Title:Nurse Initiated Auricular Acupressure for Post-operative Pain Management in Knee and Hip Arthroplasty Patients
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Informed Consent

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AURICULAR (EAR) ACUPRESSURE FOR PAIN MANAGEMENT AFTER JOINT SURGERY

Informed Consent Form to Participate in Research
Carolyn Huffman, RN, PhD, 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 on recovery after joint surgery. You are invited to participate in this study because you are scheduled to have either knee or hip replacement surgery. Your participation in this research will and last about 5 days and will require only a few minutes of your time each of those 5 days while in the hospital and at home. You will not be required to come in for any additional visits.

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 hip or knee 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 5 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 a study questionnaire. 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 Carolyn Huffman, PhD, RN. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]

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 be 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 scheduled for either hip or knee replacement surgery. 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 may have on your recovery from surgery compared to the usual care provided. Pain management after knee or hip surgery is an important part of your recovery. Auricular (ear) acupressure has been shown to help in the management of pain following surgery. This study is being done to assess whether acupressure in addition to the usually prescribed post-operative medications may be of benefit following hip or knee surgery. This study will also evaluate the feasibility of routinely offering acupressure to patients having joint replacement surgery. Acupressure is safe and does not interfere with any other medications or interventions that you will be prescribed in the post-operative period. 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, however if you have a latex allergy you will not be able to participate in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

60 people at Davie Medical Center will take part in this study. In order to identify the 60 subjects needed, we may need to screen as many as 120 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

Prior to the surgery, the study personnel will review your chart and ask you a few questions to determine your eligibility for the study. If you agree to participate and are eligible, on the day of your surgery, you will be randomized to into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group.

Acupressure group: If you are randomized into this group, the study nurse will place a total of 10 adhesive acupressure pads on your ears, 5 acupressure pads per ear, in the Pre-operative holding room. The pads will be placed on specific sites of the ear that are thought to help with hip or knee pain and overall well-being. These sites are called acupoints. Each of these pads contains a 2mm Vaccaria seed (Earseeds®). The nurse will place the pads on the identified site by hand or with the assistance 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 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 nurse will show you and your family member where the pads have been placed and record this in your medical record. You will be asked to apply pressure to each pad for 30 seconds three times a day (a total of 12 minutes per day) for a total of 5 days. The study nurse will also provide you with verbal and written instructions on when and how to apply pressure to these pads. This information will also be reviewed with you after surgery when you arrive to the unit and prior to discharge. Other than the addition of the acupressure pads to the outside of your ear, your care and treatment will be the same as any other patient who has had joint replacement surgery. You will continue to be evaluated for pain and provided treatment and medications as necessary. While in the hospital you will be reminded on how and when to apply pressure to the pads. You will also be asked to complete a study questionnaire each day for 5 days. The questionnaire will be sent home with you and you will receive reminders to apply pressure to your pads each day and complete the survey each day for a total of 5 days (this includes the day of your surgery and the days you were in the hospital). At the end of the 5th day (Day 4 Post-Op), you will be asked remove all pads and to mail the questionnaire to the study nurse in a provided postage paid envelope that has been addressed for your convenience. If you have completed the questionnaire electronically, after you complete your entry on the 4th day, you will not need to do anything else.

Control group: If you are randomized to the control group, you will continue to receive the usual/standard care of a patient having joint surgery. You will be asked to complete a study questionnaire each day for 5 days. At the time of discharge, this questionnaire will be sent home with you and you will receive reminders to complete the survey each day for a total of 5 days (this includes the day of your surgery and the days you were in the hospital). At the end of the 5th day (Day 4 Post-Op), the study team will contact you to remind you to mail the questionnaire to the study nurse in a postage paid envelope that has been addressed for your convenience. If you have completed the questionnaire electronically, after you complete your entry on the 4th day, you will not need to do anything else.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about *5 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 while in the hospital it will be replaced, if it falls off while you are at home, it will not be replaced. 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.

The principle investigator, Carolyn Huffman, PhD, RN will be reviewing the data from this research throughout the study.

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 experienced in the first 7 days after your surgery.

Based on experience with acupressure in other research studies involving patients with joint replacements, researchers believe that acupressure may be of benefit to you following surgery. 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, which are not related to this study, will be your own responsibility.

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 no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by 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 Carolyn Huffman, PhD, RN at [redacted] and

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), your past medical history including current and past medications, information related to your surgery (type of surgery, location, anesthesia received, hospital stay) and other medical conditions.

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 Carolyn Huffman 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:

Carolyn Huffman, PhD, RN
[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, *Carolyn Huffman* at [redacted] *After hours you can call* [redacted] *and ask for the Acupressure Nurse on call.*

The Institutional Review Board (IRB) is a group of people who review the 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

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