Document Cover Page

Official Title of the Study: Pilot Study for the Development and Implementation of a Virtual Reality-based Radiation Therapy Education and Anxiety Mitigation Program

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Medical College of Wisconsin and Froedtert Hospital
INTRODUCTION TO THE INFORMED CONSENT

Name of Subject: _____

Pilot study for a radiation therapy education and anxiety mitigation program

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You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

Definitions

Virtual Reality (VR) - A computer-generated 3D virtual environment

Head-Mounted Display (HMD) - A headset with two lenses that enables one to be immersed in a virtual environment

Radiation Therapy (RT) - A mechanism of treating cancer with radiation beams

Purpose

This project is being done to compare different methods of delivering educational content to breast cancer patients undergoing radiation therapy (RT), in order to determine which is most effective at reducing patients' anxiety levels and meeting patients' informational needs for RT treatment.

Length

- You will be in this research project for the time period leading up to and including your first session of radiation therapy treatment.

Activities

There are two study groups in this project: one group will receive virtual reality (VR)-based education and the other will receive patient education in the form of a video. You will be randomly assigned to one of the two groups. Please note that the procedures associated with the visits listed below will be incorporated into your regular clinic visits, so you will not need to attend any additional appointments for this study.

List of visits:

- Screening and informed consent visit
  - Total Number: 1 or 2
  - Total Time: 30 minutes
- Education intervention and phases 1 and 2 of questionnaire completion
  - Total Number: 1
  - Total Time: 60 minutes or less
- Phase 3 of questionnaire completion
  - Total Number: 1
  - Total Time: 20 minutes or less

Activities that will occur at various visits:

Non-invasive Activities

- Engagement with the educational intervention (video or VR program)
- Completion of 3 groups of questionnaires

Risks

This is a brief list of the most commonly seen side effects/risks. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Intervention risks:

- Your questionnaire responses could potentially be leaked/subject to unauthorized access
- Someone could find out you are enrolled in this trial and learn something about you that you do not want people to know
- For subjects in the VR education group:
  - Symptoms including nausea, disorientation, and dizziness have occurred in a small number of HMD device users.
  - You may feel a strong sense of presence in the virtual treatment environment, which may trigger anxiety about your upcoming treatment.
  - Contagious conditions, such as those in the eyes, nose, or scalp may transfer between different users of the head-mounted display. The study team will clean the device between each use to minimize this risk.

Benefits

This project may or may not help you, but we hope the information from this project will help us develop improved patient education for radiation therapy treatment that effectively reduces patients' anxiety levels and meets patients' informational needs prior to the beginning of treatment.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Dr. Carmen Bergom at [redacted].

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you will be receiving radiation therapy to treat breast cancer for the first time.

A total of about 36 people are expected to participate in this research state-wide within the Froedtert & the Medical College of Wisconsin regional health network.

The Director of the project is Dr. Carmen Bergom in the Department of Radiation Oncology. A research team works with Dr. Bergom. You can ask who these people are.

The Medical College of Wisconsin Cancer Center is funding the research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this project, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to compare the effectiveness of a virtual reality patient education program with an educational video in regard to reducing patients' anxiety levels and meeting informational needs both prior to and during radiation therapy treatment.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

All enrolled patients will be randomly assigned to either the VR-based education group or the video education group. The difference in groups is in the type of education that you will receive at the clinic going into your treatment.

Upon enrollment in the study, you will be assigned a unique alpha-numeric code to be used as identification in place of your name on the hard-copies of questionnaires you are asked to complete for this study.

There will be 3 main phases in this study that you will be involved in:

The first two phases will take place prior to your CT simulation appointment:

Phase 1: Questionnaires before education intervention – You will complete three self-evaluation questionnaires. You will then undergo the education intervention corresponding to the study arm you have been assigned.

Phase 2: Questionnaires immediately after education intervention – Three self-evaluation questionnaires will be administered at the end of the education intervention. Phases 1 and 2, with the education intervention, are expected to take 60 minutes or less.

Phase 3: Questionnaires after first RT treatment – After your first session of radiation therapy, you will be given three self-evaluation questionnaires. Phase 3 is expected to take 20 minutes or less.

There will be no long-term follow-up for this study.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project through the first session of your radiation therapy treatment.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor. You can contact Dr. Bergom at [redacted] or the Clinical Research Coordinator at [redacted] to let them know you want to withdraw from the study.

For subjects in the VR-based education group, if you feel any discomfort while wearing the VR headset, you are free to remove it at any time.

The research doctor may stop your participation in the project at any time for any reason without your consent. He / She will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research doctor, Dr. Bergom, or a member of the research team immediately if you experience any problems.**

<u>For subjects in the VR-based education group:</u>

VR head-mounted display: A very small number of device users have symptoms of nausea, disorientation, and/or dizziness during or after using the device. While rare, a very small number of users may have severe dizziness, seizures, eye twitching, or blackouts during or after using the device. If you do feel any discomfort while using the head-mounted display, including the symptoms listed above, please take the headset off. Further, use of this device blocks your view of the outside world. Please remain seated while using the HMD so as not to come into any harm while your surrounding vision is blocked. If you feel any discomfort during or after using the head-mounted display, please let Dr. Bergom know at [redacted].

Anxiety: The VR education program was designed to familiarize you with the radiation therapy treatment procedure. If the education makes you feel more anxious about your upcoming treatment, please talk with your radiation oncologist.

Contagions: Contagious conditions, such as those in the eyes, nose, or scalp may transfer between different users of the device. The study team will clean the device between each use to minimize this risk.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop improved patient education for radiation therapy treatment that effectively reduces patients' anxiety levels and meets patients' informational needs prior to the beginning of treatment.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs from the research team for your participation in this project.

Please note that the study team is not covering the cost of your treatment or any appointments, so you are still responsible for existing costs.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will not be paid for participating in this project.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Carmen Bergom at [redacted].
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate-Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information we will collect and use for this project is:

Information that helps us in determining whether or not you are eligible for this study, including but not limited to current breast cancer diagnosis information, history of epilepsy or conditions causing seizures, and whether or not you have previously received radiation therapy. We will also record whether or not you have previously had chemotherapy.

We will also collect and use your responses to the questionnaires that you will complete for this study.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital/Marquette University, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information indefinitely in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Carmen Bergom at 9200 W. Wisconsin Avenue, Department of Radiation Oncology, Milwaukee, WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Witness (if applicable**)** *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*