CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Randomized controlled trial of virtual reality technologies for pain management in advanced cancer patients: Protocol for efficacy, feasibility, and safety in a home setting.

Study to be Conducted at: **Prisma Health Cancer Institute**
900 W Faris Road
Greenville, SC 29605

Sponsor Name: Prisma Health

Principal Investigator: Teny Henry Gomez MD (864) 455-3987

KEY INFORMATION
You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study doctor to explain anything you do not understand.

The primary aim of this pilot study is to measure the improvement in pain using virtual reality assisted guided imagery, in cancer patients. Our study will utilize a novel approaches where some participants will be asked to wear a virtual reality head-mounted display (HMD) presenting immersive content in a home setting, while others will be presented with similar imagery on a laptop. Eighty patients recruited from the Prisma Health Cancer Institute will be randomly assigned to the intervention or control groups. All arms of the study will include patients with active cancer who are receiving the current standard of symptom management treatment. Participants will be exposed to immersive content at home for a period of 3 weeks. Self-reported outcomes will be collected between, during, and after this period and data will be analyzed to test for differences between groups. Our objectives are to assess the impact of different types of immersive content on patient-reported outcomes including pain, anxiety, depression and opioid use among patients with advanced cancer, and to determine the feasibility, acceptance and safety of immersive content in a home setting. If successful, this study will introduce for the first time, the use of virtual reality to reduce pain and improve quality of life in cancer patients, in a home setting.

The Institutional Review Board of the Prisma Health Upstate has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations. The study is approved by the Prisma Health IRB.

PURPOSE
You are being asked to participate in this study because you have advanced cancer (based on staging) and are a current patient of Prisma Health Cancer Institute.

The purpose of this study is to study the efficacy, feasibility, and safety of virtual reality assisted guided imagery and its role in pain improvement in patients with advanced cancer.

Patients with advanced cancer often experience high levels of debilitating pain and pain-related psychological distress. Unrelieved pain greatly affects patients' comfort, activities, motivation, interactions with family and friends and overall quality of life. Although there is increasing evidence

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that non-pharmacological pain management strategies are needed to treat pain in advanced cancer patients, pain is typically treated with analgesics.

Guided imagery is a form of focused relaxation that helps create harmony between the mind and body. It is a way of focusing your imagination to create calm, peaceful images in your mind, thereby providing a "mental escape." Guided imagery specifically has been shown to significantly improve cancer pain.

Therapeutic virtual reality (VR) has emerged as a promising and evidence-based treatment modality for cancer pain. Recent evidence suggests VR experiences are safe and effective in reducing acute pain and limited research exists on mental imagery-based VR modalities beyond mere distraction, such as the use of VR that employs guided imagery. There is also a paucity of research assessing VR-related symptoms, patient experience and adverse effects, such as motion sickness, nausea, and headaches. We are unaware of studies reporting the use of VR-based interventions for pain in home settings.

The study will measure PROs and opioid use in 80 patients randomized to four groups after enrollment. Eligible patients will be trained to use the VR head-mounted display (HMD) or laptop in the comfort of their own home for self-treatment of cancer pain. The study period will last for three weeks of immersive content. Outcomes will center on patient reported outcomes (PROs) including pain, anxiety, depression, fatigue as well as immersive content feasibility, acceptability, safety, and opioid use. Qualitative data will supplement these quantitative metrics to understand patients' preferences, thoughts, and feelings about the immersive content. Data will be collected before, during and after the three-week study period and compared with the control group data. Participation will last for 6 weeks.

HOW THE STUDY WORKS

The study will recruit 80 patients from Prisma Health Cancer Institute outpatient clinics. Eligible participants will receive a phone call from the research assistant to confirm eligibility. Eligible participants that do not opt-out will be emailed a recruitment letter, IRB approved consent form and informational brochure. Participants will be consented by the research assistant using Prisma Health IRB approved consent forms (this form). Participants will be randomized to one of the four arms (N=20 each) using REDCap software. The four arms of the study consist of: (1) VR with guided imagery, (2) laptop with guided imagery, (3) VR with immersive content, and (4) laptop with immersive content. Participants will be mailed the VR-HMD or laptops based on which arm of the study there are randomized to. Participants will also receive a link to a training video. Once the training is complete, participants will self-administer the immersive content daily over a three-week period while at home. There will be 3 experiences: Summer, Spring and Autumn. Each session will be approximately 20 minutes, once a day. Once each intervention is completed, the participants will mail back the VR HMD or laptops using prepaid shipping labels, and the participant will complete the surveys. In addition to surveys, VR use data will be downloaded from the devices. The devices will be cleaned with a CleanBox UV box to kills 99.9999% of bacteria, viruses, and fungi including SARS-CoV2 between participants.

Randomized participants will adhere to the following schedule:

<u>Screening Phase</u>

- Complete Edmonton Symptom Assessment Scale (ESAS)
- Complete Brief Pain Inventory
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Intervention Phase
Week 1

- Pre and Post VR Session (daily):
  - Complete numerical rating scale for pain, anxiety, depression, fatigue
- Complete Brief Pain Inventory (Beginning and end of first week)
- Complete Edmonton Symptom Assessment Scale (Beginning and end of first week)
- Complete Client Satisfaction Questionnaire (CSQ) (end of first week)
- Complete VR questionnaire (end of first week)

Week 2

- Pre and Post VR Session (daily):
  - Complete numerical rating scale for pain, anxiety, depression, fatigue
- Complete Brief Pain Inventory (Beginning and end of second week)
- Complete Edmonton Symptom Assessment Scale (Beginning and end of second week)
- Complete Client Satisfaction Questionnaire (CSQ) (end of second week)
- Complete VR questionnaire (end of second week)

Week 3

- Pre and Post VR Session (daily):
  - Complete numerical rating scale for pain, anxiety, depression, fatigue
- Complete Brief Pain Inventory (Beginning and end of third week)
- Complete Edmonton Symptom Assessment Scale (Beginning and end of third week)
- Complete Client Satisfaction Questionnaire (CSQ) (end of third week)
- Complete VR questionnaire (end of third week)

Post-Intervention Phase
Week 6

- Complete Brief Pain Inventory (end of week 6)
- Complete Edmonton Symptom Assessment Scale (end of week 6)

POSSIBLE RISKS
There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, and all data will be stored in encrypted, HIPAA compliant REDCap software. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

Some of the questions in the surveys/questionnaires are personal and may be upsetting to some participants. The study doctor and/or research assistant will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

POSSIBLE BENEFITS
It is not possible to know whether or not you may benefit from participating in this study. The treatment or procedures you receive may even be harmful. The information gained from this study may be useful and may help others.

ALTERNATIVE (OTHER) TREATMENTS
The decision to participate in this study is entirely up to you. The alternative to participating in this study is simply not to participate. If you decide not to participate in the study, you will not be penalized in any way.

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NEW INFORMATION
Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you.

COST TO YOU FOR PARTICIPATING IN THIS STUDY
There are no anticipated costs to you for participating in the study.

PAYMENT FOR PARTICIPATION
To You:
You will be paid for participating in this study. Participants will be eligible for up to $100 in Amazon.com gift cards. A $25 gift card will be emailed at the end of weeks 1 and 2, if they complete ≥75% of surveys during each of those weeks. The 3rd $25 gift card will be emailed if they complete ≥75% of surveys and initiate the HMD return after week three of the intervention phase. The remaining $25 gift card will be sent at the end of the six-week period if they complete ≥75% of the surveys at the end of the post-intervention phase

To Institution:
Prisma Health Cancer Institute is being funded by the sponsor for staff and administrative costs associated with conducting this study.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION
Prisma-Health Upstate will provide you the care needed to treat any injury, or illness, that directly results from taking part in this research study.

Injuries sometimes happen in research even when no one is at fault. The study sponsor, Prisma-Health Upstate, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the 'Contact for Questions' section of this consent.

VOLUNTARY PARTICIPATION
The study doctor and/or sponsor may withdraw the participant from the study at any time without the participant's or their legally authorized representative's permission under any circumstance.

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION
As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical

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records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Some of the organizations/entities that may receive your information are:

- The study sponsor and any company supporting the study (the sponsor's authorized representatives)
- The Institutional Review Board, which is a group of people who review research with the goal of protecting the people who take part in the study

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to the study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

If you have any questions about the privacy of your health information, please ask the study doctor.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Office of Human Research Protection of Prisma-Health Upstate for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

Principal Investigator Name: Teny Henry Gomez MD Telephone Number: 864-455-3987

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CONSENT TO PARTICIPATE

The study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given the opportunity to review my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____

Printed Name of Participant

_____ _____ _____

Signature of Participant Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of the above study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____

Signature of Investigator Date Time

Principal Investigator Phone

Co-Investigators Phone

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