PARTICIPANT CONSENT FORM AND HIPAA AUTHORIZATION

Title: Music Therapy for Comatose Brain Injured Patients
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Co-investigators: Gregory S. Huang, MD; Elisha A. Chance BSAS, CCRC; Kevin Bouslough BSAS

Introduction

In this consent form, "you" refers to the study patient/participant. If you are a legally authorized representative, please remember that "you" refers to the study patient/participant.
You are invited to take part in a research study because you have sustained a severe traumatic brain injury. First, this form will explain what the study is about. Then, it will explain what will happen if you choose to take part in the study. Any questions you have about the study will be answered. Finally, you will make a choice to participate or not to participate. This process is known as informed consent.

It is important to read and fully understand the information below. Please feel free to ask any questions that will help you understand. Once you understand the study and if you agree to take part in it, you will be asked to sign this form. You will be given a copy of this form for your records.

Roughly 20 patients who come to this hospital intensive care unit will be asked to take part in this study.

Background

A person with a traumatic brain injury may not have outward signs of being awake, but research suggests that they are able to detect touch, sounds, and smell. Several research studies have shown that patients with a major brain injury have improved brain function after receiving music therapy or other sensory stimulation processes (family voices, being touched, or smelling scents) while in the intensive care unit. Music therapy uses sound at a specific rhythm to match brainwaves to the music. The thinking is that music therapy is relaxing and helps brain activity. Research has shown that sensory stimulation during the intensive care phase of major brain injury does not cause harm to recovery.

Purpose and Study Design

The purpose of this study is to find out if music therapy can produce benefits like other studies have. The doctors in charge of the study think it might help the brain function. We are asking permission for you to listen to music therapy while in the intensive care unit.

If you decide to participate in the study, this is what will happen. Twice a day for 30 minutes, your nurse will play soothing and mildly stimulating music. The music is called "Deep Alpha (440 Hz) vol. 1," by Steven Halpern. The music is played through soft, over the ear headphones that will only be used by you. It will be played at a comfortable volume that is not too loud. You will listen to this music twice a day for seven days or until you are discharged from the intensive care unit, whatever comes first.
Your nurse will decide what time to play the music each day so that it does not interrupt any other care. He/she will check your vital signs before the music session to make sure it is safe to start. The

nurse will continue to monitor you during the music session, and the music will be immediately stopped if there are any signs of distress.

After the music therapy sessions are complete, or you are moved out of the intensive care unit, your participation in the study is complete. Your choice to take part in this study will not change the way your doctor will treat you. Your doctor will always make choices that are in your best interest. Your doctor will provide the best treatment for your injury.

The study will collect the following information before and after each music session:

- Glasgow Coma Score (GCS), is a score that measures how awake you are
- Bispectral Index (BIS), measures brain wave activity. The sensors for this monitor lay across the skin on the forehead. It does not stimulate the brain.
- Heart Rate, how many times your heart beats each minute
- Blood pressure, the pressure in your arteries when your heart pumps (systolic) and when it is at rest (diastolic)
- Respiratory rate, how many times you breathe each minute
- Right and left pupil size, the size of the black circle in the center of your eye. Nothing is placed in the eye to measure this.
- Right and left pupil reactivity to light, whether the black circle shrinks when a small light is shone at the eye.
- Richmond Agitation-Sedate Scale (RASS), is a score to measure agitation
- Intracranial pressure (ICP), measures pressure in your brain. This will only be collected if you have a special monitor for this ordered by your doctor
- Cerebral Perfusion Pressure (CPP), is a calculation that tells the doctor about circulation in the brain

Additionally, the study will collect the following information from your medical record:

- Age
- Sex at birth
- GCS at admission, discharge, and at 3 months
- Intensive care unit length of stay
- Number of ventilator days
- Hospital length of stay
- Other medical conditions you have
- Injury severity scoring
- Your survival

Risks

There is a small risk for agitation with music therapy. If agitation is present, the nurse will immediately stop the music. There is a risk of minor skin discomfort from the BIS monitor. There are no other risks expected in this study.

Benefits

There may be no direct benefit to you from taking part in this research study. However, the knowledge gained from this study may help other people like you with traumatic brain injury in the future.

Cost of Participation/ Subject Payment

There are no extra costs for taking part in this study. The music, headphones, and BIS monitoring are provided free of charge. You will be billed in a normal manner by the hospital for your care. You will not be paid to take part in this study.

Right to Ask Questions

You have the right to ask questions at any time about this study. The doctors in charge of this study are Dr. Dunham and Dr. Huang. If you have questions, you may contact Dr. Dunham or Dr. Huang at (330) 480-3907. You may also contact the Trauma Research Department at St. Elizabeth Hospital at (330) 480-3107.

If you have any questions about your rights as a research participant or if you have concerns about ethical misconduct in this study, contact Mark F Leep, Research Participant Protection Program Director, at (804) 627-5157.

Refusal or Withdrawal of Participation

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Any new information that may affect your choice to participate in this study will be shared with you. The doctor may take you out of the study if there is possible harm due to participation. The doctors and the Trauma Research Department have not been given any money to carry out this study.

Privacy & Confidentiality

A number will be assigned to protect your identity. The information we collect from you will be stored electronically with password-limited access or stored in a locked filing system with limited access to the staff involved in the study. If you agree to take part in this study, you give the researchers permission to review information from your record that is related to your brain injury. This information includes but is not limited to imaging results, age, vital signs, assessments, labs, gender, occupation, date of injury, symptoms, and dates and results of exams. The following people may examine the information we collect and records that may identify you including this signed form:

- Federal agencies that oversee research;
- The ethical board at St Elizabeth Youngstown Hospital that supervises all research, also known as the Institutional Review Board or IRB;
- The doctors listed at the beginning of this form and the research team at St. Elizabeth Hospital; and
- Regulatory officials from Bon Secours Mercy Health to make sure policies are being followed and that you are kept safe from harm.

When the study is finished, all your information and any links to your name will be destroyed. The results of this study may be presented at meetings or in published articles. However, your name and other identifying information will always be kept private.

HIPAA RESEARCH AUTHORIZATION

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared? The study doctor and study staff will use and share your health information as part of this research study. This may include your name, address, telephone number, or other facts that could identify the health information as yours.

Examples of the information that may be used are:
● Medical records (from any doctor, hospital or other healthcare provider)
● Information created or collected during the research. This could include your medical history and dates or results from any physical exams, laboratory tests or other tests

Who will receive information about me? The study doctor and study staff may share your personal health information with:
● the sponsor, including persons or companies working for or with the sponsor
● the Institutional Review Board (IRB) with oversight responsibilities for this study
● local, state, and/or federal regulatory agencies

Why will this information be used and/or given to others? The groups above will use your health information:
● to complete this research
● to evaluate the results of the study
● to check that the study is being done properly

Is my health information protected after it has been given to others? Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. However, these groups are committed to keeping your health information confidential.

What if I decide not to allow the use of my health information? You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

May I withdraw or revoke (cancel) my permission? Yes. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization? Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Will my Authorization expire? This Authorization will expire when the research study is closed, or there is no need to review, analyze, and consider the data generated by the research project, whichever is later.

May I review or copy the information obtained or created about me? Yes. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

By signing below, I confirm the statement below.
I have either read this document or it has been read to me. I have been told what the study is about and what will happen if I choose to participate. I understand both the risks and benefits of taking part in this study. I know that I can stop participating in this study at any time and will still receive the care that I need. I agree that information in my chart about my brain injury can be used for this study. All my questions have been answered. I willingly agree to take part in this study. I will receive a copy of this consent form.

Patient Name: _____

_____	_____	_____
Signature of Patient/LAR	Printed Name of Patient/LAR	Date
_____	_____	_____
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date