AURICULAR ACUPUNCTURE IN THE TREATMENT OF CHRONIC HEADACHE
IN MILITARY PATIENTS

A Research Grant Proposal

Presented to the faculty of the School of Nursing
California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Nursing
Family Nurse Practitioner

by
Liza Suela Benedito

SUMMER 2015
CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULLFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

NURSING

PROJECT TITLE: Auricular Acupuncture in the Treatment of Chronic Headache in Military Patients

AUTHOR: Liza Suela Benedito BSN, RN

DATE OF SUCCESSFUL DEFENSE: 27 July 2015

THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING.

Dr. Denise Boren
PROJECT COMMITTEE CHAIR

[Signature]

7/27/2015

Dr. Linnea Axman
PROJECT COMMITTEE MEMBER

[Signature]

7/27/2015

PROJECT COMMITTEE MEMBER

[Signature]

DATE
Student: Liza Suela Benedito

I certify that this student has met the School of Nursing format requirements, and that this project is suitable for shelving in the Library and credit is to be awarded for the project.

Dr. Denise Boren

[Signature]

July 27, 2015

Date

School of Nursing
College of Education, Health, and Human Services
California State University San Marcos
Abstract

of

AURICULAR ACUPUNCTURE IN THE TREATMENT OF CHRONIC HEADACHE IN MILITARY PATIENTS

by

Liza Suela Benedito

The wars in Iraq and Afghanistan of the past decade have resulted in thousands of casualties with a complexity of physical, psychological, cognitive, and behavioral symptoms referred to as traumatic stress response (TSR) (Lee et al., 2012). Military and Veteran Administration providers are seeking alternative therapies in efforts to reduce reliance in pharmaceutical methods to treat symptoms. Chronic headache, one of the most common of the symptoms, has been found to be effectively treated with complementary and alternative medicine (CAM) (Rossi et al., 2006). Auricular acupuncture, or acupuncture using points in the external ear, has been well received by both military providers and patients in a variety of settings. Auricular acupuncture can be easily trained to physicians, nurses, corpsmen and medics, and provides a treatment that is minimally invasive, portable, inexpensive, and has minimal side effects (King, Hickey, & Connelly, 2013). It expands treatments options and incorporates an alternative nonpharmacologic therapy that has minimum risk and side effects that can potentially affect military readiness. It also encourages patient to engage in health seeking behaviors.

The purpose of this research is to evaluate whether the routine delivery of auricular acupuncture in military patients experiencing chronic headache pain is an effective adjunctive therapy in providing headache relief.

Specific aim: Determine whether auricular acupuncture delivered over a six week period in conjunction with standard medical therapy would influence pain intensity in military patients with chronic daily headache as opposed to conventional therapy alone.

Dr. Denise Boren

Committee Chair

July 27, 2015

Date
DEDICATION

I would like to dedicate this to my parents SMSGT Alberto Suela USAF (ret) and Sonia Suela.

Thank you for your love and influence on who I am today.

ACKNOWLEDGEMENTS

Thank you to my husband Mario and my beautiful daughters Marisa, Malia, and Stephanie for their support, understanding, and love during this journey.

Thank you to my wonderful boss Mary Samson, colleague DG Kilcher, and coworkers at NHCP who encouraged me and backed me up through this entire process.

I would like to acknowledge and thank Dr. Denise Boren and Dr. Linnea Axman for their time assistance in this project. Thank you for your passion and dedication to nursing education and advancement.

Many thanks to my professors and preceptors especially Dr. Diane Daniels for your mentorship and guidance.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>v</td>
</tr>
<tr>
<td>Dedication</td>
<td>vi</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>vi</td>
</tr>
<tr>
<td>Form Page 1: Face Page</td>
<td>1</td>
</tr>
<tr>
<td>Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells</td>
<td>2</td>
</tr>
<tr>
<td>Form Page 3: Research Grant Table of Contents</td>
<td>3</td>
</tr>
<tr>
<td>Form Page 4: Detailed Budget for Initial Budget Period, Direct Costs Only</td>
<td>4</td>
</tr>
<tr>
<td>Form Page 5: Budget for Entire Proposed Project Period, Direct Costs Only</td>
<td>5</td>
</tr>
<tr>
<td>Budget Justification and biographical sketch</td>
<td>5</td>
</tr>
<tr>
<td>RESEARCH PLAN:</td>
<td></td>
</tr>
<tr>
<td>1. Specific Aims</td>
<td>9</td>
</tr>
<tr>
<td>2. Background and Significance</td>
<td>10</td>
</tr>
<tr>
<td>3. Preliminary Studies/Progress Report</td>
<td>14</td>
</tr>
<tr>
<td>4. Research Design and Method</td>
<td>19</td>
</tr>
<tr>
<td>5. Dissemination plan</td>
<td>26</td>
</tr>
<tr>
<td>6. Bibliography and References Cited</td>
<td>27</td>
</tr>
<tr>
<td>Appendix A. Migraine Disability Assessment (MIDAS) Questionnaire</td>
<td>29</td>
</tr>
<tr>
<td>Appendix B. Headache Impact Test (HIT-6)</td>
<td>30</td>
</tr>
<tr>
<td>Appendix C. Consent to participate in research</td>
<td>31</td>
</tr>
</tbody>
</table>
1. **TITLE OF PROJECT** (Do not exceed 81 characters, including spaces and punctuation.)
   
   Auricular Acupuncture in the Treatment of Chronic Headache in Military Patients

2. **RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION**
   (If “Yes,” state number and title)
   
   Number:          Title:          

3. **PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR**
   
   3a. **NAME** (Last, first, middle)  
       Benedito, Liza, Suela
   
   3b. **DEGREE(S)**  
       MSN  BSN
   
   3c. **POSITION TITLE**  
       Researcher
   
   3d. **MAILING ADDRESS** (Street, city, state, zip code)  
       32450 Galatiana Street
       Temecula, CA 92592
   
   3e. **DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT**  
       School of Nursing, California State University San Marcos
   
   3f. **MAJOR SUBDIVISION**

4. **HUMAN SUBJECTS RESEARCH**
   
   4a. **Research Exempt**  
       If “Yes,” Exemption No.
   
   4b. **Federal-Wide Assurance No.**

5. **VERTEBRATE ANIMALS**  
   
   5a. **Animal Welfare Assurance No.**

6. **DATES OF PROPOSED PERIOD OF SUPPORT** (month, day, year—MM/DD/YY)
   
   From Through

7. **COSTS REQUESTED FOR INITIAL BUDGET PERIOD**
   
   7a. Direct Costs ($)  
   7b. Total Costs ($)  

8. **COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT**
   
   8a. Direct Costs ($)  
   8b. Total Costs ($)  

9. **APPLICANT ORGANIZATION**
   
   Name California State University, San Marcos, CA
   
   Address 333 South Twin Oaks Valley Road
   
   San Marcos, CA 92096

10. **TYPE OF ORGANIZATION**
    
    Public:  
    Federal  
    State  
    Local
    
    Private:  
    Private Nonprofit
    For-profit:  
    General  
    Small Business
    Woman-owned  
    Socially and Economically Disadvantaged

11. **ENTITY IDENTIFICATION NUMBER**
    
    DUNS NO.       Cong. District

12. **ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE**
    
    Name Dr. Denise Boren
    
    Title Dean of Nursing
    
    Address 333 South Twin Oaks Valley Road
    
    San Marcos, CA 92096
    
    Tel: 760-750-7550
    
    E-Mail: dcboren@csusm.edu

13. **OFFICIAL SIGNING FOR APPLICANT ORGANIZATION**
    
    Name          
    Title          
    Address
    
    Tel:          
    FAX:          
    E-Mail:          

14. **APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE**: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

   SIGNATURE OF OFFICIAL NAMED IN 13.  
   (In ink. “Per” signature not acceptable.)  
   DATE
PROJECT SUMMARY (See instructions):
The wars in Iraq and Afghanistan of the past decade have resulted in thousands of casualties with a complexity of physical, psychological, cognitive, and behavioral symptoms referred to as traumatic stress response (TSR) (Lee et al., 2012). Military and Veteran Administration providers are seeking alternative therapies in efforts to reduce reliance in pharmaceutical methods to treat symptoms. Chronic headache, one of the most common of the symptoms, has been found to be effectively treated with complementary and alternative medicine (CAM) (Rossi et al., 2006). Auricular acupuncture, or acupuncture using points in the external ear, has been well received by both military providers and patients in a variety of settings. One of its initial uses was in operational settings as adjunctive therapy to decrease acute pain (Spira, 2008).

The purpose of this research is to evaluate whether the routine delivery of auricular acupuncture in military patients experiencing chronic headache pain is an effective adjunctive therapy in providing headache relief. The theoretical framework is the theoretical concept of Traditional Chinese Medicine (TCM). TCM explains the efficacy of acupuncture as a balance of yin and yang, with energy or qi flowing through meridians or channels throughout the body; when flow is disrupted or blocked, pain or disease can occur (Goertz, 2006). Acupuncture restores the flow of qi through the insertion of needles in specific points resulting in healing (Spira, 2008).

Specific aim: Determine whether auricular acupuncture delivered over a six week period in conjunction with standard medical therapy would influence pain intensity in military patients with chronic daily headache as opposed to conventional therapy alone.

RELEVANCE (See instructions):
Auricular acupuncture can be easily trained to physicians, nurses, corpsmen and medics, and provides a treatment that is minimally invasive, portable, inexpensive, and has minimal side effects (King, Hickey, & Connelly, 2013). It expands treatments options and incorporates an alternative nonpharmacologic therapy that has minimum risk and side effects that can potentially affect military readiness. It also encourages patient to engage in health seeking behaviors.
**Program Director/Principal Investigator (Last, First, Middle):** Benedito, Liza, Suela

**SENIOR/KEY PERSONNEL.** See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

<table>
<thead>
<tr>
<th>Name</th>
<th>eRA Commons User Name</th>
<th>Organization</th>
<th>Role on Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Boren, Denise</td>
<td></td>
<td>CSUSM</td>
<td>Chair</td>
</tr>
<tr>
<td>Dr. Axman, Linnea</td>
<td></td>
<td>CSUSM</td>
<td>Committee member</td>
</tr>
<tr>
<td>Dr. Daniels, Diane</td>
<td></td>
<td>NHCP</td>
<td>PI</td>
</tr>
<tr>
<td>Benedito, Liza</td>
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<td>CSUSM</td>
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**OTHER SIGNIFICANT CONTRIBUTORS**

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<tr>
<th>Name</th>
<th>Organization</th>
<th>Role on Project</th>
</tr>
</thead>
</table>

**Human Embryonic Stem Cells**  ☒ No  ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp](http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp). *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

**Cell Line**
RESEARCH GRANT

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells</th>
<th>2-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>4</td>
</tr>
<tr>
<td>Detailed Budget for Initial Budget Period</td>
<td>4</td>
</tr>
<tr>
<td>Budget for Entire Proposed Period of Support</td>
<td>6-8</td>
</tr>
<tr>
<td>Budgets Pertaining to Consortium/Contractual Arrangements</td>
<td>6</td>
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<tr>
<td>Biographical Sketch – Program Director/Principal Investigator (Not to exceed four pages each)</td>
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<tr>
<td>Other Biographical Sketches (Not to exceed four pages each – See instructions)</td>
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<tr>
<td>Resources</td>
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<tr>
<td>Checklist</td>
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<tr>
<td>Research Plan</td>
<td>9</td>
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</table>

1. Introduction to Resubmission Application, if applicable, or Introduction to Revision Application, if applicable *  |
2. Specific Aims *  |
3. Research Strategy *  |
4. Inclusion Enrollment Report (Renewal or Revision applications only)  |
5. Bibliography and References Cited/Progress Report Publication List  |
6. Protection of Human Subjects  |
7. Inclusion of Women and Minorities  |
8. Targeted/Planned Enrollment Table  |
9. Inclusion of Children  |
10. Vertebrate Animals  |
11. Select Agent Research  |
12. Multiple PD/PI Leadership Plan  |
13. Consortium/Contractual Arrangements  |
14. Letters of Support (e.g., Consultants)  |
15. Resource Sharing Plan (s)  |

Appendix (Five identical CDs.)

* Follow the page limits for these sections indicated in the application instructions, unless the Funding Opportunity Announcement specifies otherwise.
### Detailed Budget for Initial Budget Period

**Direct Costs Only**

List Personnel (Applicant organization only)

Use Cal, Acad, or Summer to enter months devoted to Project

Enter dollar amounts requested (omit cents) for salary requested and fringe benefits.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role on Project</th>
<th>Cal Mnths</th>
<th>Acad Mnths</th>
<th>Summer Mnths</th>
<th>Inst. Base Salary</th>
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<td></td>
<td></td>
<td></td>
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**Subtotals**

- **Consultant Costs**
  - Biostatistician to assist with data analysis, 40 hours/$100.00/hr
    - Total: 4,000

- **Equipment** (Itemize)
  - Laptop, printer, toner, hard drive, SPSS software
    - Total: 2,090

- **Supplies** (Itemize by category)
  - Acupuncture needles, sharps containers, general office supplies $934
  - Dissemination cost $400
    - Total: 1,334

- **Travel**
  - DCoE Summit
    - Total: 2,000

- **Inpatient Care Costs**

- **Outpatient Care Costs**

- **Alterations and Renovations** (Itemize by category)

- **Other Expenses** (Itemize by category)
  - Auricular acupuncture training
    - Total: 1,150

**Consortium/Contractual Costs**

**Subtotal Direct Costs for Initial Budget Period** (Item 7a, Face Page)

- **Total Direct Costs for Initial Budget Period**

<table>
<thead>
<tr>
<th>Description</th>
<th>Direct Costs</th>
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<tr>
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<tr>
<td><strong>Consortium/Contractual Costs</strong></td>
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<tr>
<td><strong>Facilities and Administrative Costs</strong></td>
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<tr>
<td><strong>Total Direct Costs for Initial Budget Period</strong></td>
<td>$28,074</td>
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</table>
## BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
**DIRECT COSTS ONLY**

<table>
<thead>
<tr>
<th>BUDGET CATEGORY TOTALS</th>
<th>INITIAL BUDGET PERIOD (from Form Page 4)</th>
<th>2nd ADDITIONAL YEAR OF SUPPORT REQUESTED</th>
<th>3rd ADDITIONAL YEAR OF SUPPORT REQUESTED</th>
<th>4th ADDITIONAL YEAR OF SUPPORT REQUESTED</th>
<th>5th ADDITIONAL YEAR OF SUPPORT REQUESTED</th>
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<td>TOTAL DIRECT COSTS</td>
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</tbody>
</table>

**TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD**

$ 28,074

**JUSTIFICATION.** Follow the budget justification instructions exactly. Use continuation pages as needed.

### Personnel
The principal investigator or lead researcher of this project per TSNRP instruction must be an active duty service member or retired from the military. Dr. Daniels is a retired Navy Nurse Corps officer who is employed by Naval Hospital Camp Pendleton Concussion Clinic as a Nurse Practitioner. She will serve as the principal investigator (PI) and be a direct participant in the project, and as a government employee will not require an additional salary from this grant.

Liza Benedito will serve as the associate investigator (AI) for this novice investigator study. Liza served in the US Navy Nurse Corps from 1996 – 2003 and has worked for the Department of the Navy at Naval Hospital Camp Pendleton for the past 9 years. She has 19 years of nursing experience. She will also participate directly in the study by presenting it to the IRB, administering and collecting the data, and assist in the data analysis. She will not require an additional salary as a government employee.

A research assistant will be hired for 6 months at the cost of $17,500 (based on an annual average salary of $35,000). The assistant will be responsible for ordering needed supplies, data entry, arranging follow-up sessions...
$35,000). The assistant will be responsible for ordering needed supplies, data entry, arranging follow up with participants, and any additional tasks needed to support this project.

**Consultation Costs**
A biostatistician will be consulted after data has been collected to assist with the data analysis and statistics using SPSS software. Approximately 40 hours of consultation will be needed at $100.00/hour for a total of $4000.

**Equipment**
A laptop and printer will be needed to collect, analyze and store data as well as produce the questionnaires for the study. In order to use SPSS software a laptop with Windows XP 1 GHz Intel processor with 1GB RAM and CD-ROM can be purchased for $500. Estimated cost for a printer is $150 and $200 for toner. The cost for SPSS software is $1140. A back up hard drive to store data should be obtained, estimated cost $100. Total cost for equipment is $2,090.

**Supplies**
Auricular acupuncture needles can be purchased from a reputable acupuncture supply company. One box of 100 needles costs approximately $60. The number of participants is 44 and each will receive 4 needles (2 in each ear) during weekly visits for 6 weeks. 24 needles will be needed for one patient, total amount needed for all patients is 1056 needles. 11 boxes will be ordered at $60 each for a cost of $660. Two sharps containers will be needed ($12 each) for a cost of $24. General office supplies to include paper and printing costs is estimated at $250. Total cost of supplies is $934.

**Training**
Both the PI and AI must attend auricular acupuncture training. Training can be obtained through military treatment facility training programs if they are available or an approved civilian course such as the Auriculotherapy Certification Institute. The total cost for the training, onsite practicum, and certification exam per person is $775. Total cost is $1550 for both PI and AI. The training is online and the onsite practicum can be done at local sites by certified auriculotherapists.

**Travel**
The travel costs for dissemination of research findings at the annual DCoE Summit would include airfare, lodging, registration fees, car rental and food for the PI and AI and is estimated at $2000.

**Dissemination**
The Defense Center of Excellence for Psychological Health and Traumatic Brain Injury hosts an annual summit in Falls Church, VA. The results of this study would be presented the following year after completion via poster presentation. Costs for the assembly of the poster, printing, and stand is estimated at $400.
RESOURCES

Follow the 398 application instructions in Part I, 4.7 Resources.
RESEARCH PLAN

Specific Aims

The wars in Iraq and Afghanistan of the past decade have resulted in thousands of casualties with a complexity of physical, psychological, cognitive, and behavioral symptoms referred to as traumatic stress response (TSR) (Lee et al., 2012). In their efforts to reduce reliance in pharmaceutical methods to treat the symptoms of TSR, military and Veteran Administration providers are seeking alternative therapies. Chronic headache, one of the most common of the symptoms affecting this population, has been found to be effectively treated with complementary and alternative medicine (CAM) (Rossi et al., 2006).

Practitioners of Traditional Chinese Medicine (TCM) have used acupuncture for over 2500 years to improve health and treat disease (Goertz, 2006). Auricular acupuncture, or acupuncture using points in the external ear, has been well received by both military providers and patients in a variety of settings. One of its initial uses was in operational settings as adjunctive therapy to decrease acute pain (Spira, 2008). Battlefield acupuncture, an auricular acupuncture protocol using 5 specific acupoints in the ear, can be easily trained to physicians, nurses, corpsmen and medics, and provides a treatment that is minimally invasive, portable, inexpensive, and with minimal side effects (King, Hickey, & Connelly, 2013). Review of literature has found studies demonstrating its efficacy in acute pain syndromes, however no studies were found using battlefield acupuncture protocol in treating chronic headache in military populations.

Problem Statement
Auricular acupuncture has proven to be an effective method of acute pain relief in injured service members, however less is known about its effectiveness as routine adjunctive therapy in treating chronic daily headache in military patients that suffer from TSR symptoms as a result of TBI and or PTSD.

**Purpose of the Research**

The purpose of this research is to evaluate whether the routine delivery of auricular acupuncture in military patients experiencing chronic headache pain is an effective adjunctive therapy in providing headache relief.

**Research Question and Hypothesis**

The research question is, “Does auricular acupuncture effectively decrease pain intensity in military patients with chronic headache pain?” The hypothesis is “Auricular acupuncture effectively decreases chronic headache pain in military patients”.

**Specific Aim**

Determine whether auricular acupuncture delivered over a six week period in conjunction with standard medical therapy would influence pain intensity in military patients with chronic daily headache as opposed to conventional therapy alone.

**Background and Significance**

Over two million service members have served in the recent wars in Iraq and Afghanistan and have resulted health problems. Traumatic Brain Injury (TBI) and Post Traumatic Stress Disorder (PTSD) have been called the “signature wounds” of the Iraq and Afghanistan wars and improvised explosive devices in thousands of casualties that require long-term management of a unique combination of physical and mental (IED’s) or other roadside bombs have been called the
“signature weapons” of the wars (Ritchie, 2013). Injuries from IED’s have resulted in TBI and PTSD as well as traumatic physical injuries, amputations, hearing loss, chronic pain syndromes, and disability. The constellation of symptoms that results has been called Traumatic Stress Response or TSR and includes a spectrum of physical, psychological, cognitive, and behavioral effects with headache as the most commonly reported symptom (Lee et al., 2012). Current literature cites preliminary prevalence reports of up to 47% of Iraq and Afghanistan combat veterans reporting headaches related to mild TBI events (Patil et al., 2011).

In the last decade, both military treatment facilities and Veteran Administration healthcare facilities have expanded the use of Complementary and Alternative Medicine (CAM) in order to reduce reliance on opioids and pharmaceutical approaches in managing these conditions and TSR symptoms (King, Hickey, & Connelly, 2013). According to the National Center for Complementary and Alternative Medicine (NCCAM), CAM therapies are a broad group of diverse medical and health care practices and products, also referred to “complementary health approaches” that are not generally considered part of conventional western medical treatment. CAM practices are divided into broad categories, such as mind and body medicine, body-based practices, and natural products (NCCAM, 2013). Combined use of evidenced based CAM practice used in conjunction with traditional western-based medicine has been termed “Integrative Medicine” (Sniezek, 2012). Integrative medicine is increasingly being used in health care systems in the US with integrative medicine programs being established at leading medical centers, including major Military and Veteran treatment facilities, offering a way to incorporate a variety of treatments with the aim of improving healthcare outcomes for our veterans (King, Hickey, & Connelly, 2013).
Chronic headache diagnoses are among the frequent conditions of CAM users and CAM practitioners consider it to be one of the conditions most likely to improve significantly as a result of CAM therapies (Rossi et al., 2006). Chronic headaches are found to be more prevalent in military patients than in the general civilian population, affecting 17.4% of men and 34.9% of women (Plank & Goodard, 2009). Chronic daily headaches are defined as headaches lasting more than four hours and occurring at least fifteen days/month (Plank & Goodard, 2009). The burden of headache is impacted by lost productivity, absenteeism, and increased healthcare utilization, and is associated with maladaptive chronic pain behavior and loss of quality of life (Patil et al., 2011). In addition, associated psychological issues such as anxiety, depression, sleep disturbance, and PTSD is likely to exacerbate the frequency and intensity of headaches (Patil et al., 2011). Standard interventions and polypharmacy treatments can cause unfavorable side effects and logistical difficulties affecting Military readiness and identifying appropriate treatment interventions is critical given the number of service members and veterans affected by these conditions (Lee, et al., 2012).

Traditional acupuncture or medical acupuncture, which falls under the mind and body practice category of CAM (NCCAM, 2013), is one of the most commonly researched and widely accepted forms utilized in VA and Military facilities (Plank & Goodard, 2009). It has been found to be effective in treating the individual conditions of TSR such as chronic pain, headaches, insomnia, depression and anxiety (Lee et al., 2012).

In recent years auricular acupuncture, a form of acupuncture utilizing stimulation points in the ear, has been well received and found effective in treating acute and chronic pain syndromes in military personnel (King, Hickey, & Connelly, 2013). It is one of the many
treatments in Ayurvedic Medicine as well as Traditional Chinese Medicine (TCM), and is referenced in the “Yellow Emperor’s Classics of Internal Medicine,” one of the oldest Chinese medical texts dating back to 500 B.C. (Goertz, 2006). In this form of acupuncture, it is believed stimulation points on the external ear are associated with specific organ systems of the body (Goertz, 2006). Historically auricular acupuncture has been most widely used to treat drug addiction, however it is believed that auricular acupuncture can be easily administered in a variety of settings, and be used to treat a numerous conditions (King, Hickey, & Connelly, 2013).

Battlefield acupuncture is a term used to describe auricular acupuncture initially provided to war wounded for pain relief with significant results. It is an auricular acupuncture protocol developed by Col Richard Niemtzow (USAF) for the treatment of pain that has been used in both clinic and deployment settings (King, Hickey, & Connelly, 2013). The battlefield acupuncture protocol places in sequential manner ASP (Aiguille D’acupuncture semi-permanente studs) needles in a series of five acupoints: cingulate gyrus, thalamus, omega-2, point zero, and shen men (Niemtzow, 2007). The patient is asked to ambulate after each ASP needle is placed in an acupoint. If pain relief is not achieved, a needle is placed in the same acupoint of the opposite ear. Pain intensity is evaluated with each placement and whichever ear produces the greatest pain relief, needles are placed in similar manner into each acupoint (Niemtzow, 2007). When the pain is relieved no other studs are placed and they remain in the ear for three to four days before they fall out on their own. This protocol has been used in military and veteran patients throughout their care continuum and has been demonstrated to reduce pain intensity. Other protocols have since been developed by the Helms Medical Institute in treating military populations to include the Auricular Trauma Protocol and PTSD Auricular Protocol (King,
Hickey, & Connelly, 2013). Studies have demonstrated its effectiveness in acute pain syndromes however there is no current literature demonstrating its’ use in chronic headache syndromes.

**Significance to Nursing**

Integrative medicine experts in the military are advocating training in the technique of auricular acupuncture, as there are numerous benefits. These benefits are it is inexpensive and portable, there are minimal side effects and the treatment is minimally invasive, and it can be administered easily in a variety of clinical settings including operational settings by physicians, nurses, corpsmen or medics who can be readily trained (King, Hickey, & Connelly, 2013). It expands treatments options and incorporates an alternative nonpharmacologic therapy that has minimum risk and side effects that can potentially affect military readiness. It also encourages patient to engage in health seeking behaviors. Training and education of military health providers in auricular acupuncture techniques typically requires four to eight hours of didactic teaching and clinical practice and a short examination and both military privileged and non-privileged providers (nurses, corpsmen, medics) can be trained to provide the treatment. (King, Hickey, & Connelly, 2013).

**Preliminary Studies / Progress Report**

CINAHL, Google Scholar, and PubMed were used to research auricular acupuncture and investigate the use of it in a military population. Literature search terms included acupuncture, auricular acupuncture, battlefield acupuncture, complementary and alternative medicine, CAM, integrative medicine, military, veterans, TBI, PTSD, headache, trauma spectrum response, TSR, Traditional Chinese Medicine, TCM, MIDAS, and HIT-6.
Plank & Goodard (2009) conducted a pilot on the effectiveness of traditional acupuncture for chronic daily headaches. The purpose of their study was to evaluate if a set group of acupuncture points, delivered over a predefined period of time would influence frequency, duration, and intensity in patients with chronic daily headache (Plank & Goodard, 2009). Both military and civilian subjects were recruited and four standardized acupuncture points (two in the foot, and two in the hand) were utilized on twenty-six subjects suffering from chronic daily headache over twelve weeks. Results showed continued improvements up to eight weeks with pain scores rising by twelve weeks but not returning to baseline levels. They determined monthly maintenance acupuncture may prevent this rise and a standardized approach was needed to create reproducibility across the discipline. Limitations of this study were a small sample size and using both military and civilian subjects, which could affect generalizability. Their measurements, pain, quality of life, and depression all improved however and there were little to no side effects.

Spira (2008) conducted a noncontrolled, descriptive study that arose from a treatment option for pain offered to troops serving during a nine-month deployment to Iraq. His subjects were selected from five hundred sailors, Marines, soldiers, and Special Forces personnel receiving care at a Battalion Aid Station (BAS) at Al Asad Marine Corps Air Station in Al Anbar Province, Iraq. Treatments were also given at the BAS at Camp Fallujah and other forward operating bases. Traditional acupuncture was administered to 132 different patients with a total of 435 treatments administered for various acute and chronic conditions, primarily orthopedic pain conditions. Although this study was not a randomized controlled trial, it found the data collected provided useful knowledge regarding the utility of acupuncture in a operational setting.
Spira, 2008). The majority of subjects were interested and open to the treatment in order to avoid medication treatments that would impose side effects impeding their ability to participate in the mission. In addition, Spira analyzed the cost of treatment and noted a substantial savings as compared to traditional medicine methods. His studied showed acupuncture to be a useful and practical, cost-effective adjunctive therapy in this environment.

Goertz (2006) conducted a pilot study using randomized controlled clinical trial design to compare the effects of standard emergency medical care to auricular acupuncture plus standard emergency medical care in patients with acute pain syndromes. Eight seven active duty members or dependents between the ages of 18 and 50 with acute pain were studied at the emergency room at Malcolm Grow Medical Center at Andrews Air Force Base, Maryland. A numerical rating Scale was used to measure pain level from baseline and participants. Only two acupuncture points in the ear were used, the cingulate gyrus and thalamic nuclei, which are believed to mediate acupuncture analgesia (Goertz, 2006). The needles remained in the ear until they fell out on their own in approximately four to six days. Outcome measures of pain were assessed at baseline, immediately after the treatment, and at a twenty-four hour follow up. In the acupuncture group experienced a 23 % reduction in pain before leaving the ER, while pain levels in patients receiving standard treatment alone remained unchanged (Goertz, 2006). Goertz found that both groups experienced a similar reduction in pain 24 hours later. This pilot study showed that placing small needles at two acupuncture points in the ear appeared to be effective in decreasing acute pain levels in an emergency. The cost of treatment was also assessed and found to be minimal at $1.52 per patient.
Lee et al. (2012) published a systematic review of reviews on the effectiveness of acupuncture research across components of the trauma spectrum response. The co-morbid symptoms of military patients returning from combat include symptoms of depression, fatigue, anxiety, and chronic pain, and the overlapping physical, psychological, cognitive and behavioral effects are called traumatic stress response (Lee et al., 2012). The complexity of TSR often requires a multi modal approach, biopsychosocial, whole person approach and the authors aimed to study acupuncture as a promising treatment option for TSR, as it has been found effective in treating several of the individual conditions of TSR (Lee et al., 2012). Fifty-two studies were reviewed with nearly half on chronic pain, and only five reviews that met their inclusion criteria were on traditional acupuncture use on headache. The remainders were on the use of acupuncture on substance abuse, sleep disturbance, depression, fatigue, and cognitive function. Lee et al. determined at the time of their study, there have been no reviews examining acupuncture efficacy across the entire trauma spectrum response.

In 2013, King, Hickey & Connelly published the article, “Auricular Acupuncture: A Brief Introduction for Military Providers”, which gives a fundamental description of auricular acupuncture and its application in military settings. It provides an overview of the history of auricular acupuncture and its foundation in Traditional Chinese Medicine. Battlefield acupuncture is described based on the protocol developed by Colonel Richard Niemtzow. The author’s acknowledged the need for further studies and research to establish a base of evidence for this treatment in veterans so that it is becomes more readily available and accessible as a standard of care.

**Major Variables Defined**
Auricular Acupuncture.  Auricular acupuncture refers to acupuncture on the stimulation points of the external ear (Goertz, 2006).

Battlefield Acupuncture.  Battlefield acupuncture refers to the auricular acupuncture protocol utilizing five specific acupoints on the external ear: the cingulate gyrus, thalamus point, Omega 2, Point zero, and Shen men (Niemtzow, 2007). This protocol was developed to provide a system of rapid relief of pain in an operational setting and has been used in both acute and chronic conditions.

Chronic Daily Headache.  Chronic daily headache is defined as headaches lasting more than four hours and occurring at least fifteen days per month (Goertz, 2006).

Pain Intensity.  Pain intensity is measured by the Migraine Disability Assessment (MIDAS) and the Headache Impact Test (HIT-6). The Migraine Disability Assessment (MIDAS) is a seven question, self report, retrospective questionnaire used to determine how severely headaches affect a patient’s life based on number of days impacted in the past three months (Sauro et al., 2010). The Headache Impact Test (HIT-6) is a six-question, self-report scale test that attempts to measure the impact on quality of life and helps describe and communicate the patients’ feelings about their headache (Sauro et al., 2010).

Demographic Variables.  Gender is defined as male, female or transgender. Age is the chronological age of the participant. Ethnicity refers to the participants’ self identified cultural background.

Summary

In summary, the literature reviewed revealed there were few studies on acupuncture in the treatment of headaches specifically in a military population, and none found on auricular
acupuncture in treating headache in military patients. There is an increase demand for alternative therapies in treating military patients with the complex symptomology that occurs as a result of traumatic stress response. Traditional Chinese Medicine identify key components in their theory of identifying and diagnosing illness, and the practice of acupuncture uses this theory to explain its efficacy. Military and Veteran Administration providers have turned to complementary and alternative therapies to treat these conditions and headache is one of the most common conditions in this population. According to the literature, headache can be effectively measured using the Migraine Disability Assessment (MIDAS) and the Headache Impact Test (HIT-6) (Sauro et al., 2010). Several studies have reported the effectiveness of acupuncture in treating headache however less is known about the use of auricular acupuncture as adjunctive treatment in chronic headache. Battlefield acupuncture, a protocol using five specific acupoints has been used for acute pain in both operational and civilian settings. Its use in chronic headache management has been minimally reported and studied.

**Research Designs and Methods**

**Theoretical Framework**

The practice of acupuncture is deeply rooted in both Traditional Chinese Medicine as well as ayurvedic medicine. Ayurveda originating in India and traditional Chinese medicine are two of the oldest and most developed systems of natural healing. Both systems are well recognized by the World Health Organization and practices are expanding across the globe. The Theory of Chinese Medicine (TCM) is used to explain acupuncture mechanisms and efficacy and encompasses a very different view than western medicine in regards to health and disease. In TCM, the human body is made up of bodily organs with distinct but interdependent functions,
and individuals are believed to be interconnected with the universe around them (Li & Xu, 2011). Health is maintained by balancing these forces, whereas treatment of disease is focused on restoring the balance and maintaining bodily homeostasis and self-adjustment within an environment (King, Hickey, & Connelly, 2013).

There are multiple concepts in TCM. The concepts applied to acupuncture include the five elements as its worldview and methodology, the holistic concept as guidance, *yin* and *yang* forces, the monism of *Qi* or “chee”, the physiology and pathology of *zang fu* organs, and the core meridians (Li & Xu, 2011). *Yin* and *yang* refer to two opposing forces working together to achieve balance and excess or deficiency in either causes illness and treatments should be aimed to restore balance (King, Hickey, & Connelly, 2013). The five elements are wood, fire, earth, metal and water. Each element is related to organs that are zang organs (Yin qualities) or fu organs (yang qualities) and acupuncture affects the channels that connect zang and fu organs through associated acupoints (King, Hickey, & Connelly, 2013). *Qi* or “chee” is the vital life force and a person’s energy, and when in excess or deficient, illness can occur (Plank & Goodard, 2009). Qi flows on the meridian channels and acupuncture inserted along these channels are believed to regulate, restore, and correct the imbalance of qi (Goertz, 2006; Plank & Goodard, 2009). Holistic viewpoint of the individual is central to TCM and considers the social, emotional, physical, and spiritual well being. The theory applied to acupuncture efficacy is balancing *yin* and *yang*, which can be compared to parasympathetic and sympathetic systems (Plank & Goodard, 2009). Acupuncture meridians traverse all parts of the body and qi course through these channels. Imbalanced or blocked qi is thought to cause pain and dysfunction, and
Acupuncture is felt to correct the imbalance of flow through the meridians (Plank & Goodard, 2009).

Ayurveda is the traditional system of Indian medicine. It means “science of life” or “practices longevity” and reflects the language of the Vedas, the oldest books of India (Ros, 2015). Ayurveda believes in the “five great elements” of earth, water, fire, air, and space forming the universe including the human body. It stresses balancing the elements of the body and classifies special points called marmas or sensitive points, and describes the body in terms of various channels systems, much like the meridian systems of traditional Chinese medicine (Ros, 2015).

Research Question and Hypothesis

**Research Question.** “Is auricular acupuncture an effective adjunctive therapy in decreasing pain intensity in military patients with chronic headache pain?”

**Hypothesis:** Auricular acupuncture is an effective adjunctive therapy in decreasing chronic headache pain in military patients.

Research Proposal

A pilot study to evaluate whether auricular acupuncture delivered weekly over a six-week period, in conjunction with standard medical therapy, would influence pain intensity levels of military patients with chronic daily headache as opposed to standard medical therapy alone.

Identification of Setting

The setting for this study is the TBI Neurology Clinic at Naval Hospital Camp Pendleton, California.

Research Design
The design of this study is quasi experimental because it will be a controlled study without randomization. It is also a non-equivalent control group pretest-post test design as measurements are of a group receiving auricular acupuncture intervention as adjunctive headache therapy, and of another group not getting the intervention and receiving standard headache therapy. Measurements will be taken prior to beginning the study and immediately after.

Sample and Sampling Plan

The target population and sample is a non-randomized convenience sample. Subjects will be active duty members assigned to the Wounded Warrior Program at Naval Hospital Camp Pendleton who are receiving treatment in the TBI Neurology clinic for headache management. The sample will be selected from the Wounded Warrior database of patients meeting diagnostic criteria for chronic daily headache and carry TBI/PTSD diagnosis. Participants will be invited to participate in the study. Generalizability is to a military population 19-40 years of age.

The target sample size is determined by using G Power Analysis 3.1 for Mac. An alpha level of 0.05, a power of 0.80, and effect size 0.5 were used for a pilot study and the total target sample size was calculated as 74. An additional 20% is added for attrition to bring the sample size 88, or 44 in each group.

The inclusion criteria for this study are: active duty male or female between 19 and 40 years of age with TBI/PTSD diagnosis; six month history of headaches on a current medical regimen through the TBI Neurology clinic; 15 discrete headaches in 31 day period; and has not received acupuncture for any condition in past 12 mos. The exclusion criteria for this study are: organic pathology as cause of headache (i.e. cancer, MS, stroke); systemic disorder or illness, or
recent surgery; change of headache treatment less than 2 weeks prior to study; pregnancy; and or regular use of alcohol or recreational drugs.

The method of obtaining sample will be to assign subjects to a treatment group based on initial response to the MIDAS (Appendix A) and HIT-6 (Appendix B) questionnaires with a goal of similar levels of severity assigned to each group.

Threats to internal validity include selection the selection process. It cannot be assumed that the experimental and control group have equivalent levels of pain or assess pain similarly. Control for this is adhering to the inclusion criteria and utilizing groups with similar baseline measures. Propensity matching can be used and involves the creation of a single propensity score that captures the conditional probability of exposure to a treatment given various preintervention characteristics (Polit & Beck, 2012). Experimental and comparison groups can be matched on this score. History, maturation, and attrition are threats to internal validity in a non-equivalent control group pretest posttest design. Control for maturation and attrition is limiting the study time to a six-week period.

Limitations to the study are lack of randomization; pretest posttest design however this design is useful to be able to infer that the intervention is a plausible explanation for any necessary gains; psychological influences in the subjects; there remains the possibility that something other than the intervention could account for observed differences; the subjects will be primarily male gender due to the larger population of males in the military; and results can only be generalized to primarily male veterans and not to other patient populations.

**Instruments and Data Collection**
Subjects in the auricular acupuncture group are to be given weekly treatments of auricular acupuncture over a six-week period of time in addition to their standard medical regiment previously prescribed for headache treatment by a clinician trained in Auricular Acupuncture utilizing 2 acupoints known to mediate analgesia, the cingulate gyrus and thalamus acupoints (Niemtzow, 2007). Subjects in the standard medical treatment group receive only their prescribed medical headache regiment. Both groups are to be given MIDAS (Appendix A) and HIT-6 (Appendix B) questionnaires immediately before the study is started, and upon the end of the 6 weeks.

The Migraine Disability Assessment (MIDAS) is a test used to determine how severely headaches affect a patient’s life based on number of days impacted. Developed by Dr. Richard Lipton and Dr. Walter Stewart and published in *Neurology* 2001, it is found to be both reliable and valid (Sauro et al., 2010). A MIDAS score of 0-5 indicates little or no disability and is assigned a MIDAS Grade I. A MIDAS score of 6-10 indicates mild disability and is assigned a MIDAS Grade II. A MIDAS score of 11-20 indicates moderate disability and is assigned a MIDAS Grade III. A MIDAS score of 21+ indicates severe disability, and is assigned a MIDAS Grade IV.

The Headache Impact Test (HIT-6) includes six questions that help describe and communicate patients’ feelings about their headache. The HIT-6 shows good internal consistency and test-retest reliability, construct validity and responsiveness in general headache patients (Yang et al., 2011). The HIT-6 questions are answered with never, rarely, sometimes, very often, and always. Based on the scores, patients may fall into one of four categories of disability: little or no impact, some impact, substantial impact, or very severe impact (Sauro et al., 2010). Both Sauro et al. (2010) and Yang et al. (2011) studied the validation of HIT-6
comparing it to MIDAS. Internal consistency was evaluated using Cronbach alpha with a value > 0.80 considered good internal reliability. The Cronbach alpha for HIT-6 was found to be 0.82-0.90 and the Cronbach alpha for MIDAS was 0.83-0.87 (Yang et al., 2012; Sauro et al., 2010).

After obtaining informed consent, patients will be assigned a research number and the data will be collected manually from the results of the MIDAS and HIT-6 questionnaires and transcribed into a secure database. Data will be collected at 2 points in time, prior to initiation of study and at the end of the 6th week. Results of the questionnaires will be stored in a locked file for security and confidentiality. SPSS software will be used for analysis of the data.

**Analysis**

The primary analysis is to assess pain intensity and disability in chronic headache patients in the military. Independent t test will be used to compare the data of each instrument in the two groups with a level of significance assigned as $p \leq 0.05$ for a pilot study. The Mann-Whitney $U$ test is a non-parametric test that can be used if the distribution of the data is not normal. Descriptive statistics will be used to analyze demographics and the mean, median, and mode will be reported. IBM SPSS Software will be used to analyze the data.

**Research Variables**

The independent variable in this study is auricular acupuncture utilizing battlefield acupuncture protocol. The dependent variable is pain intensity using the Migraine Disability Assessment (MIDAS) that grades disability on an interval measurement from 1-4, and the Headache Impact Test (HIT-6) that also grades disability from 1-4. The demographic variables in this study will be used to describe the population and are: gender (nominal; 0=Male, 1=Female);
age (ratio); and ethnicity (nominal; 1=African-American, 2=Caucasian, 3=Hispanic, 4=Asian, 5=other).

**Bias**

Selection bias can occur as the sample is selected from a smaller population of military patients with TBI/PTSD. The use of a non-randomized convenience sample has potential for bias as subjects are invited to participate in the study and are assigned to a group. Awareness of measurement tools in a pretest posttest design can also create bias. Performance bias can occur as participants not receiving the intervention may choose to seek additional treatment elsewhere. Administrator and researcher bias can occur if groups are treated differently and if subjects are previously known.

**Ethical Considerations**

IRB approval will be needed from Naval Hospital Camp Pendleton and California State University, San Marcos. Informed consent will be obtained from the patients participating in both groups. Patients with TBI/PTSD are vulnerable both physically and mentally and patients must be offered counseling and are allowed to withdraw from treatment if they choose. Safety and patient confidentiality will be closely monitored.

**Dissemination Plan**

The results of this research to include recommendations, feasibility, and costs will be submitted to the Navy Triservice Nursing Research Program. Results of the study will be presented at the annual Defense Center of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury Summit in Falls Church, VA.
References

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Appendix A

The Migraine Disability Assessment (MIDAS) Questionnaire

Answer the following questions about the headaches of any kind you’ve experienced over the past three months. Use zero for questions where you have not experienced any activity disruption during the past three months.

- How many days have you missed work or school because of a headache?
- Not including the days from question one, how many days have you lost productivity by at least half at school or work?
- How many days have you skipped performing household chores or regular household activities because of a headache?
- Not including the days from question two, how many days was your productivity in performing household chores reduced by at least half?
- How many days did you miss leisure or social activities because of your headaches?

What is your total score?

<table>
<thead>
<tr>
<th>MIDAS SCORE</th>
<th>DISABILITY</th>
<th>DISABILITY MIDAS GRADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>Little or No Disability</td>
<td>I</td>
</tr>
<tr>
<td>6-10</td>
<td>Mild Disability</td>
<td>II</td>
</tr>
<tr>
<td>11-20</td>
<td>Moderate Disability</td>
<td>III</td>
</tr>
<tr>
<td>21+</td>
<td>Severe Disability</td>
<td>IV</td>
</tr>
</tbody>
</table>

This survey was developed by Richard B. Lipton, MD, Professor of Neurology, Albert Einstein College of Medicine, New York, NY, and Walter F. Stewart, MPH, PhD, Associate Professor of Epidemiology, Johns Hopkins University, Baltimore, MD.
Appendix B

The HIT-6 is a copyright of Quality Metric Incorporated. This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches.

To complete, please check one box for each question.
1. When you have headaches, how often is the pain severe?
   Never  Rarely  Sometimes  Very Often  Always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?
   Never  Rarely  Sometimes  Very Often  Always

3. When you have a headache, how often do you wish you could lie down?
   Never  Rarely  Sometimes  Very Often  Always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?
   Never  Rarely  Sometimes  Very Often  Always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?
   Never  Rarely  Sometimes  Very Often  Always

6. In the past weeks, how often did headaches limit your ability to concentrate on work or daily activities?
   Never  Rarely  Sometimes  Very Often  Always

   COLUMN 1  COLUMN 2  COLUMN 3  COLUMN 4  COLUMN 5
   (6 points)  (8 points)  (10 points)  (11 points)  (13 points)

To score, add points for answers in each column. Please share your HIT-6 results with your doctor.

Total Score: _____________ Higher scores indicate greater impact. Score range is 36-78.
Appendix C

Consent Form for Participation in a Research Study
California State University San Marcos

Auricular Acupuncture in the treatment of Chronic Headache in Military Patients (as submitted to IRB)

Description of the research and your participation

You are invited to participate in a research study conducted by Liza Benedito MSN(c), RN. The purpose of this research is to determine if auricular acupuncture is effective adjunctive therapy in treating chronic headache in military patients.

Your participation will involve completing two headache questionnaires before and after auricular acupuncture treatment. The treatment will be administered weekly for six weeks along with your normal headache regimen.

Risks and discomforts

There are risks associated with this research is discomfort associated with this research. This includes pain at the insertion site of the acupuncture needle. Your provider has been trained and certified in the administration of auricular acupuncture and measures will be taken to minimize any discomfort to include discontinuing the treatment.

Potential benefits

There are no known benefits to you that would result from your participation in this research. This research may help us to understand the benefit of auricular acupuncture in treating headache pain.

Protection of confidentiality

Confidentiality: The institutional review board of Naval Hospital Camp Pendleton; California State University San Marcos; the Uniformed Services of Health Sciences, Bethesda, MD; and other Federal agencies that provide oversight to the protection of human subjects may see your records. We will do everything we can to protect your privacy. Your identity will not be revealed in any publication resulting from this study.
Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Liza Benedito at (951)303-6527. If you have any questions or concerns about your rights as a research participant, please contact the California State University Institutional Review Board at (760)750-5029.

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant’s signature_______________________________ Date:_________________

A copy of this consent form should be given to you.