Virtual Reality for Improving Pain and Distress in Patients With Advanced Stage Colorectal Cancer

NCT04069702

Version date: 07/30/2021

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

CONCISE SUMMARY
This study is being done to test the feasibility, acceptability, safety, and impact of exposing patients to a single 30-minute virtual reality underwater/sea environment (called VR Blue) for reducing pain and pain-related symptoms in patients with advanced stage colorectal cancer. All participants will be patients with stage IV colorectal cancer. The purpose of this VR Blue intervention is to reduce pain and pain-related symptoms such as tension and distress, and enhance patients' abilities to cope with pain. We also want to better understand patients' experiences, preferences, thoughts, and feelings about the virtual reality experience to optimize VR Blue for future study.

The greatest risks of this study include the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have a diagnosis of colorectal cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

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 Sarah A. Kelleher, PhD from Duke University Medical Center. Duke University is funding this study.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Sarah Kelleher will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
Virtual Reality has the potential to improve pain and pain-related symptoms in individuals suffering from persistent pain. We want to understand the feasibility, acceptability, safety, and impact of a virtual reality protocol in patients with advanced colorectal cancer. Thus, the purpose of this study is to gather

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

initial data on advanced colorectal cancer patients' immediate response to the exposure of a single virtual reality session. We will collect data on the impact of VR Blue on pain, tension and distress. We will also collect qualitative data to better understand patients' experiences, preferences, thoughts, and feelings about the virtual reality experience to optimize VR Blue for future study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 20 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will complete 1 study appointment lasting approximately 2 hours. This study visit will involve a virtual reality session and 3 brief questionnaires using a tablet (iPad) or paper/pencil. Your virtual reality session involves exposure to a single 30-minute virtual underwater/sea environment (VR Blue). VR Blue is an immersive computer-generated environment featuring calming scenic graphics and relaxing nature music. A member of the study team will familiarize you with the virtual reality glasses and screen, and guide you through a demonstration of the virtual reality environment. You will be oriented to the virtual reality's video and auditory stimuli with an emphasis on becoming relaxed and fully immersed in the virtual environment. Following this orientation, you will complete the 30-minute VR Blue exposure. The 3 questionnaires will be given at the beginning of the study appointment prior to starting VR Blue (<25 minutes), at the midpoint during VR Blue (<5 minutes), and immediately following VR Blue (<25 minutes). The questions will ask about your symptoms (pain, tension, distress) and how you think and feel about your symptom and cancer experience as well as your reaction to your experience with VR Blue.

You will continue to receive usual medical care and will not be asked to change or decline any strategies for pain management.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study one day for approximately 2 hours for the study appointment. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
The risks associated with this study are minimal and rare. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Discussing your thoughts, feelings, and/or experience with pain may be upsetting. You have the option of not discussing concerns you find upsetting. You also have the option to discontinue participation at any time.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

During the study appointment, you will be asked to complete a 30-minute virtual reality session. There are some risks associated with virtual reality. During the VR Blue session, there is the potential for "cybersickness," a type of motion sickness involving feelings of dizziness, headache, nausea, eyestrain, sweating, postural disequilibrium and/or vertigo. Anticipated risks associated with cybersickness are comparable to typical "everyday" use of computers. If you begin to feel any effect of this type, you may immediately stop the virtual reality session. You will be asked to report these symptoms and will have the option of discontinuing participation if these symptoms are problematic.

The study investigators and the study team will take all precautions possible to avoid and minimize these risks. Should any of these occur, appropriate emergency care (e.g., 911) will be provided.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct benefits to you. You may find that your participation in the study intervention enhances your ability to cope with pain and pain-related distress. Further, you may experience decreases in the severity of your symptoms. We also hope the information learned from this study will benefit other patients with cancer.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke Human Subjects Research Compliance, Duke University Health System Institutional Review Board, and Duke Cancer Institute. If any of these groups review your research record, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

As part of this study, Dr. Kelleher and her study team will ask you to complete assessments. The assessments are done solely for this research study and are not part of your regular care. Assessment results will not be included in your medical record.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

The Palliative Care Research Cooperative Group (PCRC) will use or share your protected health information (PHI) in compliance with the PCRC Data Sharing Policy. Consistent with the PCRC Data Sharing Policy, the data from this study also will be transferred and stored on a server maintained by the PCRC at the University of Colorado (U of CO). U of CO's Office of Information Technology (OIT) Department provides University employees with centralized file sharing services. Centralized file servers are Windows-based virtual systems hosted in OIT's vmware server environment. These servers are proactively monitored by the automated monitoring system, patched on a monthly basis with latest security patches and updates, and backed up nightly by OIT's Enterprise backup solution, consistent with good data storage practices. The study records will be retained in your research record for at least 10 years after the study is completed. Any research information already included in your medical records will be kept indefinitely. Any de-identified data that are collected and entered will remain in the PCRC Data Repository 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 Repository. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. Data will be presented in aggregate reports without patient-level identifiers.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
Participants will receive a total of $40 for completing the study appointment.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center or your local community hospital emergency room in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Kelleher at (919) 416-3405 during regular business hours or by page at 703-946-9130.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study

Pilot Testing a Virtual Reality Protocol for Improving Pain and Pain-Related Distress in Patients with Advanced Stage Colorectal Cancer

decide to withdraw, we ask that you contact Dr. Kelleher in writing and let her know that you are withdrawing from the study. Her mailing address is Sarah Kelleher, PhD, 2200 W. Main St., Ste. 340, Durham, NC 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kelleher at 919-416-3405 during regular business hours and 703-946-9130 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at 919-668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time