Study Title: Battlefield auricular acupressure (BAApress) for Emergency Department Observation of psychiatric patients with co-occurring chronic and acute pain management.

Principal Investigator PI: Michelle Olshan-Perlmutter, PMHCNS, NP
Co-investigators: Kelly R. Hobgood, MD; Carolyn Huffman, WHNP, PhD
Study Coordinator: Nicolas Archer, MSN;
Study Staff: Jean May

Sponsor or funding source: Departmental

Background, Rationale and Context

Pain can have a significant impact on psychiatric patients, as it can exacerbate symptoms and interfere with treatment. Pain can cause or worsen anxiety and depression, is associated with increased disability and poorer quality of life in people with severe and persistent mental illness. (Birgenheir et. al., 2013, Onwumere et al., 2022, Stubbs et al., 2015). Additionally, both severe and persistent mental illness and pain are associated with increased suicide risk (Fu XL et al., 2021, Racine, 2015).

Evidence suggests that individuals with mental illness may be one population with particularly high rates of chronic non cancer pain (CNCP) and may also be more likely to receive prescription opioids for their pain (6). Individuals with serious mental illness, who are most at risk for developing opioid-related problems, continue to be prescribed opioids more often than their peers without mental illness (Owen-Smith et al., 2020).

As of January 1, 2018, The Joint Commission requires hospitals to have non-pharmacologic modalities available for pain management in an effort to decrease the need for opioids. Acupuncture and acupressure have been used for centuries in the management of a variety of disorders including pain. A recent meta-analysis (Zhong et al., 2019) of 26 RCTs (all included studies were in China) favored the use of acupressure for pain management over usual care based on total effective rate (RR =1.25, [CI= 1.13, 1.37], p <.0001) and total analgesia use (RR=0.41, [CI= 0.24, 0.68] p = .0006). There were no serious adverse events reported in the 26 trials (N=1063 in treatment groups) and no withdrawals from the studies were reported due to adverse events. More recently, in an effort to increase access to non-pharmacological modalities for pain management, the VA has developed a **battlefield auricular *acupressure* (BAApress) protocol**. Unlike acupuncture, acupressure can be easily applied with training and is within the scope of practice for nurses, according to the North Carolina Board of Nursing (NCBON, 2013). Although acupressure has been used for centuries in traditional Chinese medicine, there are few studies assessing the use of nurse-initiated acupressure as an adjuvant for co-occurring pain. Thus, we propose assessing the effectiveness of BAApress for chronic and acute pain management for psychiatric patients in a psychiatric emergency room setting. In addition, by analyzing measures and demographics we hope identify patients that may benefit most from BAApress acupressure.

This feasibility study is being performed in collaboration with the BAApress training and Intervention Fidelity study IRB00084011. This study is similar to Fidelity study IRB00068022, Auricular Acupressure for Pain Management as a Non-Opioid Adjuvant Therapy for Opioid Tolerant Patients (PI Heather Columbano). The purpose of this study is to test the feasibility of Emergency Department nurse-initiated battlefield auricular acupressure as an adjunct to medication for pain management for psychiatric Emergency Department Observation patients.

The Battlefield Auricula Acupressure interventionists (nurse) will complete Auricular training modules and complete competency assessments and intervention assessments throughout the study. Study interventionist will include the possibility that a study participant may be part of a competency assessment and that their session may be recorded and securely uploaded to a server per IRB and institutional policies.

Objectives

1. To determine psychiatric patients' acceptance of BAApress as an adjunct treatment to address co-occurring pain.
2. To determine if the addition of BAApress protocol will lower pain scores and decrease pain medication usage.
3. To determine ability of ED nurses to incorporate BAApress into their workflow.

Methods and Measures

Design

Feasibility trial, no control group

Setting:

This study will utilize the location of Atrium Health Behavioral Health Charlotte Emergency Department ED and Observation unit for initiation of study procedures.

Subject Selection Criteria

Any patient admitted to Behavioral Health Charlotte Emergency Department Observation Unit for psychiatric reasons and with co-occurring pain.

- **Inclusion Criteria**

  Patients requiring admission to psychiatric emergency room who also have documented chronic or acute pain
  1. Age greater or equal to 18
  2. History of chronic or acute pain with or without opioid use disorder
  3. Expected length of stay at least 2-3 days at the time of recruitment
  4. Able to read and understand the informed consent form

- **Exclusion Criteria**
  1. Since this is a feasibility pilot, only English-speaking participants will be eligible.
  2. Cognitive impairment (Intellectual Disability Disorder or Dementia)
  3. Patients who have a legal guardian
  4. Participants with a history of skin disease (e.g., psoriasis) involving the ear, adhesive allergy, recent scar tissue on ear, or current abrasions or cuts on ear,
  5. Use of some types of hearing aids (obstructing the placement of beads)

- **Sample Size**
  A total of between 10-20 patients will be recruited from Atrium Health BH Charlotte ED Observation unit

Interventions and Interactions

Terms: AA = Auricular acupressure
Acupressure pad= hypoallergenic adhesive pad containing a 2 mm Vaccaria seeds (Earseeds®)
Acupoint = specific area of body where acupressure is applied.
BAApress= Battlefield Auricular Acupressure

- Participants will be informed of the study once they are identified by the behavioral health care team, which includes patient's psychiatric provider and medical consultation provider as an appropriate candidate.
- Informed consent will be obtained by study personnel or the interventionist, the BAApress interventionist will confirm consent for participation.
- A study team member will perform visual analogue Scale and Brief Pain Inventory with the participant to establish baseline pain score and impact pain has on general activity, mood, walking ability, normal work, relationship with other people, sleep and enjoyment.
- The participant will be asked to also complete baseline questionnaires prior to the initiating placement of the AA including data collection form and General Anxiety Disorder Scale (GAD-7)- A self-administered 7 item scale that draws from DSM-V criteria for general anxiety disorder (GAD) to identify GAD and measure symptom severity. It is routinely used to measure changes and track treatment progress.
- BAApress interventionists will record the time from the moment they meet with the patient in an available room for the purposes of placing acupressure pads and activating each pad until they exit the room. BAApress interventionists will make notation if recorded time includes activity unrelated to placement of acupressure pads. After placement of acupressure pads, BAApress interventionist will enter procedure note in a shared specific file for interventionist and complete the REDCap nurse questionnaire.

Day 1

The baseline and day 1 activity can take place on the same day, but it is not required. Following completion of informed consent and baseline questionnaires, the trained BAApress interventionist nurse will place the acupressure pads.

- If the ear contains lesions, skin breakdown, or show signs of irritation, the acupressure pads will not be placed, and this will be noted in the study record.

- If the participant consented to the recording portion of the study, they will be reminded of the process and the BAApress acupressure nurse will confirm that the participant still agrees to participate in the recording portion of the study.

- Acupressure pads will be placed prior to any pain medication.

- A total of 10 adhesive acupressure pads will be placed, 5 acupressure pads per ear. Patients will be given a handout showing location of each point where acupressure pad will be placed. The pads will be placed bilaterally on the following 5 auricular sites: 1) Cyngulate gyrus, 2) Thalamus, 3) Omega 2 4) Point Zero, and 5) Shen Men. These sites were selected based on the Veterans Administration Battlefield Auricular Acupressure Protocol for acute and chronic pain. This is the protocol the Veterans Administration uses for acupressure therapy for acute and chronic pain management and is taught to both nurses and physicians.

- Each ear will be cleansed with alcohol, beginning at the base of the ear (lobule) to the apex. The acupoints will be visually located and marked with a sterile surgical marker.

- The pads will be placed by visual identification of the preselected acupoints as per BAApress protocol. The pads will be placed on the on the identified site by hand or with the assistance of tweezers, with the seed portion of the pad aligning with the identified acupoint.

- To secure the pad, gentle but firm pressure will be applied to the pad, making sure that pressure is applied to the entire pad.

- After placement, the interventionist will apply moderate pressure to each acupressure pad for 30 seconds (total time 2.5 minutes per ear). Both right and left ear site will be stimulated at the same time with pressure in the following order: 1) Cyngulate gyrus, 2) Thalamus, 3) Omega 2, 4) Point Zero, and 5) Shen Men.

- Participants will tell the BAApress interventionist nurse when they feel a tingling sensation in the ear or feel moderate tenderness or pressure as confirmation

that moderate pressure is being applied. Description of sensations felt by participant will be recorded by the BAApress interventionist.

- The BAApress interventionist will document pad placement and activation in EPIC.

- BAApress interventionist will review with participant how and when to activate each pad and give participant a picture of a right and left ear with the acupressure points location on each ear. Participants will be reminded to gently press on each pad for 30 seconds at least three times a day to activate for a total of 3 days.

- If the acupressure pads fall off before day 3, they will not be replaced. The BAApress interventionist will record the missing pad/pads.

- After completion of day 3 study activities, the study team will remove the acupressure pads by gently pulling on the edges of the pad and lifting off with their fingers or using tweezers to loosen the pad if needed.

- If participants are discharged prior to 3 days, they will be contacted via telephone call by study personnel and/or via text messaging depending on participant preference to remind them to complete the questionnaire and to activate their pads 3 times per day.

- At the end of the third day, the study personnel will call the patient, or they will receive a text letting them know the study team needs to arrange a telephone call to provide instruction on how to remove the acupressure pads. If participant cannot be reached by phone, they will be instructed on removing pads by gently pulling on the edges of the pad and lifting off with their fingers or using tweezers to loosen the pad if needed. Participants will be reminded to complete final post intervention questionnaires after removal of pads that study personnel will review with them.

- The BAApress interventionist nurse may record and take pictures of the treatment visit. These recordings will be used to ascertain fidelity to the intervention protocol as it relates to a) proper placement of acupressure seeds and b) provision of instructions to the participant.

- Each study participant will be asked to sign a separate consent giving permission for the intervention to be recorded and used for education and research purposes. The recordings will be done to limit exposure of the study participant's face.

- The study team will perform Visual Analogue Scale (VAS) and Brief Pain Inventory with participants one to two times a day for 3 days.

- The study team will have the participant complete GAD-7 every morning for 3 days.

- The study team will complete BAApress Questionnaire daily with participant every morning for 3 days.

End of Study Assessment

Verify completion of day 5 study questionnaires: VAS, Brief Pain Inventory, GAD-7, BAApress Questionnaire and Pain Management Satisfaction

Primary Outcomes

Patient reported pain and general activity scores (Visual Analogue Scale) and (Brief Pain Inventory)

Secondary Outcomes to be measured:

- Pain medication usage. Trajectory of am and pm pain scores
- General Anxiety Disorder Scale (GAD-7). Patients are asked to rate the frequency of anxiety symptoms daily on a Likert scale (0-3). In general, patients with GAD or other common anxiety disorders exhibit GAD-7 scores of 10 or greater.
- Pain Management Satisfaction to determine patient satisfaction
- Acupressure Acceptability questions - We will ask acceptability questions. "How satisfied were you with how your pain has been treated?" using the Likert scale to measure "Very satisfied =5, Satisfied=4, Somewhat satisfied = 3, Somewhat dissatisfied= 2, Dissatisfied 1, Very Dissatisfied 0." Would you consider using auricular acupressure in the future for pain or if recommended by your nurse or physician? a. No, would not use again (Score of 0) b. Maybe (Score of 1), c. Yes, I would consider using in the future (Score of 2) 3. Is there anything else you would like to tell us that may be helpful for us to know regarding ear acupressure? (Each answer will be collected and assessed for future studies).
- BAA Press placement survey (interventionists only): The Interventionist (Acupressure nurse) will be asked to capture time related to completion of study tasks and other qualitative questions to assess overall feasibility.
- Additional Data collection: contact information, relevant demographic data that will be recorded are: DOB, age, gender, ethnicity/race. Relevant medical history will be duration of pain medications including narcotic use (in years) and comorbid chronic or acute pain diagnoses.

Study activity	**Baseline**[a]	**Day 1**	**Day 2**	**Day 3/End of study**
Informed Consent signed	x			
Data Collection Form	x	x	x	x
Complete Baapress Questionnaire	x	x	x	x
Administer or record Pain score assessment (VAS)[b]	x	x	x	x
Brief Pain Inventory	x	x	x	x
Pain Management Satisfaction				x
Generalized Anxiety Disorder Scale (GAD-7)	x	x	x	x
Acupressure placement and patient education		x		
*Optional interventionist recording of AA placement[d]		x		
Study team collect completed questionnaire				x
Compensation administration				x
BAA press placement survey (interventionist only)	x	x	x	x

[a] Baseline and Day 1 can be completed on the same day. Baseline activities are to be completed prior to Acupressure administration.
[b] The study team will perform the pain score assessment with the participant two times a day for three days.
[c] Participants will receive reminders to complete the study questionnaires if discharged prior to 3 days.
[d] Only participants who agree to participate in the optional recording/photography at the time of informed consent will have their acupressure placement session recorded.

Analytical Plan

Sample Size: This is a feasibility study with no control group. Target enrollment is 10- 20 participants. Data from this study will be used to generate parameter estimates to calculate power for future studies.

Results will be analyzed initially using descriptive statistics. Any group comparisons will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables.

Human Subjects Protection

Good Clinical Practices and HIPAA guidelines will be followed to ensure the safety and wellbeing of patients electing to participate in this study. PHI used during this study will be collected and recorded in accordance with the standards set forth in the Health Insurance Portability and Accountability Act (HIPAA). Confidentiality of medical information will be maintained throughout the study. All paper case report forms (CRFs) and informed consent forms (ICFs) will be stored in a locked drawer. Study participants will be assigned a unique identifier that will be used on CRFs. Data collected for this COVID-19 ALS Registry will also be stored and analyzed electronically in Atrium Health's REDCap Database. REDCap is a secure web platform for building and managing online database projects and surveys and is used extensively by academic and research institutions. This REDCap study will further restrict access to study staff.

Subject Recruitment Methods

To assist with recruitment. Patients when admitted to Atrium Behavioral Health Emergency Room may be identified by screening behavioral health treatment team and referred to study personnel.

Study personnel will review eligibility and approach patient regarding participation. Only eligible patients willing to complete all survey's pre and post procedures and provide written consent will participate. The study team will ensure that the participant understands the voluntary nature of participating in the research study and that study participation study will not affect the care that they will receive.

The study personnel will maintain a record of eligible study participants. This list will include name, MRN, psychiatric and pain diagnosis, and will be kept in a secure file on a secure computer and only accessible to study staff. The file of eligible participants will be destroyed at the end of recruitment.

Compensation

Participants completing the study will receive $25.00 in a Walmart gift card.

Informed Consent

Signed informed consent will be obtained from each subject. The study personnel will obtain informed consent at the time participant is admitted to Observation unit and it is determined patient meets criteria. No study procedures will begin until the IRB approved method of obtaining consent is completed.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the stored data collection forms. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel.

Following data collection, subject identifying information will be destroyed three years after the completion of the study consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigators will be responsible for the overall monitoring of the data and safety of study participants. The principal investigators will be assisted by other members of the study staff. Although no serious safety events have been reported in the literature related to auricular acupressure, participants will be asked to report any events to study personnel. Participants and the acupressure nurses will be instructed to monitor and report any concerns to the principal investigators.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

Appendix A: Data Collection Form 3 9 23
Appendix B: BAApress Questionnaire1
Appendix C: Brief Pain Inventory
Appendix D: PainManagementSatisfaction_Bat
Appendix E: GAD-7 Anxiety Scale
Appendix F: BAApressPlacement_BattlefieldA (For Interventionist use)
Appendix G: Vaccaria 600 EarSeeds Package Insert
Appendix H: Visual Analogue Scale

References

1. Alam, A., Gomes, T, Zheng, H., Mandani, M. M., Juurlink, D. N., & Bell, C. M. (2012). Long-term analgesic use after low-risk surgery: A retrospective cohort study. Journal of the American Medical Association, 172(5), 425-430.
2. Birgenheir,D. G., Ilgen, M. A., Bohnert, A.; Abraham, K. Bowersox, N. Austin, K.; Kilbourne, Pain conditions among veterans with schizophrenia or bipolar disorder

General Hospital Psychiatry. Volume 35, Issue 5, September–October 2013, Pages 480-484

3. Fu XL, Qian Y, Jin XH, Yu HR, Wu H, Du L, Chen HL, Shi YQ. Suicide rates among people with serious mental illness: a systematic review and meta-analysis. Psychol Med 2021. doi: 10.1017/S0033291721001549:1-11.
4. Hah, J.M., Bateman, B.T., Ratliff, J., Curtin, C., & Sun, E. (2017). Chronic opioid use after surgery: Implications for perioperative management in the face of the opioid epidemic. *Anesthesia & Analgesia, 125*(5), 1733-1740.
5. He, B. J., Tong, P. J., Li, J., Jing, H. T., & Yaom X. M. (2013). Auricular acupressure for analgesia in peri-operative period of total knee arthroplasty, *Pain Medicine, 14*, 1608-1613.
6. Liu M, Tong Y, Chai L, Chen S, Xue Z, Chen Y, Li X. Effects of Auricular Point Acupressure on Pain Relief: A Systematic Review. Pain Manag Nurs. 2021 Jun;22(3):268-280. doi: 10.1016/j.pmn.2020.07.007. Epub 2020 Sep 17. PMID: 32950391.
7. North Carolina Board of Nursing (2013). Complimentary Therapies: Position statement for RN and LPN practice.
8. Onwumere, Julianaa,b; Stubbs, Brendonc,d; Stirling, Marye,f,g,h; Shiers, Davidi,j,k; Gaughran, Fionab,l; Rice, Andrew S.C.m; C de C Williams, Amandan; Scott, Whitneyo,p, Pain management in people with severe mental illness: an agenda for progress. PAIN 163(9):p 1653-1660, September 2022. | DOI: 10.1097/j.pain.0000000000002633
9. Owen-Smith A, Stewart C, Sesay MM, Strasser SM, Yarborough BJ, Ahmedani B, Miller-Matero LR, Waring SC, Haller IV, Waitzfelder BE, Sterling SA, Campbell CI, Hechter RC, Zeber JE, Copeland LA, Sherrer JF, Rossom R, Simon G. Chronic pain diagnoses and opioid dispensings among insured individuals with serious mental illness. BMC Psychiatry 2020;20:1–10.
10. Racine M. Chronic pain and suicide risk: a comprehensive review. Prog Neuropsychopharmacology Biol Psychiatry 2018;87:269–80.
11. Stubbs B, Gardner-Sood P, Smith S, Ismail K, Greenwood K, Patel A, Farmer R, Gaughran F. Pain is independently associated with reduced health related quality of life in people with psychosis. Psychiatry Res 2015;230:585–91.
12. The Joint Commission (2017, August 29). Pain assessment and management standards for hospitals. *R^3 Report,* 11.
13. Yeh, C.H., Chien, L-C, Huang, L. C., Suen, L. (2014). Auricular point acupressure for chronic pain: A feasibility study of 4-week treatment protocol. *Holistic Nursing Practice, 28*(3), 184-194.
14. You E, Kim D, Harris R, D'Alonzo K. Effects of Auricular Acupressure on Pain Management: A Systematic Review. Pain Manag Nurs. 2019 Feb;20(1):17-24. doi: 10.1016/j.pmn.2018.07.010. Epub 2018 Oct 16. PMID: 30340870.
15. Zhong, Q., Wang, D., Bai, Y-M., Du, S., Song, Y-L., & Zhu, J. (2019). Effectiveness of auricular acupressure for acute postoperative pain after surgery: A systematic review and meta-analysis, *Chinese Journal of Integrative Medicine, 25*(3), 225-232.