BFA treatment.

-Showering is ok as long as the ears are only pat-dried or you can avoid drying ears with towel entirely.

-If you experience new or continued redness, swelling or pain, remove the needles or return to clinic for evaluation and/or needle removal.

-You may experience drowsiness, lightheadedness, or euphoria during the treatment or within 30 minutes of treatment.

-Do not have an MRI scan with the needles in place (If you need to have an MRI, please remove needles prior to scan).

-Continue to take all prescription medication according to your provider's instructions.

-Please keep notes of your response to this treatment including effects on pain, sleep, well-being, and energy, and keep us informed.

-Please keep all regularly scheduled follow-up visits. Return sooner should your condition worsen.

## Battlefield Acupuncture

Patient Education Information Sheet

North Florida/South Georgia  
Veterans Health System (NF/SGVHS)

[www.northflorida.va.gov](http://www.northflorida.va.gov)

Primary Care



# Battlefield Acupuncture

## What is Acupuncture?

Traditional acupuncture came from China over five thousand years ago as a way to treat many different health problems. Over the years research has shown that acupuncture works not only on the area with the needles but all over the body as well to reduce pain. This works by suppressing pain transmission at the spinal cord as well as releasing chemicals to reduce the feeling of pain. It has been proven a safe and effective way to treat pain over thousands of years.

## What is Battlefield Acupuncture?

While traditionally you may think of acupuncture as many needles all over the body, Battlefield Acupuncture is just in the ear. The theory is that the entire body is represented in the ear and by placing small needles in the surface some of the pain is able to be suppressed.

## Who should avoid Acupuncture?

- If you are pregnant (or think you may be).
- Afraid of needles to the point of passing out.
- Have a bleeding disorder or are on certain medications.
- Have a Pacemaker, Defibrillator or other similar electronic devices
- Are scheduled for an MRI. We would want to remove any remaining needles or magnets before MRI procedure is performed



the

## The process:

- Very small needles or magnets are used.
- They are placed in five points in the surface of the ear.
- You may have some mild discomfort.
- The needles stay in for two to six days.
- If they bother you, they can easily be removed at home.

## After care:

- Relax the day after, no heavy exercise, house work or yard work.
- No alcohol for one day after.
- Return to normal activity after 24 hours.
- When the needles fall out dispose of them in a container with a lid.
- Do not scrub the ear.
- Take notes of how you feel, sleep and your pain level.

## Possible side effects:

- Infection: redness, swelling, warmth, increased pain
- Bleeding or bruising.
- Feeling dizzy or nauseated.
- Fainting.
- Feeling euphoric or lightheaded.
- Drowsiness.
- Discoloration involving the skin where the needles are placed
- It is possible for symptoms to become worse after a treatment, this is almost always temporary and a good sign that you are responding to the treatment.

Battlefield Acupuncture



Acupuncture  
Needles