Jefferson Office of Human Research
Informed Consent OHR-8
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Department: Oncology Nursing

Principal Investigator: Anne Delengowski, RN, MSN, AOCN, CCCTM

Study Title: Improving the Patient Experience During Bone Marrow Biopsy/Aspiration (BMBA): Do Interventions Decrease Distress and Pain.

Lay Title: Improving Patient Experience During Bone Marrow Biopsies

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

The purpose of this research is to explore ways of improving the patient experience during visits for bone marrow biopsies. This procedure can be painful and cause distress. This study will look at alternative ways of promoting relaxation and distraction both while waiting before the procedure and during the procedure.

How this Research is Different from Standard Medical Care

Depending on which group you are assigned to, you may receive different tools to help promote relaxation and reduce distress during your procedure. These include changes to the room environment, music, guided meditation, and virtual reality. These are all techniques that have been used to help reduce pain and distress for cancer patients, but they have not been specifically used during bone marrow biopsies.

Number of Participants

About 60 people will take part in this research in the whole study at Jefferson.

Duration

You will be in this research study for a single bone marrow biopsy procedure visit.

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You may personally benefit from taking part in this research. Some of the possible benefits may be decreased distress, decreased pain, and improved satisfaction. Your participation will help us understand what methods are best to improve the overall patient experience during this procedure.

Alternatives to Taking Part in this Research

The alternative to being in this study is to not take part.

Payment

You will not be paid for taking part in this study. If this research or the information or specimens you provide result in commercial profit, you will not receive any money from that profit.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form. This will include completing the post-procedure survey.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will be given any research results that could affect your health.

Detailed Information Section

Drugs/Devices

The two interventions used in this study are described below:

Intervention 1 uses a virtual reality headset to provide a guided meditation experience. Virtual reality, or VR, is a simulated experience that combines going to a movie with the interactions of playing a computer or video game. It usually involves wearing a headset over the eyes and using a controller or remote to interact with the VR content. The content for this study is a guided meditation application. Guided meditation is a relaxation technique used to provide stress relief and reduce tension. A teacher, video, or audio recording is used to help focus on breathing, pleasant scenery, or music.

Intervention 2 will be changes to the procedure room environment. These will include nature imagery and a selection of music. You will be able to choose from a selection of music stations or to pick your favorite type of music to listen to before and during the procedure. Music therapy and nature imagery help provide stress relief and promote relaxation.

There is a 50% chance you will be assigned to one of these interventions. There is also a 50% chance you will be assigned to a control group. Control group participants will receive normal standard of care during their procedure and be asked to answer questions about their experience.

Procedures

While you are in this study, you will have your bone marrow biopsy procedure as part of your normal care. Please note that additional tests and procedures are not expected but may be needed to check on your health condition.

Name of Procedure: Bone Marrow Biopsy / Aspiration

Description: After numbing the procedure area with lidocaine, a small fragment of bone will be removed along with a small sample of marrow using a needle. This will be done one time during your visit.

Name of Evaluation: Vital Signs

Description: Before your bone marrow biopsy procedure, your heart rate, blood pressure, and respiratory rate will be recorded. Each will be taken once before your procedure.

Risks

Taking part in this study involves certain risks. There may be different risks depending on what group you are assigned to. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

Intervention 1: Virtual reality may cause symptoms associated with motion sickness, including nausea, dizziness, disorientation, and vertigo. Mild eyestrain or headaches may also occur.

Intervention 2: There are no known risks associated with music therapy or décor changes.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study interventions or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give you other compensation for the injury. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Disclosure of Financial Interest

This study has been funded by the DAISY Foundation's J. Patrick Barnes Grant.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, health care providers, race, and ethnicity
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- Vitals, including heart rate, blood pressure, and respiratory rate
- Questionnaires about your experience

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Institutional Review Boards (ethics committees that review research) including the Jefferson IRB

- Health insurance providers
- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your private information, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Contacts

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

For Questions About:	**Person or Office**	**Contact Information**
The Study or Research Related Injury	Main Investigator: Anne Delengowski Investigator: Michelle Lasota	(215) 955-7098 (267) 438-6652
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

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Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	_____
Your Name	Your **Signature**	Date
_____	_____	_____
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

The investigator's signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

_____	_____	_____
Name of Investigator	Signature of Investigator	Date
_____	_____	_____
Name of Witness	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

THOMAS JEFFERSON UNIVERSITY IRB

APPROVAL DATE 10/28/2021

Approved until END OF STUDY

☐ **Copy of Signed and Dated Consent Form Given to the Subject/LAR**