MedStar Health
Research Institute

Title of research study: Pilot study to evaluate virtual reality for cancer pain management

Investigator: Hunter Groninger MD

The Palliative Care Research Cooperative Group (PCRC) is the only US research cooperative focused specifically on the science of palliative and end-of-life research and will be providing oversight on the conduct of this research study. By participating in a PCRC study, you will be part of a large group of study participants across the nation, and the findings from the research will be distributed quickly and widely. The Principal Investigator of this study is Dr. Hunter Groninger from MedStar Health. A grant from the Palliative Care Research Cooperative is funding this study.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have a diagnosis of cancer and reported moderate to severe pain in the last week.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study is being done to study the impact of virtual reality (VR) on pain management for outpatients diagnosed with cancer. In different clinical settings, VR has been shown to help improve both acute and chronic types of pain. We are interested to learn if it can help patients who have pain from cancer or cancer treatments.

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately three weeks. In order to participate, you will need to engage in a brief session with the study coordinator to learn how to use your VR

headset. You will need to complete a brief survey. These will take place at Washington Cancer Institute at MedStar Washington Hospital Center either at a time that aligns with one of your medical visits, or at another time if you prefer. Then, once you are at home, you will need to follow instructions for daily use of your VR headset. A calendar will be provided to you indicating which days the VR headset should be used, how often it should be used, and a space for you to write in the approximate times you used the headset. At the end of each week, the coordinator will contact you to complete a brief survey.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?***

Is there any way being in this study could be bad for me?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

- Loss of confidentiality of Personal Health Information
- Brief dizziness or motion sickness while using the VR headset
- Temporary eye strain. If you wear corrective eyeglasses or contact lenses, you may wear them while using the VR headset. If you notice eye strain while using the VR headset or shortly after using the headset, stop use immediately and let a member of the research team know.
- Risk of falling and injury if VR headset is used while standing or walking. It is important to only use the VR headset while in a comfortable seated or reclined position to minimize risk of injury.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include temporary improvement in your pain control.

There may also be benefit to others through increasing knowledge about a new way to improve pain control in patients living with cancer.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at: Dr. Hunter Groninger, Principal Investigator, MedStar Washington Hospital Center, 202-877-7445, hunter.groninger@medstar.net

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 60 people here will be in this research study out of 60 people in the entire study nationally.

What happens if I say yes, I want to be in this research?

If you agree to take part in this study, you will first complete surveys about your pain experience. Then you will receive a Meta Quest 2 virtual reality headset and hand controllers with Nature Treks VR application software (https://naturetreksvr.com) that features ten non-violent, nature-based experiences in peaceful environments (e.g. forest, river, beach, etc.). You will be able to select the nature environment to play during each VR session.

The VR headset requires a Meta/Facebook account for use. In order to protect privacy, the research team has created a "dummy" Meta account specifically for this research study that has been used to activate the device. This account does not contain payment information, personal information, and cannot be linked to you in anyway. If you encounter technical challenges while using the VR headset or study coordinator, the research team will assist you with correcting any problems or providing a replacement headset at no charge to you, if needed.

You will receive instructions as to use of the VR headset and software, including relevant safety precautions, so you may use in the home environment. You will receive instructions as to how and when to complete 10-minute sessions of NatureTreksVR on your VR headset. There will be different instructions about how and when to use VR each week for three weeks. At the end of each week, we will telephone you to complete 4 surveys. The surveys should take 10 minutes or less to complete. They are for research purposes only.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- following the directions of the research study as outlined by the research coordinator
- contacting the research coordinator or the principal investigator if you experience any side effects from the study or if you have any questions or concerns

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can document that you voluntarily chose to leave the research study.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

Risks and side effects that rarely occur include:

- Loss of confidentiality of Personal Health Information
- Brief dizziness or motion sickness while using the VR headset
- Temporary eye strain. If you wear corrective eyeglasses or contact lenses, you may wear them while using the VR headset. If you notice eye strain while using the VR headset or shortly after using the headset, stop use immediately and let a member of the research team know.
- Risk of falling and injury if VR headset is used while standing or walking. It is important to only use the VR headset while in a comfortable seated or reclined position to minimize risk of injury.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You and your insurance company will be charged for the health care services that you would ordinarily have to pay for. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will have to pay for yourself.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, and/or the Food and Drug Administration will be granted direct access to your medical records to conduct and/or oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential in any publication.

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

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information

The following entities may receive your health information:

- Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other MedStar Health research centers and MedStar Health contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The Palliative Care Research Cooperative Group (PCRC) that is funding this study will use or share your protected health information (PHI) in compliance with the PCRC Data Sharing Policy.

Consistent with the PCRC Data Sharing Policy, de-identified quantitative data from this study will be transferred and stored on a server maintained by the PCRC at the University of Colorado (U of CO), which are maintained and monitored by U of CO's Office of Information Technology (OIT) Department to comply with good data storage and security practices. **De-identified means that your name and any other personal information that people could use to learn your identity will be removed before we place the data in the repository.**

All de-identified data that are collected and entered will remain in the PCRC Data Repositories indefinitely. This de-identified information could be used for future research studies or distributed to other investigators for future research studies without obtaining additional informed consent from you or your legally authorized representative. All future data analysis will be performed on de-identified data in the PCRC Data Repositories. When information and data resulting from this study is presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Quantitative data will be presented in aggregate reports and only anonymous excerpts from qualitative data will be used.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire December 31, 2023. After the expiration date, MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless MedStar Health obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Hunter Groninger MD
Institution: MedStar Washington Hospital Center
Department: Palliative Care, Department of Medicine
Address: 110 Irving St. NW, Room 2A68, Washington, DC 20010

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

What else do I need to know?

If you agree to take part in this research study, we will pay you $50.00 for your time and effort at completion of your part in the study. You may keep the VR headset for ongoing personal use at no charge at the end of the study. We will give you directions on how to reset the headset to factory settings if you would like to remove the account created by the research team for the purpose of this study and link the headset to a personal Facebook/Meta account for future use. If you wish to return the device at the end of the study, the study coordinator will pick up the device at your next scheduled appointment at MedStar Washington Hospital Center. If returning the device in person is inconvenient or not possible, we will mail you a pre-paid shipping label to return the device by mail.

Instead of being in this research study, your choices may include: not to participate in this research study. The important risks and possible benefits of these alternatives include: you will continue to receive your usual medical care.

Your information and related research data (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date