Audio Distraction during Traction Pin Placement

RANDOMIZED CONSENT FORM

Introduction

We would like to ask you to take part in a research study observing the use of audio distraction during traction pin placement. Research studies include only people who choose to take part. It is your choice if you want to be in the study. No one can force you to be in the study. You do not have to participate in this study to receive treatment for your disease. If you decide not to participate in this study, your doctor will continue to treat you, you will not be penalized and you will not lose any benefit you are entitled to. The study doctor will also describe what treatment options you have.

Before you decide to participate in this study, it is important that you read this information thoroughly to understand why the research is being done and what it would involve for you. This informed consent form explains the purpose of the study and what will happen if you take part. Your study doctor and the study nurse will describe the study and go through this consent form with you and answer any questions you have. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team.

If you decide to take part in this research study, you will be asked to sign and date this consent form and you will be given a copy of the signed and dated consent form.

This study is being conducted by Dr. Brain Cunningham and his research team at Regions Hospital/HealthPartners.

Purpose:

We want to see if listening to music during traction pin placement changes patient experience in any way. This study may provide important information regarding use of audio distraction in the form of music for future patients undergoing traction pin placement. We hope to obtain 50 patients for this portion of the study.

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about the use of audio distraction during traction pin placement because you broke your leg or hip and need traction pin placed in your leg.

Traction pin placement is a common way to temporarily manage femur fractures and unstable hip fractures while awaiting surgery. Skeletal traction is thought to reduce discomfort by improving alignment and stretching out the leg to reduce muscle spasms. Skeletal traction may also help prevent surgical complications.

Procedures:
If you choose to participate: You will be randomly assigned to either audio distraction or no audio distraction. If you are randomized into the audio distraction group, you will be provided with a MP3 player along with a pair of headphones to use for the duration of the procedure. You will be able to choose between ten music genres already loaded on the player. At the end of the procedure for both groups (audio distraction or no audio distraction), we will collect the following information on a 1-10 scale:

- Overall experience of the procedure
- Pain during procedure
- Anxiety during procedure

How long will I be in the study?
You will be in the study from the time you are consented to participate in this study until the traction pin placement procedure is over and you complete the 3 survey questions.

The study may be stopped early by the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety
- if you do not follow our directions for this study

Risks and Benefits of Being in the Study:
There are no additional risks beyond the standard risks associated with traction pin placement for this study.

We hope the information collected will help future patients with hip or femur fractures that require traction pin placement.

Compensation:
You will receive a 20$ Target Gift Card for participating in this study.

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment must be provided by you or your third party payer, if any (such as health insurance, Medicare, etc.)

Costs:
The cost of your procedure and standard care will be billed to you/your insurance in the ordinary manner. Neither you nor your insurance provider will be charged for the costs of any of the analysis that are completed as part of this research study. You will not have any additional cost for participating within this study.

Confidentiality:
The records of this study will be kept private. In any sort of report we may publish, all information will be completely de-identified.

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know. There may be special procedures to follow for your safety.

Your only choices are to participate, or not to participate. It is up to you whether you want to be in this study.

Who oversees this study?
HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If ...	You should contact	Contact information
You are harmed by the research or have a questions about clinical procedures in the study	Dr. Brian Cunningham or his research director, Sandy Vang	651-254-6961
You have questions about your rights as a research subject	IRB office	952-967-5025

Statement of Consent:
- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____
Name of participant (print)

_____
Participant signature Date

For Site Use only:

- I have carefully explained to the participant the nature and purpose of this study.
- The participant has been given enough time and an adequate place to read and review this form.
- The participant has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research
- I have explained and discussed potential risks and benefits
- The alternate treatments available to the participant and the benefits and risks of each

_____

Name of person obtaining informed consent (print)

_____

Signature of person obtaining informed consent Date

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?
To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?
When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners Health Care to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- information about your medical conditions and history

The collected information may contain your name, address, telephone number, social security number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?
By signing this Authorization, you allow the research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at HealthPartners/or Dental Clinic) to the following:

Who may have access:	Purpose:
HealthPartners consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remain accredited

Will you keep my health information confidential?
We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves HealthPartners, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?
If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?
Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed.

What if I change my mind?
If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?
You have the right to see and get a copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once you complete the study.

_____
Subject Name (print)

_____
Subject Signature Date