Official Title: An Evaluation of Pain, Anxiety, Desire for Repeat Procedure, and Satisfaction Utilizing Music Therapy for Chronic Low Back Pain Patients During Lumbar Medial Branch Blocks

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WAKE FOREST School of Medicine

Department/Section of *Anesthesiology*

STUDY TITLE: **An Evaluation of Pain, Anxiety, Desire for Repeat Procedure, and Satisfaction Utilizing Music Therapy for Chronic Low Back Pain Patients During Lumbar Medial Branch Blocks"**

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

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine if music therapy during interventional pain procedure of lumbar medial branch blocks for chronic lower back pain will lower pain scores and anxiety levels, while increasing patient desire for repeat procedure as well as patient satisfaction. You are invited to be in this study because you experience lower back pain with a diagnosis of Lumbar Spondylosis. Your participation in this research will involve answering questionnaires on the day of and prior to your scheduled procedure, questionnaires following the procedure. You will remain in the study until you receive a follow up phone call

Participation in this study will involve listening to music during, completing questionnaires prior to and immediately following the lumbar medial branch block procedure All research studies involve some risks. A risk to this study that you should be aware of is the possibility of no change in your pain and or anxiety level during lumbar medial branch block procedure. 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. There may be other choices available to you. Some other choices may include completing the lumbar medial branch block without the use of music. 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 A. 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]

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 Lumbar Spondylosis, have failed conservative treatments and are scheduled to have a diagnostic lumbar medial branch blocks using fluoroscopic guidance. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor 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 determine if music therapy during interventional pain procedure of lumbar medial branch blocks for chronic lower back pain will lower pain scores and anxiety levels, while increasing patient desire for repeat procedure as well as patient satisfaction. In addition, to determine if patients with higher Pain Catastrophizing Scale Scores will benefit to a greater extent than "non-catastrophizers" to music therapy intervention**.**

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

150 people will take part in this study from the Wake Forest Baptist Health System, which may involve any of the various Wake Forest Baptist Health System locations

WHAT IS INVOLVED IN THE STUDY?

If you choose to participate in this study, you will be asked the following:

- Sign this informed consent if agree to participate
- Complete a series of questionnaires prior to your already scheduled Lumbar Medial Branch Block

- Complete another series of questionnaires following your procedure.

You will be randomized 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 to being placed in one of the two study groups.

Group 1 Music group:
The music group will listen to patient's preferred music on Pandora station broadcast via an Ipad or MacBook with wireless earbuds unless precluded by hearing aids in which an alternative headphone set will be utilized. Music will be listened to during the lumbar medial branch block. You will complete a series of questionnaires prior to the procedure and once again following your procedure.

Group 2 Control group:
The control group will be provided earbuds or alternative headphone as well, however, with no music.

You will complete a series of questionnaires prior to the procedure and once again following your procedure.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until you receive a follow up phone call to access your pain level following the procedure. 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. This study poses minimal risk to the participant.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. Risks possible side effects of what we are studying include, no change in pain during the lumbar medical branch nerve block procedure, possible increased agitation during the procedure and disruption of communication with health care providers while listening to music. Some questions within the questionnaires may make you uncomfortable

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. Any possible risk or side effects associated with the Lumbar Medial Branch Block procedure will be reviewed and discussed during the signing of the "Consent to Treat".

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.

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 reduction to any pain, anxiety which can normally be experienced during the lumbar medical branch nerve block procedure.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, 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 The department of Anesthesiology

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we get from you and/or any 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: Date of birth, vital signs.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information 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.

Only the following people or organizations will be granted access to your Protected Health Information:
1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research or are providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest Baptist Hospital

2) 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.

3) Representatives from government agencies such as the US Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research

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.

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 deidentified 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. 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.

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 m*ay 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]

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

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject: _____

Legal Representative Signature: _____ Date: _____ Time: _____ am pm