IRB NUMBER: STUDY20221489
IRB APPROVAL DATE: 10/17/2023
IRB EFFECTIVE DATE: 10/25/2023
IRB EXPIRATION DATE: 10/16/2024

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 07.2022)

Project Title: Music Therapy in Patients Undergoing Pancreatic Surgery (MUSIC PUPS): A Mixed Methods Feasibility Study.

Principal Investigator: Samuel N. Rodgers-Melnick, MPH, MT-BC

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
You are being asked to participate in this study because you are an adult who is scheduled to undergo pancreatic surgery at UH Cleveland Medical Center.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
You are invited to participate in a voluntary research study. The purpose of this research is to find out if it is possible to:
1) provide a tailored music-assisted relaxation and imagery (MARI) intervention to adults hospitalized for pancreatic surgery who are experiencing post-surgical acute pain;
2) collect small blood samples via finger prick from those adults who receive the MARI intervention;
3) collect information about patients' symptoms using a mobile device.

This study is being conducted by Samuel N. Rodgers-Melnick, MPH, MT-BC. **We are looking to enroll 20 participants in this study.** What researchers learn from this study will help to support future research of MARI among patients undergoing pancreatic surgery. Your participation in this study will last for as long as your hospital stay for pancreatic surgery. There is also the possibility to participate in an interview about your experience in the study one to two weeks after discharge.

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Please take the time to read this consent and talk about it with others. You may talk about this study and this consent form with family, doctors, and friends before you sign it.

Key Study Procedures

Your participation will involve answering a few questions about your pain, stress and anxiety, as well as providing a small blood sample via finger prick immediately before and after receiving a 30-minute MARI intervention from a board-certified music therapist (MT-BC) in your room. You will also answer the same questions and provide a blood sample 15 minutes after the MARI intervention. We will provide you with a device that you can use to listen to the MARI intervention and rate your pain, stress, and anxiety during the rest of your hospital stay.

More detailed information about the study procedures can be found under "Detailed Study Procedures."

Key Risks

You may experience discomfort providing blood samples via finger prick. There is also a slight risk of losing privacy and confidentiality as a result of participating in this research study.

More detailed information about the risks of this study can be found under "Detailed Risks."

Benefits

Although not guaranteed, there is the possibility that the MARI intervention may reduce your pain and help you feel better after your surgery. Future patients undergoing pancreatic surgery may also benefit from what researchers learn from this study.

Alternatives to Study Participation

Instead of participating in this research study, you can continue to work with your care team to manage your pain.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures

Your participation in this study will last as long as your hospital stay after your pancreatic surgery. There is also the possibility to participate in an interview one to two weeks after you are discharged.

On the day after your surgery, a researcher will briefly meet with your post-surgical clinical team to make sure there is no clinical reason for you not to participate. If your clinical team believes you are able to participate, then the researcher will ask you a few questions about your pain in your private hospital room to make sure you are eligible to participate. If you are not eligible to participate in the study, you may still receive music therapy services during your hospital stay.

If you are eligible, you will answer some questions about your music and imagery preferences. About an hour later, a research assistant (RA) will meet with you to ask you some questions about your pain, stress, and anxiety on an iPad. If you are currently using a patient-controlled analgesia (PCA) pump, the RA will collect information about your medication usage from the PCA pump. The research assistant will also collect a few drops of blood from your finger using a Spot On Sciences HemaSpot-HF.

Once the RA has collected your information and the blood sample, a board-certified music therapist will provide a 30-minute MARI intervention using your music and imagery preferences. During the MARI intervention, the music therapist will guide you through an exercise to relax the muscles, practice deep breaths, and explore a relaxing place while providing guitar accompaniment in a style of music

you prefer. After the MARI intervention, the music therapist will ask you a few questions about your experience and how you feel.

Immediately after the MARI intervention, the RA will return to your room to ask you the same questions about your pain, stress, and anxiety on the iPad. The RA will also collect more blood from your finger. Finally, 15-minutes later, the RA will again ask you about your pain, stress, and anxiety and collect one more sample of blood from your finger.

After the RA has collected the blood sample, the RA will give you a mobile device similar to an iPod to use for the rest of your hospital stay. This device will contain two apps: (1) an app you can use to listen to a recording of the MARI intervention, and (2) an app you can use to rate your pain, stress, and anxiety. We will ask you to listen to the MARI recording at least three times per day until you are discharged from the hospital. The device will notify you in the morning, afternoon, and evening to rate your pain, stress, and anxiety. Once per day during the week Monday through Friday, the RA will meet with you to ask you about your experience with the device and if you have had any difficulty with the MARI intervention or with rating your pain, stress, or anxiety. The RA will collect the device from you before you are discharged and give you a link, file, and/or a CD to listen to the MARI recording after you leave the hospital.

If during your inpatient stay, you express suicidal ideation or report anxiety greater than or equal to 7 on the 0-10 numeric rating scale, your clinical care team will be notified immediately, and they will intervene per their protocol.

This study includes an optional interview after discharge from the hospital. You don't have to participate in the interview to participate in this study. If you agree to participate in an interview, a researcher will call you to schedule an interview over a HIPAA-compliant commercial tele-health platform (e.g., Zoom Health for Healthcare) one-to-two weeks after you are discharged from the hospital. During that interview, a researcher will ask you about your experience in the study and

what you thought about the MARI intervention. This interview will take about 20 minutes.

Would you like us to contact you for the interview portion of this research? If you say yes now, you may still refuse to participate in the interview later.

□ Yes
□ No

Researchers will also look at your medical record to collect information about your demographics (age, sex, etc.), clinical characteristics (e.g., your diagnosis, surgery type and admission date), and pain medications that were given to you during your hospital stay.

Researchers will send your blood samples securely to Dr. Manoj Bhasin's lab at Emory University where they will figure out if enough blood has been collected to be able to do gene expression analysis. Gene expression refers to how often or when proteins are created from the instructions within your genes. Your blood samples may or may not undergo gene expression analysis. It is important to know that gene expression analysis is not genetic profiling. If your blood samples undergo analysis, researchers will not look at your genes. They will look for the changes over time in gene expression that suggest there was a relaxation response. The relaxation response is a physical state of deep relaxation in which your body releases chemicals that slow your breathing and heart rate.

Researchers hope that this study will help them plan future research to figure out if pain intensity changes after the MARI intervention are related to specific changes in gene expression profiles and in body functions that occur during the relaxation response.

Detailed Risks

You may not like the MARI intervention included in the study. If that happens, you may ask the MT-BC to stop the intervention and choose not to participate in the rest of the intervention.

It is possible that you may feel some discomfort providing the blood samples via finger prick.

As with any research study, there is a slight risk of losing privacy and confidentiality. To help prevent this, your paper records will be secured in locked file cabinets and electronic records will be kept in a password-protected database that only research staff can access. Your blood samples will be labeled with a unique study ID containing no identifiable information and then stored securely in a locked and badge-accesses research office until they are shipped to the lab for processing.

Financial Information

There is no cost to participate in this study. If you participate in the interview after your hospital stay, we will send you a $25 gift card for your time within 14 days after the interview.

To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.

Research-Related Injury

In the event you suffer a research related injury as a result of being in this study, University Hospitals is available to provide medical treatment for such injury. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of University Hospitals or any of the physicians or other study personnel. If you believe that you have been injured as a result of participating in the study, please immediately contact the Principal Investigator or

your study doctor at University Hospitals. If you cannot reach the Principal Investigator or your study doctor, do not delay treatment. You may seek treatment by another doctor. If you are seen or treated by a doctor other than the Principal Investigator or your study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you to assist with your treatment. Always contact the Principal Investigator or your study doctor to alert them of any treatment you receive for an injury or illness you experience during this Study.

The costs for medical treatment as a result of a research related injury may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

University Hospitals has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for University Hospitals to provide other forms of compensation (such as lost wages or other indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. To help avoid injury, it is very important to follow all study directions.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Termination of Participation

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or

loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If your clinical condition worsens enough that you are transferred to the ICU.
- If it appears to be medically harmful to you.
- If you fail to follow directions for participating in the study.
- If it is discovered that you do not meet the study requirements.
- If the study is canceled.
- For administrative reasons, including competitive enrollment (e.g. the target number of subjects has entered the study).

Confidentiality

We will help to protect your privacy and confidentiality by the following methods:

- Your name will only appear on this consent form and a linking log.
- The linking log that links your participant study ID to your identifiable information will be stored on a password-protected, encrypted computer or secure server.
- All information that is stored electronically will identify you only by the number assigned to you at the beginning of the study.
- You will not be identified in any presentations or publications.
- Only approved research staff will have access to your information.
- Your blood samples will be labeled with your unique study ID and then stored securely in a locked and badge-accesses research office until they are shipped to the lab for processing.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for

future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal information.

There are exceptions to this promise of confidentiality. First, we are legally obligated to report to the appropriate individuals and authorities any information that is disclosed concerning elder abuse or neglect or potential harm to you or others. Second, the clinical care team will be notified if you express suicidal ideation during your inpatient stay.

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Music Therapy in Patients Undergoing Pancreatic Surgery (MUSIC PUPS): A Mixed Methods Feasibility Study" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Samuel Rodgers-Melnick, MPH, MT-BC, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will

know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- Your name.
- Your date of birth.
- Your phone number and email addresses.
- Your hospital admission and discharge dates.
- Your medical record number.
- Dates and times related to when you provide symptom information on the mobile device and when you listen to the recorded MARI intervention.

This PHI will be used to find your medical record and to collect information about your demographics, diagnosis, pain medications used during your hospitalization and other information about your hospital stay. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- Other staff from the Principal Investigator's medical practice group that are involved in the research.
- University Hospitals, including the Center for Clinical Research and the Law Department.
- Any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation.
- Government representatives or Federal agencies, when required by law.

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Samuel N. Rodgers-Melnick, MPH, MT-BC
Integrative Health Research & Data Specialist, Connor Whole Health,
University Hospitals Cleveland Medical Center,
11100 Euclid Avenue, Wearn 548A, Cleveland, Ohio 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which

you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. f this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Samuel N. Rodgers-Melnick, MPH, MT-BC can also be contacted at 216-844-7727. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's

rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X		
Signature of Participant	Date	Time
X		
Printed Name of Participant		

X		
Signature of person obtaining informed consent	Date	Time
X		
Printed name of person obtaining informed consent		