RESEARCH CONSENT FORM
Analgesic Effect of Music Listening During Pain Elicitation in Fibromyalgia
Protocol #STUDY00144158
PI: Rebecca Lepping, PhD
rlepping@kumc.edu
913-588-0287

INTRODUCTION

You are being asked to join a research study. You are being asked to take part in this study because you have chronic pain due to fibromyalgia. You do not have to participate in this research study. The main purpose of research is to understand the effect of listening to music or nature sounds on how you respond to a painful stimulus. It will create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Drs. Rebecca Lepping and Andrea Nicol as the primary researchers. About 40 people will be in the study at KUMC.

BACKGROUND

Patients with fibromyalgia (FM) are more sensitive to things that cause pain. Previous studies have shown that things like listening to music or nature sounds may help patients with FM have less self-reported pain, get up and move from sitting more quickly, and have more activity in part of the brain that tells the body to stop sending pain signals.

PURPOSE

By doing this study, researchers hope to learn more about how music or nature sounds affect a person's sensitivity to pain.

PROCEDURES

If you are eligible and decide to participate in this study, you will be asked to complete a

total of 2 study visits over approximately 1 week.

You will be randomly assigned (like rolling the dice) to one of four groups.

	Visit 1	Visit 2
• Group 1:	Nature sounds	Nothing
• Group 2:	Nothing	Nature sounds
• Group 3:	Classical music	Nothing
• Group 4:	Nothing	Classical music

You will have a 1 in 2 chance (50%) of receiving nature sounds at one of the visits, and a 1 in 2 chance (50%) of receiving music at one of the visits. At the other visit you will wear the headphones, but will not hear anything through them. The study team will not know which group you are in, or what you are hearing during the testing. It is important you do not tell the researchers what you are hearing.

Study Visit 1: This visit will occur at the KU Hoglund Brain Imaging Center where the following tests and procedures will be performed:

- Survey and Questions: You will be asked questions about your symptoms and pain and asked to complete surveys.
- Pain Tolerance Testing: You will undergo testing to measure your pain tolerance using two different instruments. One will apply pressure to your thumbnail the other will apply poking sensations to your forearm.
- Heart Monitoring: You will be asked to wear a heart monitoring device during the visit. The device will be attached to your skin with three electrodes: one under your collar bone, one under your rib cage on the opposite side, and a third on your stomach.
- You will wear headphones during the pain tolerance testing. During each of the testing sessions you will listen to the assigned audio track (nothing, nature sounds, or classical music). The audio tracks will be randomly assigned when you enroll in the study as described above. You will not be able to choose what you will hear. It is important you do not tell the researchers what you are hearing.

Study Visit 2: This visit will occur at the KU Hoglund Brain Imaging Center where the following tests and procedures will be performed:

- Pain Tolerance Testing: You will undergo testing to measure your pain tolerance using two different instruments. One will apply pressure to your thumbnail the other will apply poking sensations to your forearm.
- Heart Monitoring: You will be asked to wear a heart monitoring device during the visit. The device will be attached to your skin with three electrodes: one under your collar bone, one under your rib cage on the opposite side, and a third on your stomach.
- You will wear headphones during the pain tolerance testing. During each of the

testing sessions you will listen to the assigned audio track (nothing, nature sounds, or classical music). The audio tracks will be randomly assigned when you enroll in the study as described above. You will not be able to choose what you will hear. It is important you do not tell the researchers what you are hearing.

Description of Study Tests and Procedures:
Certain information may be collected from you or your medical records including: age, sex, race/ethnicity, marital status, education level, medical history and conditions, including pregnancy, and the type and amount of medications you may or may not be currently taking. Changes in hormones during pregnancy can change pain tolerance. Because of this, pregnant women cannot participate in this study.

Surveys that assess the following will be given at Study Visit 1:

- The intensity of your pain and questions about how you would describe your pain
- Symptoms of depression or anxiety
- Levels of physical functioning
- Sleep disturbances
- Hypothetical reward choices, for example, whether you would prefer to get $25 now or $60 in 21 days
- Music experience

For the baseline visits, the study team will provide you an iPad or laptop at your visit to complete the questionnaires. The completed questionnaires will be saved to the RedCap database, and accessible for the research staff to view after you submit your responses. Should you not wish to fill out the questionnaires through RedCap, paper versions are available to use instead.

Pain Tolerance Testing [Quantitative Sensory Testing (QST)]:
We will measure your pain tolerance using a special instrument which will apply pressure to your thumbnail. We will start with a low intensity of pressure and then increase it, according to your rating of pain intensity. For each of the pressure assessments, you will be asked to rate the intensity (e.g., mild, moderate, or intense) of these sensations on a numerical pain scale. We will also use a pinprick stimulator that will be applied to your forearm. This stimulator is shaped like a pencil that has a thin wire coming out of one end. When it is pressed gently against your arm, the wire will draw back inside the pencil shaft. The stimulator will not damage your skin. You will be asked to rate the intensity (e.g., mild, moderate, or intense) of these sensations on a numerical pain scale after a single application and after a series of 10 applications. This pattern of a single application and a series of 10 applications will be repeated three times.

RISKS

You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.

Quantitative Sensory Testing Risk:
The pressure sensitivity exam may result in temporary discomfort or pain, skin reddening and/or indentation marks, and, in rare cases, minor bruising, at the body areas tested. **You may stop any test at any time if the testing becomes too uncomfortable.**

Discomfort with being asked personal questions: It is possible you may feel discomfort by being asked personal questions about your health history. You may refuse to answer any question on the questionnaires or surveys for any reason. If any of these questionnaires or surveys find a potential problem regarding your health or wellbeing, including thoughts of suicide, the study team will contact your primary doctor to communicate this potential problem. If these thoughts of suicide are severe, the study team will take you to the emergency room. You or your health plan will be responsible for the costs associated with that care.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

Individuals are unlikely to benefit from this study.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at the University of Kansas Medical Center.

COSTS

The study will pay for research-related items or services that are provided only because you are in the study. For your participation in this study, the items and services that will be paid for by the study include:

- Research visits that include questionnaire administration and QST

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as a part of your regular care
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.
- Health care or emergency room visits related to problems identified by any of the questionnaires, including thoughts of suicide.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

PAYMENT TO SUBJECTS

You will receive a payment of $100 at the end of Study Visit 2.

You will be given a ClinCard, which works like a debit card. After Study Visit 2, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

IN THE EVENT OF INJURY

If you experience harm or other problem during this study, you should immediately contact Andrea Nicol, MD at 913-588-3479. If it is after 5:00 p.m., a holiday or a weekend, you should call the KUMC Page Operator at 913-588-5000 and ask to have Andrea Nicol, MD paged. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation

about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities. You may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KU Medical Center by Drs. Rebecca Lepping and Andrea Nicol, members of the research team, the KUMC Research Institute, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

All study information that is sent outside KU Medical Center will have your name and other identifying characteristics removed, so that your identity will not be known. Because identifiers will be removed, your health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your health information will not expire unless you cancel it.

QUESTIONS

Before you sign this form, Dr. Lepping or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Rebecca Lepping. The mailing address is Dr. Rebecca Lepping, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Dr. Lepping or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____	_____	_____
Signature of Participant	Time	Date

_____
Print Name of Person Obtaining Consent

_____	_____
Signature of Person Obtaining Consent	Date