DOES INTERACTIVE GROUP DRUMMING (IGD) IMPROVE THE HOSPITAL EXPERIENCE OF PATIENTS UNDERGOING STEM CELL TRANSPLANT (HCT)? -A PILOT STUDY – CCCWFU 04417

Informed Consent Form to Participate in Research

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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 invited to take part in this study because you are entering our Hematopoietic Cell Transplantation (HCT) Program. 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 is to determine if it is possible to perform group drumming as an intervention during HCT, to begin to understand how interactive group drumming during HCT treatment affects patients' well-being (good and bad) during the treatment course and in the first four weeks after completion of the drumming sessions.

How Many People Will Take Part in the Study?

Approximately 35 people at 1 research site (Wake Forest Baptist Comprehensive Cancer Center) will take part in this study.

What Is Involved in the Study?

This study will involve your participating in four (4) interactive group drumming sessions (10-30 minutes each), and completing surveys and questionnaires. For this study, a group is defined as a minimum of the patient and two drumming facilitators. Hospital staff or family members may join the group and play the drums. Over the next several weeks, you will complete fourteen surveys about music and your quality of life. Participation in this study will require approximately 160 minutes of your time.

Pre-Study

Before you start the first drumming session, pre-study or baseline, measurements of how you use music and your anxiety levels will be taken. This will involve 2 surveys. Each of these surveys asks you to rate your feelings on scales. For 1 survey you will have 8 questions/items to rate, the other has 20. You will also be given an information sheet about the drumming sessions and have the opportunity to talk with drumming facilitators.

Drumming Sessions
The drumming sessions will occur in your room while you are in the hospital receiving treatment. The first session will occur as soon as possible after you are admitted. The second will occur within the first 3 days. The third and fourth sessions will occur within one week after your transplant infusion. The actual days of drumming sessions may vary depending on your expected length of hospital stay, your platelet levels, and how you are feeling. In the case of myeloma patients, third and fourth IGD sessions will occur during the expected duration of daily returns to the hospital during treatment.

The drumming sessions will be led by at least one instructor and last between 10-30 minutes. Before and after each session you will fill out a survey with 16 items that will measure your mood, energy, relaxation, distress, pain and anxiety. There is also a place where you can write your own comments.

After your Standard of Care Medical Treatment and the Drumming Sessions
After all 4 sessions of drumming and standard of care treatment are completed, you will fill out 3 follow-up surveys. Two of these surveys will be the same surveys you filled out before the start of the drumming sessions and involve measurements of anxiety levels and your use of music: using (1) a survey to measure your use of music to promote wellness, (2) STAI-Y1 (a 10-question state anxiety inventory). The third is a questionnaire to gather your suggestions and comments about the study and to measure your satisfaction with the IGD intervention.
Study follow-up inquiry will occur about 4 weeks after last IGD session, either at your follow-up medical visit to WFBMC, or by mail, if you will not return to campus. This final survey will ascertain how you have been using interactive drumming or other music to improve emotional health and/or cope with distress since the end of the fourth drumming session. The return of this final survey will complete your participation in the study.

How Long Will I Be in the Study?
You will be in the study for about 2 months. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk with the investigators first.

What Are the Risks of the Study?
The risks to you for participating in this study include risks related to the drumming sessions, which could include tired hands or arms. Facilitators will tell you how to minimize and/or avoid this risk. At no time will you be required to play your drum in a manner that causes discomfort.

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 may discuss the risk of being in this study with the study staff.

Risks of Surveys and Questionnaires
In this study, you will complete questionnaires and surveys that ask about your emotions and pain. These feelings may be heightened while you are taking these surveys.

Risk of Providing Confidential or Private Information

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

Taking part in this research study may involve providing information that you consider confidential or private. We will code research records, keep research records secure and allow only authorized people to have access to them.

There also may be other side effects from drumming that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects and other risks.

Reproductive Risks and other Issues to Participating in Research

There is no reproductive risk in this study.

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. Previous study results suggest that the benefits of participating in this study may be the following: increased energy, reduced pain, anxiety, and distress. In addition, you may experience the fun of making music, you may gain an understanding about the benefits of using music interactively as part of a balanced and enriched lifestyle, and you may gain an understanding of how the creative process of music making promotes wellness. You may also acquire a new skill that will enable you to promote your own well-being through interactive music.

What Other Choices Are There?

You may choose not to participate in this study. Your choice to participate or not to participate will not affect your medical care in any way.

What Are the Costs?

There are no costs to you in this study. We will provide the drum for you. 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 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. Government agencies, like the FDA, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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 research study. Information about the research 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.

Will You Be Paid for Participating?

You will receive one of the following forms of compensation for your time and participation in the study. A drum will be assigned to you at the beginning of the first IGD session. You will use the instrument during each of the four IGD sessions and may take it away from the hospital to be used at home after the last IGD session. After you complete and return the last questionnaire for the study, you can choose to receive one of the following incentives: a pair of concert tickets to the Winston-Salem Symphony, the Piedmont Opera, or the Piedmont Wind Symphony, an iTunes gift card, or a gas card.

Who is Sponsoring this Study?

This study is being sponsored by Wake Forest Baptist Comprehensive Cancer Center. The Cancer Center is providing resources to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor.

What About My Health Information?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information from your medical record that we will review and record for this research study includes**:** the results of blood tests to determine your platelet levels, your vital signs (heart rate, blood pressure, and respiration rate), to determine physiological changes during IGD over time, and information about when you are expected to return to the clinic for follow up and to complete this study.

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.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

The study investigators, study staff, monitors, auditors, IRB or other regulatory agencies will have direct access to your original medical record for verification of clinical trial procedures or data, without violating your confidentiality and to the extent permitted by other applicable laws.

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 indefinitely after the study is finished. 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 Ruth Moskop, PhD or John Beck that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to either of these addresses:

Ruth Moskop, PhD
[redacted]

or

John R. Beck
[redacted]

or

Richard McQuellon, PhD
[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 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.

Survey and Questionnaire results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be

directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

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. The investigators also have the right to stop your participation in the study at any time. This could be because of any change in your condition that the investigators believe may put you at risk or prevent you from completing the study.

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 one of the study investigators, Dr. Richard McQuellon, [redacted], Dr. Ruth Moskop at [redacted] or John Beck 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].

You will be given a copy of this signed consent form. (Signatures on next page)

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