Tandem VR: Synchronized Nature-Based Experiences in Virtual Reality for Hospice Patients and their Caregivers

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Tandem VR: Synchronized Nature-Based Experiences in Virtual Reality for Hospice Patients and their Caregivers

Study to be Conducted at: ***Prisma Health Hospice of the Foothills***

390 Keowee School Road

Seneca, SC 29672

Sponsor Name: *Prisma Health and Clemson University*

Principal Investigator: *Dr. J. Keais Pope and Dr. Jason R. Thrift*

KEY INFORMATION

Potential participants 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 the participants so the participants may decide whether or not to participate in this research study. Please ask the study doctor to explain anything the participant does not understand.

Our study will use an approach where participants will be asked to wear a virtual reality (VR) head-mounted display (HMD) presenting personalized, immersive, nature-based VR to both patients and their caregivers in an intervention known as Tandem VR. Patients and their caregivers recruited from the Prisma Health Hospice of the Foothills will be assigned to the intervention. The patients and caregivers will participate in the Tandem VR of their choosing provided by the team in the patient's home. Surveys will be collected before and after this experience and the answers to the questions will be analyzed to see if the experience had any impact on the patient and caregiver.

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

PURPOSE

The purpose of this study is to identify the impacts of personalized nature-based Tandem VR experiences of patients enrolled with hospice services and their caregivers.

Patients in hospice services may have reduced ability to travel and visit locations they have visited before or hoped to visit for the first time. Caregivers working with patients in hospice services often are unable to engage in such activities as well due to the care needed for their loved ones. Due to an inability to do these meaningful experiences, a patient's functional status may be negatively impacted, affecting their quality of life. When the patient's quality of life diminishes, the burden falls on the caregiver, also leading to further isolation, and loneliness for both parties involved. The psychological distress of the patient and caregiver is interconnected, highlighting their responsiveness to distressful situations. While caregivers survive beyond the patient, reducing their physical and psychological impact offers long-term benefits in their well-being and bereavement process.

Being outdoors in natural environments can activate regions of the brain associated with relaxation. Evidence suggests that nature-based VR experiences can have similar effects, thereby reducing the symptoms both physically and psychologically. Nature-based VR experiences in HMDs offer a powerful tool for hospice teams to help patients and their caregivers.

The use of simultaneous personalized nature-based VR, or Tandem VR, experiences may provide the needed strategy for the well-being of patients and their caregivers by allowing them to engage in meaningful experiences simultaneously. Events such as family gatherings for picnics or hiking in familiar outdoors spaces often hold valuable memories. The images, videos, and sounds can be personalized in nature-based VR experiences for use by the patient and caregiver. In Tandem VR, the patient and caregiver can see memorable nature experiences concurrently. They can interact during the experience to recall precious moments or joyful times. Providing stimuli of sights and sounds, panoramic views, and allowing interaction are key components that can reduce burdensome symptoms.

Participation will last for 1 intervention in Tandem VR.

HOW THE STUDY WORKS

The study will investigate how Tandem VR assists with reducing symptoms associated with pain, fear associated with fear of death, and quality of life for individuals enrolled in hospice care in the home setting. The study will also see how Tandem VR assists informal caregivers with psychological distress associated with caring for an individual in hospice care. The Tandem VR intervention will be an addition to current treatment therapies the patient is prescribed and will not replace any current home care needs. The patient will continue receiving all previous medications and therapies before, during, and after participation in the study.

Tandem VR uses synchronized virtual nature images and videos to provide a patient and their informal caregiver with an experience with a setting the individuals have never been to or are not capable of attending. This intervention is not FDA approved, nor is it undergoing any trials. The intervention is a complementary therapy to currently prescribed treatments.

Participants will be screened to determine if they meet criteria to participate. They will be consented into the study and complete the intake form. Once enrolled, participants wills be asked to complete three questionnaires prior to engaging in the tandem VR experience with their caregiver. Afterward, they will be asked to complete the same three questionnaires as before the Tandem VR experience.

Patients and caregivers will also be given the opportunity to participate in an interview regarding the experience. Following the Tandem VR experience, each participant will have the opportunity, if they choose to, to participate in the Patient Advisory Council (PAC). The PAC will meet with the research team to discuss the overall experience the patient and caregiver had in Tandem VR.

Clemson University will be the only collaborator during this study, with research team members assisting with data collection and analysis throughout the study. All data associated with the Clemson personnel will be de-identified allowing for team members to discuss the findings of the intervention.

POSSIBLE RISKS

There are no known medical risks related to participation in this study. The greatest risk is the possible release of participant's personal health information. Participant's study records are confidential, but absolute

confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure participants are not identified by name.

Some of the questions in the questionnaires are personal and may be upsetting to some participants. The study doctor or staff will be available to discuss these questions should participants have a concern or problem. Participants do not have to answer any questions that participants do not want to answer. Should any aspect of the experience be distressing or feel negative in any way, participants can stop participation immediately.

Due to the movement within a VR environment, unintended affects may occur. A concern known as cybersickness can happen from a sense of movement while standing, sitting, or lying still. The effects can be dizziness, lightheadedness, or even disorientation. Nausea and vomiting have occurred at times. Should the patient or caregiver experience any symptoms of cybersickness from being within the VR environment, they need to report these sensations immediately. Once reported, the Tandem VR experience will be ceased.

POSSIBLE BENEFITS
It is not possible to know whether participants may benefit from participating in this study. The treatment or procedures participants 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 participant. The alternative to participating in this study is simply not to participate. If the participant decide not to participate in the study, the participant will not be penalized in any way.

NEW INFORMATION
The participant's doctor will tell the participant about new information that may affect the participant's willingness to participate in this research study. Alternatives, or other choices, concerning the participant's care will be discussed at that time.

There are no plans to share individual research results with the participant.

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

PAYMENT FOR PARTICIPATION
To Participant:
Participation in the study will provide the participant and their caregiver with a $10 gift card each (total value $20) as thanks for working within the study.

Participation in the study will also allow participants to be on the Patient Advisory Council (PAC) where participants and their caregiver can assist the researchers with participant's perspective on the experience in Tandem VR. The payment participant and caregiver dyad will receive is $50 per person. This is strictly voluntary and no obligation to participate in the PAC.

To Institution:
Prisma Health Hospice of Foothills Care 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 will provide participants with 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, or the investigators as part of this study have no plans to pay participants or give participants other compensation for an injury, should one occur. However, participants are not giving up any of participants legal rights by signing this form.

If participants think participants 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 researchers' names and phone numbers 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. Participants may refuse to participate or withdraw from the study at any time. If participants refuse to participate or withdraw from the study, participants will not be penalized or lose any benefits and participants decision will not affect participants relationship with participants 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 participant's 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 participant's medical records that is related to the research study. The study doctor and his/her research team will use and disclose (release) participants health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure participants are not identified.

Some of the organizations/entities that may receive participants 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.
- Participating investigators at Clemson University.

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

The right to use participants health information for research purposes does not expire unless participants withdraw their agreement. Participants have the right to withdraw their agreement at any time. Participants can do this by giving written notice to the study doctor. If participants withdraw their agreement, they 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. Participants have the right to review participants health information that is created during participants participation in this study. After the study is completed, participants may request this information.

If participants have any questions about the privacy of participants 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, participants may contact the principal investigator, whose information is included below.

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

Principal Investigator Name: J. Keais Pope and Jason R. Thrift
Telephone Number: Dr. Pope (864-455-3987)
Dr. Thrift (864-940-8536)

CONSENT TO PARTICIPATE

The study researcher, _____, 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

_____	_____	_____
Signature of Investigator	Date	Time

Principal Investigator		Phone
	J. Keais Pope, MD	(864) 455-3987
	Jason R. Thrift, PhD, RN, CHSE	(864) 940-8536
Co-Investigators		Phone
	Matthew Browning, PhD	(540) 315-7095
	Tracy Fasolino, Ph.D., FNP-BC, ACHPN	(864) 888-7158
	Olivia McAnirlin, PhD	(207) 249-5170