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Informed Consent

Department of Anesthesiology

AURICULAR (EAR) ACUPRESSURE FOR PAIN MANAGEMENT AS A NON-OPIOID, ADJUVANT THERAPY FOR OPIOID TOLERANT PATIENTS

Informed Consent Form to Participate in Research
Heather Columbano, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see the effects of auricular (ear) acupressure in addition to standard of care treatment given to patients admitted to the chronic pain/addiction medicine service, will lower pain scores and decrease pain medication usage. You are invited to participate in this study because you have been admitted to the chronic pain/addiction medicine service at Atrium Health Wake Forest Baptist. Your participation in this research will last about 3 days and will require only a few minutes of your time on each of those 3 days.

Participation in this study will involve placement of 10 adhesive acupressure pads on your ears, 5 acupressure pads per ear. The pads will be placed on specific sites of the ear that are thought to help with pain and overall well-being. These sites are called acupoints. Each of these pads contains a 2mm Vaccaria seed (Earseeds®). They will remain on the outside of the ear for approximately 3 days or until they fall off or are removed. Each day you will be asked to apply a small amount of pressure with your finger to each of the pads and answer study questionnaires.

All research studies involve some risks. A risk to this study that you should be aware of is skin irritation at the site of the adhesive. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Heather Columbano, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]. After hours you can call [redacted] and ask for the (the anesthesiologist on-call).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have been admitted to the chronic pain/addiction medicine service at Atrium Health Wake Forest Baptist. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study nurse or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to find out what effects (good and bad) acupressure applied to the outside of the ear (Auricular Acupressure), in addition to the standard of care medication regimen, will have on you pain. Specifically we want to see if Auricular Acupressure in addition to the standard of care medication regimen will lower pain scores and decrease how much pain medication patients use during their admission.

Acupressure is safe and does not interfere with any other medications or interventions that you will be prescribed during your admission. The acupressure seeds used in this study are currently on the market for purchase by the general public. The acupressure pad being used in this study is hypoallergenic and contains no latex.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 20 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

The study nurses will meet with you to review your medical history and medication use and determine if you are eligible to participate in the study. If you choose to participate in this study you will be asked to sign this informed consent form and you will be offered auricular acupressure therapy as an addition to the treatment regimen prescribed for your care.
The study team and clinical team will ask you your pain scores throughout your admission, we will use these scores for our study data.

BASELINE:

A study team member will provide you the study questionnaires and explain how to complete the questionnaire for the 3 days that you are in the study.

- You will be asked about your medical history and general demographics information

- You will be asked to complete the baseline part of you study questionnaire which will ask questions about your pain and how it affects your daily living, sleep and mood.

- A study team member will ask you some questions about your medical history, opioid use history, and demographics information.

Days 1-3
Auricular Acupressure:
The Baseline visit and Day 1 visits may take place on the same day but it is not required.
After you complete the baseline questionnaires, the study interventionist (acupressure nurse) will place a total of 10 adhesive acupressure pads on your ears, 5 acupressure pads per ear. The pads will be placed on specific sites of the ear that are thought to help with pain and overall well-being. These sites are called acupoints. Each of these pads contains a 2mm Vaccaria seed (Earseeds®).

The study acupressure nurse will place the pads on the identified site by hand or with the assistance of tweezers ensuring that the seed portion of the pad will align 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 study acupressure nurse 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.

The study acupressure nurse will show you where the pads have been placed and document this in your medical record. You will be asked to apply pressure to each pad for 30 seconds three to six times a day (a total of 7.5 -15 minutes per day) for a total of 3 days. You will also be provided with written instructions on when and how to apply pressure to these pads.

Other than the addition of the acupressure pads to the outside of your ear, your care and treatment will be the same as if you were not participating in this study.

You will continue to be evaluated for pain and will be provided with treatment and medications as necessary.

While in the hospital you will be reminded on how and when to apply pressure to the pads and when to complete your study questionnaires.

Day 1 – Day 3 (End of Study)
You will be asked to complete study questionnaires each day for 3 days.
In addition to the questionnaires mentioned above, we will ask you to record what your pain level is when you first wake up in the morning and your worse pain level of the day. You will

also be asked to record the times you applied pressures to the acupressure beads.
On the last day (day 3) you will be asked additional questions to get feedback on your experience. At the end day 3, you will be asked to remove all pads and we will collect your completed survey.

PICTURES AND RECORDINGS

As part of the study, we may make an audio recording and take pictures of study personnel placing the acupressure seeds on your ears. This is being done for education purposes only. If this is done, study personnel will use a special computer application on an iPad device to make an audio recording of the session and take pictures of your ears. The recordings and pictures will then be uploaded to the study site and stored securely on password protected computers. Once the recording and pictures have been uploaded to the study site, the pictures and recording will be deleted from the iPad to ensure confidentiality of your data. Every effort will be made to limit the audio recording (will record clinician giving information related to the placement of the acupressure pads on your ears and instructions) and pictures of your ears only. Your voice, however will be recorded.

You decision to participate in the pictures and recording portion of the study is completely voluntary and you will still receive the study intervention (acupressure) even if you decline participating in recording session for the study. At the end of this consent form, you will be asked to consent to or decline optional recording of the session

How Long Will I Be in the Study?

You will be in the study for about 3 days.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the acupressure pads we are studying include:
Skin irritation or discomfort at the pad site may develop. The pads may fall off. If the pad falls off they will not be replaced, however, you will still be able to complete your daily study tasks until you are done with the study. Since the skin of the ear will not be punctured, the risk of an infection is very small. The skin of the ear will be cleaned with isopropyl alcohol prior to placement of the pad.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any

medical conditions you have including any allergies to adhesives or problems you have had in the past with your skin (skin reactions to medications, adhesives, history of psoriasis). This may help avoid side effects, interactions and other risks.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff and/or your surgeon.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be a decrease in pain or discomfort and decrease in the need for pain medication.

Based on experience with acupressure in other research studies involving patients' pain, the study doctors believe that acupressure may be of benefit. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have.

You can treat yourself with acupressure even if you do not take part in the study.

WHAT ARE THE COSTS?

All study costs, including the acupressure pads, will be paid for by the study.
Costs for your regular medical care such as prescribed medications for your chronic pain will be your responsibility as these are standard of care.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a gift card for $25 for completing the study. This gift card will be given to you after the last study questionnaire is collected.
If you are discharged, or if you are transferred outside of the unit (i.e. rehabilitation facility, ICU), for clinical care before you complete the study you will be withdrawn from the study however, you will still be compensated for your time and the study team will mail your gift card to you.
If you decide to leave the unit against medical advice before you complete the study, you will not receive compensation.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest Department of Anesthesiology, Wake Forest Department of Nursing and the Wake Forest Clinical and Translational Science Institute. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security

number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call **Heather A. Columbano, MD at [redacted] After hours you can call [redacted] and ask for the (the anesthesiologist on-call)**.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** age, body-mass index (BMI), demographics, your medical history including current and past medications, information related to your admission (pain scores, medications administered during admission), and information collected from your study questionnaire.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information may be collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This

information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified, and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Heather Columbano, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Heather Columbano, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical

Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, **Heather Columbano, MD at [redacted]. After hours you can call [redacted] and ask for the (the anesthesiologist on-call)**

The Institutional Review Board (IRB) is a group of people who review research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

STUDY CONSENT SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

OPTIONAL AUDIO RECORDING AND PICTURE SIGNATURES

I agree to have an audio recording of the clinician placing the acupressure pads on my ears and pictures of my ears with and without the acupressure pads in place. I understand that every effort will be made to limit the pictures to my ears only and that the audio recording will be transmitted securely to a secure platform. The pictures and the recording will be used for educational and research purposes. Pictures may be used in future educational materials with auricular acupressure. Audio recording will be reviewed by acupressure experts for research purposes only and destroyed once the study is completed.

____ YES, I give permission to audio recording of my acupressure session and the taking of pictures of my ears for educational and research purposes.

____ NO, I do not give permission to audio recording of my acupressure session and the taking of pictures of my ears.

Participant Signature: _____ Date: _____ Time: _____ am pm