PRISMA HEALTH

Tandem VR: Synchronized Nature-Based Experiences in Virtual Reality for Hospice Patients and their Caregivers NCT Number: NCT06186960 Unique ID: 2079177-3 Date: 5/21/2024 Study Protocol with Amendments	
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Study Location(s)	**Prisma Health-Hospice of the Foothills**

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I. ABSTRACT

The aims of this study are to identify the impacts of personalized nature-based Tandem VR experiences on the quality of life, pain, and fear of death in patient-caregiver dyads enrolled with **hospice services** and determine the acceptance of a personalized nature-based Tandem VR experience by hospice teams as a non-pharmacological modality for addressing needs of dyads. Our study will use a synchronized Tandem VR approach where patient-caregiver dyads wear a head-mounted display presenting immersive nature-based content. This **mixed methods study** will recruit **20+ patient-caregiver dyads** from **Prisma Health Hospice of the Foothills** enrolled in home hospice services nearing the end of life. Self-reported outcomes will be collected before and after the 5–15-minute intervention. Our objectives are to assess the effectiveness of Tandem VR on patient reported outcomes including quality of life, pain, and fear of death, and acceptance of the Tandem VR intervention in the home setting. If successful, this study will introduce a treatment incorporating patient-caregiver dyads to help reduce symptomatology and improve quality of life.

II. INTRODUCTION

A. BACKGROUND

Nature-based virtual reality (VR) experiences in head-mounted displays (HMDs) offer powerful, non-pharmacological tools for hospice teams to help patients undergoing end-of-life (EOL) transitions.[1] Being outdoors in natural environments can activate the parasympathetic nervous system and brain regions associated with physiological relaxation.[2] Evidence suggests that nature-based VR experiences can have similar effects[3], thereby reducing the symptom burden in physical and psychological domains.[4,5] These symptoms negatively impact functional status, leading to isolation, loneliness, and poor quality of life (QOL).[6,7] In a recent study by McAnirlin, Browning, Fasolino… Thrift & Pope (under review), patients with end-stage Chronic Obstructive Pulmonary Disease (COPD) showed improvements in shortness of breath and comfort during a personalized nature-based VR experience.[8]

Implementing nature-based VR allows patients to feel present as if they were genuinely standing in outdoor environments without the challenges of leaving their homes.[9] Personalizing these VR experiences allows patients to revisit familiar and non-threatening spaces where memorable experiences occurred.[10,11] Implementing such a personalized, technologically-advanced intervention among patients enrolled in hospice is expected to significantly mitigate stressors associated with serious illness and EOL events by bringing joy and closure at the end of their lives.[12]

Patients are not the only individuals in the hospice setting who can benefit from nature-based VR experiences. Informal caregivers, such as a spouse, partner, or friend, play crucial roles in hospice patients' physical, emotional, and practical care. On average, these caregivers deliver an estimated 66 hours per week of care and are intimately involved in the EOL phases.[13] Providing this amount of care requires significant physical and emotional sacrifices. Caregivers' own health often deteriorates as the burden and strain of caregiving increases.[14] The psychological distress of the patient-caregiver dyad is interconnected and highlights the interdependence and responsiveness to distress as a unit.[15] While caregivers survive beyond the patient, reducing their physical and psychological impact offers long-term benefits in their well-being and bereavement process.[16] What is currently missing from hospice care services and this public health issue is a strategy to help reduce burnout and the impact of caregiving on informal caregivers. Therefore, the use of simultaneous personalized nature-based VR, or Tandem VR, experiences may provide the needed strategy for the well-being of the dyad by allowing them to engage in meaningful experiences simultaneously.

Dyads have missed opportunities to engage in meaningful experiences, given the progressive nature of serious illnesses. Events such as family gathering 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 each dyad. In Tandem VR, the dyad experiences 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 with high resolution, and allowing interaction are key components in distraction techniques that can reduce the symptom burden during EOL phases. Evidence supports the use of distraction techniques through VR experiences, with one

study reporting a 30-50% reduction in pain scores.[16] The uptake of Tandem VR by hospice teams offers a person-centered strategy for the patient's wellbeing and the psychological needs of informal caregivers.

B. IMPORTANCE / JUSTIFICATION FOR STUDY

The primary objective of this study is to assess the impact of personalized nature-based Tandem VR experiences on QOL, pain, and fear of death in patient-caregiver dyads enrolled in hospice services.

Additionally, the study will determine the acceptance of personalized nature-based Tandem VR experiences by hospice teams as a non-pharmacological modality for addressing the needs of dyads.

Ongoing and statistically significant research show that VR experiences, interventions, and meditations can significantly lower patients' physical pain, anxiety, and depression levels and reduce medication use. Using personalized, nature-based VR experiences, the patient-caregiver dyads can simultaneously engage in an immersive encounter to help alleviate symptoms associated with declining health and EOL phases. Preliminary data on using Tandem VR for patients with serious illnesses demonstrate a positive impact by reducing pain and anxiety while allowing the dyad to reconnect in a peaceful, nature-based environment (McAnirlin et al., under review). A growing body of evidence on the value of VR for patients with serious illnesses supports this innovative approach and positions the proposed research at the forefront of scientific and clinical transformative care. Our team is committed to investigating this therapeutic modality for patients and their caregivers by providing an experience that is comforting, peaceful, and practical in its implementation. The study further extends the need for person- and caregiver-centered, non-pharmacological interventions to reduce physical, psychological, and spiritual distress. Inspired by Prisma Health's mission to transform the healthcare experiences for patients and families, the Tandem VR intervention helps patients and their caregivers dealing with EOL concerns. Our team is committed to inspiring a new treatment modality, providing patients with an experience that is inspiring, respectful, and practical in its implementation. The project extends the need for person-centered outcome measures of symptom burden, an area in which additional research is needed.

III. HYPOTHESIS & OBJECTIVES

A. HYPOTHESIS

Patients transitioning to EOL have declining functional status, limiting their participation in meaningful moments and experiences. The loss of physical strength and increasingly burdensome symptoms prevent them and their caregivers from engaging in personal and profound "Bucket List" items, such as outdoor excursions. Many of these individuals require significant help from a spouse, family member, friend, or neighbor with activities of daily living (ADLs), medication management, and other household needs. These informal, unpaid caregivers often experience stressors in the role and develop physical and mental health issues (Adashek & Subbiah, 2020).

Informal, unpaid caregivers (CGs) are defined as a relative, possibly a spouse or partner, friend or neighbor, who supports the broad range of needs of the patient (Jacops et al., 2022). The care may often include financial and legal support (Li et al., 2018). Nearly 66 million Americans serve as CGs (National Alliance for Caregiving & American Association of Retired Persons, 2015).

Providing the necessary care creates financial issues and social isolation (Faronbi, Faronbi, Ayamolowo, & Olaogun, 2019). With CGs being the primary source of care, the annual estimated loss of income is $522 million, and replacing these with unskilled paid care at minimum wage would cost $221 billion a year (Chari, Engberg, Ray, & Mehrotra, 2015). As a dyad, they may be bound to the home for extended periods without reprieve from outside sources. As social isolation continues, physical and psychological issues become exacerbated (Donovan & Blazer, 2020).

VR is a cutting-edge technology increasingly used by palliative care and hospice organizations worldwide to help bring meaning, joy, healing, and closure to many patients at the end of their lives (Carmont & McIlfatrick, 2022). This technology includes a VR headset that patients wear over their eyes, providing a complete, 360-degree, immersive virtual experience. An example of the benefit of this technology is a patient who has dreamed of visiting another country but cannot leave their bed due to sickness, frailty, and weakness. An immersive VR experience brings distance

areas to the patient at the bedside and helps them complete unreachable locations while providing existential closure.

The experience can also be shared through Tandem VR. In this environment, not only does the patient get to visit another place where they have never been, the caregiver can go with them. The dyad is joined via two headsets controlled by a central laptop or tablet device to project the same videos and imagery into the experience simultaneously. The dyad can communicate openly to each other, especially their emotions from the interaction. Personalizing the experience for the dyad also helps them to see a place that feels authentic to them, allowing them to feel a part of the environment without having to navigate the challenges of travel. The novel concept of Tandem VR provides a strategy to develop person-centered care simultaneously with the caregiver to relive or create meaningful experiences.

We propose an innovative, mixed-methods study to test the impact and acceptance of Tandem VR in the hospice home setting. This study seeks to: (1) Identify the impacts of personalized nature-based Tandem VR experiences on the QOL, pain, and fear of death in patient-caregiver dyads enrolled with hospice services. (2) Determine the acceptance of personalized nature-based Tandem VR experiences by hospice teams as a non-pharmacological modality for addressing the needs of dyads. This study will recruit 20+ patient-caregiver dyads from Prisma Health Hospice of the Foothills, who be receiving the Tandem VR intervention from Research Recruiters implementing the treatment modality. The Research Recruiters, Prisma Health social workers and Tandem VR research team members, will screen, determine eligibility with the research team, implement, and evaluate the use of the Tandem VR intervention with patient-caregiver dyads. The study will collect patient-caregiver reported outcomes including quality of life, pain, and fear of death. The investigators will also measure acceptability and impact of exposure to Tandem VR. The investigators will also collect qualitative data following participants' Tandem VR experience to better understand patient and caregiver preferences, thoughts, and feelings about the intervention. Outcomes will be measure before and after the intervention. We expect that this study will demonstrate Tandem VR

is an effective non-pharmacologic treatment for improving QOL at EOL and will be acceptable and safely deployed in the home settings.

Since the treatment is administered via technology at home, barriers associated with a clinical environment (such as noise, time, patient accessibility) are not impediments to the treatment. This consistency of treatment combined with the use of validated symptoms assessment scales will provide our study with excellent methodological quality. If successful, this data will be used to optimize Tandem VR and enable us to apply for external funding involving a larger population of hospice patients. The results will also inform best practices for the implementation of Tandem VR for patient-caregiver dyads in hospice care.

B. OBJECTIVES

The primary aim of this study is to measure the impact on QOL using Tandem VR with patient-caregiver dyads transitioning to EOL. Our study will utilize an approach where participants will be asked to wear a VR HMD presenting Tandem VR content in a home setting. In addition to measuring the improvement in QOL, this study seeks to assess the efficacy of Tandem VR on patient-caregiver reported outcomes including pain and fear of death and assess the acceptability and safe use of Tandem VR in a home setting. The study will recruit 20+ patients from Prisma Health Hospice of the Foothills, who will be enrolled for treatment with Tandem VR. Research Recruiters will assist eligible patient-caregiver dyads in using the Tandem VR intervention in the comfort of their own home. The objective is to gather data on patients transitioning to EOL after being exposed to Tandem VR. The study will collect patient-caregiver reported outcomes including QOL, pain, and fear of death. The investigators will also assess acceptability and safety of Tandem VR at home. The investigators will also collect qualitative data following participants' Tandem VR experience to better understand the dyads' preferences, thoughts, and feelings about the intervention. Qualitative data will be garnered through audio recording in Otter, direct observation, and an interview. Outcomes will be measured before, and after the intervention. We expect that this study will demonstrate Tandem VR is an effective

non-pharmacologic treatment for improving QOL at EOL in patient-caregiver dyads; moreover, we expect Tandem VR will be acceptable and safely deployed in home settings.

IV. DESIGN & METHODS

A. STUDY DESIGN

Mixed-methods interventional study design: The study will recruit 20+ patient-caregiver dyads from Prisma Health Hospice of the Foothills enrolled in home care or at the hospice house. Once recruited, the dyads will be screened using the inclusion and exclusion criterion to ensure study eligibility. Dyads will also be offered the opportunity to participate in the Patient Advisory Council (PAC) to add further details on the experience in Tandem VR.

B. SETTING

Prisma Health Hospice of the Foothills will be the organization utilized for recruitment and data collection. This organization offers several hospice and bereavement services to Oconee, Pickens, Greenville, and Anderson County residents. Hospice of the Foothill's goal is to provide the highest quality of life as long as possible for patients dealing with life-limiting illnesses and support the family as the primary provider of care.

1. Resources Available

The study will recruit 20+ patient-caregiver dyads from Prisma Health Hospice of the Foothills enrolled in home care or admitted at Prisma's Hospice house facility, The Cottingham House. The dyads will use the PICO Neo 3 head mounted-display (HMD) with synchronized software via laptop for tandem interaction. Research recruiters will assist in the recruitment of participants for the study and implementing the Tandem VR intervention. The following script will be used for recruitment in emails or by word of mouth:

I would like to invite you to participate in a research intervention viewing synchronized nature-based scenes in a virtual reality environment known as Tandem VR. This experience will be valuable to healthcare teams as a complementary therapy for hospice patients and their caregivers. We would like to have you and your caregiver

participate in the study as part of a home visit. We anticipate the intervention and interview would take approximately 60 minutes. As a participant in the study, you and your caregiver will receive a $10 electronic gift card, and you will also be eligible to participate in the Patient Advisory Council (PAC) to share your experience in Tandem VR with the research team. For any questions please contact Dr. Keais Pope or Dr. Jason R. Thrift, through email or cell phone: joshua.pope@prismahealth.org and 978.270.6955, or jasont@clemson.edu and 864.940.8536.

Investigators

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J. Keais Pope, MD

Dr. Pope is an Assistant Medical Director and attending physician for Hospice of the Foothills in Greenville, SC, with Hospice and Palliative Care experience. His primary clinical role is overseeing, managing, and treating patients to help them maintain symptom control and dignity, comfort, and peace during the dying process. He has been involved in investigative studies with team members of the VRN Lab, helping to develop the Tandem VR intervention. Dr. Pope is the Co-Principal Investigator (Co-PI) in this study and will provide management of the clinical aspects of the study.

Jason R. Thrift, Ph.D., RN, CHSE

Dr. Thrift is an Assistant Professor at the Clemson University School of Nursing with nine years of experience. His current research interests include virtual reality for patient treatment modalities and virtual reality simulation for

student nurse education. He is a Certified Healthcare Simulation Educator (CHSE), having conducted and developed simulated experiences for educational purposes. He is an affiliate member of the Clemson University Virtual Reality and Nature (VRN) Lab in the Parks, Recreation and Tourism Management department, working with this team to investigate VR technologies for patient care initiatives. Dr. Thrift is the Co-Principal Investigator for the study and will serve as the research expert for the study.

Matthew Browning, Ph.D.

Dr. Browning is an Associate Professor, Parks, Recreation and Tourism Management Clemson University, Founding Director of the VRN Lab and Research Innovation Suite (RIS) Operations. His research encompasses three domains (nature, health, and virtual reality) and their intersections. As director of the VRN Lab, the two foci are (1) conducting basic and applied research on the therapeutic effects of simulated natural environments on human health, well-being, and community resilience; and (2) enhancing the frequency, richness, and meaningfulness of nature-based connections and interactions. Dr. Browning will provide overall management of the VR intervention development.

Tracy Fasolino, Ph.D., FNP-BC, ACHPN

Dr. Fasolino is a Professor at the Clemson University School of Nursing and a Distinguished Palliative Care Leader. She strives to advance nursing research and evidence-based practice within the Upstate through health system partnerships and academic settings. Her area of research is symptom management for patients with chronic, non-cancer illnesses, focusing on pulmonary conditions. She has published numerous articles and has been funded in palliative care. She will serve as a research and clinical expert when working with patients and caregivers dealing with serious illnesses.

Olivia McAnirlin, Ph.D.

Dr. McAnirlin is the founding Manager of the VRN Lab and Coordinator for RIS Operations while being a Ph.D. candidate pursuing a degree in Parks, Recreation, and Tourism Management. Her research interests include studying the psychological and physiological impacts of nature and virtual reality and using virtual reality as a form of storytelling. Dr. McAnirlin will provide overall management of personalizing and deploying the VR interventions with dyads.

Micayla McMahon

Micayla McMahon is a second-year medical student at the University of South Carolina School of Medicine Greenville, South Carolina. Her primary role is a research assistant in addition to completing pre-clinical years of medical education. She has been involved in investigative studies by collaborating with members of the VRN lab to become proficient in troubleshooting VR technology and uploading content to VR headsets. Research assistant duties include educating the team on how to upload VR experiences, data collection on dyad visits, and updating content to align with the dyad's requested bucket list experiences.

Fu Li

Mr. Li is currently pursuing his Ph.D. in Parks, Recreation, Tourism Management at Clemson University, and he is an active member of the VRN. His research centers on the convergence of extended reality (XR) technology with healthcare, park, and urban design. His primary focus is on synchronizing XR experiences with physiological, psychological, and behavioral data to understand human interactions with environments. Mr. Li will be a key contributor to the development of software for the Tandem VR experience.

Griffin Thomas

Mr. Thomas currently is an undergraduate student in the Pre-Med program at Clemson University. The primary responsibilities of the undergraduate research assistants are to assist with data collection, assist with team meetings, prep manuscripts, coordinator with dyads and research personnel for implementation, manage incentive distributions, assist with PAC meetings, monitor headset cleaning practices, troubleshoot VR issues, and gain experience working with ID research teams.

Eleanor Farrell

Ms. Farrell currently is an undergraduate student in the School of Nursing at Clemson University. The primary responsibilities of the undergraduate research assistants are to assist with data collection, assist with team meetings, prep manuscripts, coordinator with dyads and research personnel for implementation, manage incentive distributions, assist with PAC meetings, monitor headset cleaning practices, troubleshoot VR issues, and gain experience working with ID research teams.

The study will require purchasing a tablet device to set up the synchronized tandem experience within Tandem VR, connecting to the PICO Neo 3 HMDs. We have allocated $2000 to fund purchasing of a tablet device with Network Attached Storage (NAS) allowing dyads to view the synchronized tandem experience through the Prisma Health Seed Grant. We have allotted $850 for the NVIVO qualitative software and Otter software for qualitative transcription. Approximately $400 has been allotted to fund four lunches for Research Recruiters for assisting with the recruitment of dyads, training on the intervention, and implementation of the Tandem VR intervention for the study. Funding of $520 has been allotted to provide $20 to the patient-caregiver dyads ($10 gift cards for each) for participation in the study. Approximately $1200 has been allotted for the Patient Advisory Council to meet with researchers to discuss the experience within Tandem VR ($50 to each member of the patient dyad participating).

C. PROPOSED INTERVENTION

1. Treatment

The Tandem VR intervention will include immersive, 360-degree audio-visual experiences of available Upstate SC

nature scenes using Pico Neo 3 HMDs (Figure 1).

These experiences will be personalized to each dyad using a novel software system developed during this project. The system contains seamless, pre-loaded, and customized, virtual reality experiences of the patient's choosing as the patient elected earlier on their VR intake form during consent. VR experiences from around the world and an estimated 50+ nature-based locations in the Upstate will be available to patients and caregivers to choose from. Dyads will indicate which locations elicit positive memorable experiences and in what order these locations should be presented, to create a cohesive storyline. The software is expected to then form a single video file that will transfer to each HMD via the cloud for playback during the Tandem VR experience. These individual videos will range from 5 to 15 minutes and include well-known forested areas, rivers, ponds, and parks. Personalized audio is expected to be available for each location as well and include a large selection of mix-and-made restorative nature sounds such as water flowing, wind, and bird songs.[17] Dyads will engage with the intervention at least one time through the assistance of training hospice team members.

2. Devices

Pico Neo 3 is an all-in-one VR system but will be used in tandem with a tablet device to allow for synchronized viewing by patient-caregiver dyads through the HMDs. iPad device with Network Attached Storage (NAS) to connect HMDs in the synchronized experience. The Tandem VR nature-based content will be developed for this study.

D. POPULATION

Prisma Health Hospice of the Foothills patients with projected life expectancy of <6 months (established by hospice experts) and their informal caregivers. Study will be conducted in the home setting.

1. Inclusion Criteria

- Ability to speaking English
- Participants, patients and caregivers, must be at least 18 years old or older.
- Projected life expectancy of <6 months (established by Prisma Hospice Medical Directors and hospice staff)
- Cognitively intact (has sufficient judgment, planning, organization, self-control)

2. Exclusion Criteria

- Have cognitive impairment that affects protocol participation. This will be done with the assistance of Research Recruiters (social workers, other hospice personnel recruited for the study, and the research team members such as the Research Assistants, PIs and Co-Is) to assess eligibility.
- Have a condition that interferes with VR usage, including but not limited to seizures, facial injury precluding safe placement of headset.
- Have a prognosis of hours or actively dying at the time enrollment.
- Patients with motion sickness
- Patients with claustrophobia
- Patients with visual and hearing impairment
- Patients with inability to speak English.

3. Sample Size

n/a

4. Local Number of Participants

The study will recruit 20+ patient and caregiver dyads from Prisma Health Hospice of the Foothills

5. Study-Wide Number of Participants

This is a multi-site study, and we expect to recruit a total of 20+ patient-caregiver dyads from Prisma Health Hospice of the Foothills across the upstate of South Carolina through hospice and bereavement services in Oconee, Pickens, Greenville, and Anderson counties.

6. Recruitment Methods

Prisma Health Institutional Review Board approvals will be obtained for the study.

Participants will be primarily recruited using flyers and word-of-mouth. Research Recruiters (n=10) will be CITI trained, affiliated with, and working alongside with Prisma Health Hospice of the Foothills staff. Recruiters will assist with consenting dyads, launching the intervention, data collection, and offering expert insights on the use of the intervention as a non-pharmacological modality. Ongoing dialogue between the social workers and the research team will allow for continuous improvement in the intervention delivery and offer data on the acceptance of the intervention for hospice patients and caregivers. All information will be explained in a nontechnical fashion and ample time will be available for the participants to ask any questions. This study will recruit a total of 20+ patient-caregiver dyads who will then be screened using the inclusion and exclusion criterion to ensure participant eligibility.

Flyers about the study, word-of-mouth from Research Recruiters.

E. SPECIFICS OF STUDY PROCEDURES

Screening and Pre-intervention

- Enrolled participants will be consented to per approved Prisma Health consent.
- Consented participants will be screened by the research assistant to ensure eligibility of participants, based on inclusion/ exclusion criterion and will complete the Tandem VR Intake form.
- Eligible participants will meet with the Research Recruiters and baseline data will be collected including demographics. Also, participants will complete Wisconsin Brief Pain Questionnaire (WBPQ), Collett-Lester Fear of Death (FOD) scale, and McGill Quality of Life (QOL) scale directly before and after the intervention.
- Research recruiters will meet with participants in the home setting to assist dyads and implement the Tandem VR intervention.
- Upon completion of the intervention, Research Recruiters will collect the Tandem VR equipment and readminister the WBPQ, FOD, QOL instruments, and semi-structured interviews.
- Consent from dyads will have been obtained by the Research Recruiters to participate in the Patient Advisory Council (PAC) to work with the researchers on understanding the experience.

Intervention

All procedures completed below will be done on one home visit.

The Tandem VR intervention will be carried out in the patient-caregiver dyad's home setting with the Research Recruiters implementing the experience. Each member of the dyad will initially complete the McGill Quality of Life Questionnaire-E (MQOL-E), Wisconsin Brief Pain Questionnaire (BPQ), and Collet-Lester Fear of Death (FOD) Scale prior to beginning the Tandem VR experience through an electronic medium.

Following completion of the pre-intervention forms, the dyads will be assisted by the Research Recruiter to don the VR HMD. The Research Recruiter will ensure safety for both participants while using the devices. The Research Recruiter will then initiate the Tandem VR experience using the iPad device to synchronize the nature-based scene for viewing. The duration of the experience will be 5-15 minutes.

Upon completion of the Tandem VR intervention, the HMD devices will be removed from the dyad participants. They will then complete the three instruments of the MQOL-E, BPQ, and FOD. Following the completion of the post-intervention documents, the Research Recruiter will conduct the semi-structured interview with the participants. Each participant will be asked the following questions to reflect on their experience:

- Tell us about your experience in Tandem VR?
- What was it like being together in the Tandem VR experience?
- Was there anything about the Tandem VR experience that helped you?
- Was there anything about the Tandem VR experience you feel could be improved?
- Were there any unusual sensations such as dizziness, lightheadedness, or disorientation while you were in the Tandem VR experience? If so, please explain.

These procedures will be carried out with each dyad for a duration of 8-16 weeks to ensure enough participation in the study. Research Recruiters will also identify participant dyads that can participate in the PAC to discuss the experience with the primary research team.

At this point the study will be completed for the dyads.

The study will recruit 20+ patient-caregiver dyads from Prisma Health Hospice of the Foothills.
The participants will be enrolled in the study for 1 intervention with Tandem VR. Each dyad will receive $20 for participating in the study (a $10 gift card to the patient and $10 gift card to the caregiver).

Cleaning and Disinfection of VR -Head Mounted Display (VR- HMD)

As part of a clinical study, virtual reality headsets will need to be reused between patients. At the end of the intervention the VR- HMD will be disinfected. Infection control measures include:
· Hand hygiene will be performed prior to cleaning and disinfection of HMD.
· Headsets that are disinfected will be handled with clean hands to prevent contamination.
· Participants will be instructed to not use headsets if there is a break in their integrity or have visible soiling.

<u>Cleaning of HMD</u>:

Use manufacturer's approved (VRCOVER antibacterial wipes) wipes for removal of all visible bioburden from headset and controller for disinfection.

Disinfection of HMD:

Follow cleaning instructions using disinfection wipes.
The above cleaning protocol has been approved by Prisma Health Infection Prevention.

Participants will continue to follow-up as normal with their physicians at Prisma Health Hospice of the Foothills.

1. Study Timelines

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Table 1 Schedule of Assessments (Study Calendar)

Procedures	Pre-Intervention	Post-Intervention	PAC Meeting (Week 8)
Informed consent	X		
Inclusion/exclusion criteria	X		
Demographics	X		
Cognitive Assessment	X		
McGill Quality of Life Questionnaire-E (MQOL-E)	X	X	
Wisconsin Brief Pain Questionnaire (BPQ)	X	X	
Collett-Lester Fear of Death (FOD) Scale	X	X	
Semi-Structure Questions		X	
Dyads for PAC			X

Timeline of Study

*N_{total} ≥ 20 Patient-Caregiver Dyads

Inclusion Criteria:

- Ability to speaking English
- Projected life expectancy of <6 months (required Hospice eligibility per Centers for Medicare/Medicaid)
- Cognitively intact (has sufficient judgment, planning, organization, self-control)

Exclusion Criteria:

- Have cognitive impairment that affects protocol participation. This will be done with the assistance of Research Recruiters (social workers, other hospice personnel recruited for the study, and the research team, such as the Research Assistants, PIs, and Co-Is) to assess eligibility.
- Have a condition that interferes with VR usage, including but not limited to seizures, facial injury precluding safe placement of headset.

- Have a prognosis of >6 months from the time enrollment.
- Have a prognosis of hours or actively dying at the time enrollment.
- Patients with motion sickness
- Patients with claustrophobia
- Patients with visual and hearing impairment
- Patients with inability to speak English.

****All patients in the dyad will continue their current standard of symptom management throughout the study of 8-16 weeks****

2. Study Endpoints

For each dyad, the study will end after 1 use of the intervention. Dyads will be recruited to participate in the PAC extending time for a period of 8 weeks where they will meet with researchers to discuss the experience.

We anticipate the total duration of the study to be approximately 12 months following which all the compiled data will be analyzed and published.

3. Outcome Measures/Data

Primary outcomes

1. Well-being will be measured upon the patient's enrollment in the study and post-intervention with the McGill Quality of Life Questionnaire-E (MQOL-E).

This assesses eight important life domains: cognition, healthcare, environment, feeling like a burden, and their relationships with physical, psychological, social, and existential/spiritual domains. The 20-item questionnaire uses a 0-10 response scale and is used internationally by hospice teams to assess QOL.

2. Change in pain interference as assessed with the Wisconsin Brief Pain Questionnaire (BPQ) [Time Frame: Pre-Intervention(baseline), Post-intervention]

Pain will be assessed with the Brief Pain Inventory (BPI). Patients will rate their pain from 0=no pain to 10=worst pain imaginable in response to items such as "average pain," "worst pain" and "least pain" over the last 7 days and "pain right now". An average of the responses to these items is used to create a single pain severity score.

3. Change in perception of fear of death with the Collett-Lester Fear of Death Scale [Time Frame: Pre-Intervention(baseline), Post-intervention]

4. Open-ended questions will be asked to determine the perceived benefit and value of the Tandem VR post-intervention with patient-caregiver dyads.

Secondary Outcomes

Follow-up semi-structured interviews with the hospice team and Research Recruiters will provide valuable information about the likelihood of integrating this intervention as a treatment modality for future dyads.

4. Data Collection Methods and Instruments Used

In this study, demographic data will be collected from all the participants. Demographic data will include age, sex, and race which will be used for secondary data analysis. In addition, EPIC EMR chart review would be used to collect demographic data from all the participants. In addition, we will also collect the medical record number (MRN), type of diagnosis, and life expectancy. Patient reported outcomes (PROs) will be measured using standardized symptoms assessment tools per study protocol. Standardized symptom assessment tools used in this study will include:

- McGill Quality of Life Questionnaire-E (MQOL-E)
- Wisconsin Brief Pain Questionnaire (BPQ)
- Collett-Lester Fear of Death Scale
- Tandem VR Interview Guide
- Tandem VR Intake Form

- (McGill Quality of Life Questionnaire-E (MQOL-E)
  http://www.npcrc.org/files/news/mcgill_quality_of_life.pdf
  Appendix A

- Wisconsin Brief Pain Questionnaire (BPQ)
  Appendix B

- Collett-Lester Fear of Death Scale
  Appendix C

- Tandem VR Interview Guide
  Appendix D

- Tandem VR Intake Form
  Appendix E

All data will be stored in a HIPAA secure Box folder.

5. Data Management

Our study includes participant data collection with information obtained from the PHI within the EHR by the **Prisma Social Workers** (PSW) and/or the **Prisma Research Team Members** (PRT). These team members are employees of Prisma Health System. The following quantitative and qualitative data (for which we have participant consent to share in de-identified form) will be collected as part of the project and will be de-identified before sharing with the Clemson research team.

Data Elements

Demographics. Demographic data that will be collected by the PRR/PRT from the patient will include year of birth, gender, racial group, ethnicity, primary diagnosis for enrollment into hospice, length of time in hospice care services. The PRR/PRT will collect how long the informal caregiver has been serving in the role.

Qualitative Data. Qualitative field notes from dyad encounters with interventions and transcribed responses to semi-structured follow-up questions will be stored on the EXCEL spreadsheet provided.

- Tell us about your experience in Tandem VR?
- What was it like being together in the Tandem VR experience?
- Was there anything about the Tandem VR experience that helped you?
- Was there anything about the Tandem VR experience you feel could be improved?
- Were there any unusual sensations such as dizziness, lightheadedness, or disorientation while you were in the Tandem VR experience? If so, please explain.

Quantitative Data. Patient-level data retrieved from the EHR by the PRR/PRT will be de-identified before sharing with the Clemson team. We will collect pre- and post-assessments of the intervention on paper surveys from the patient and caregiver. These assessments will be de-identified, stored in a locked cabinet, and will include the following instruments:

- McGill Quality of Life Questionnaire-E (MQOL-E)
- Wisconsin Brief Pain Questionnaire (BPQ)
- Collett-Lester Fear of Death Scale
- VR Tandem Intake VR Request form

Types of data

The EXCEL spreadsheet below contains the specific patient-level variable listing that will be collected by the PRR/PRT. The PRR/PRT will establish the guideline for managing confidentiality of the single data file containing the participant names and study ID numbers. Time Frame: The PRR/PRT will collect these data points prior to the participant's completion of the research intervention and following the intervention. These data will allow the researchers to determine the effectiveness of the intervention.

EXCEL Spreadsheet. Patient level data retrieved from EHR by PRR/PRT

Patient's Information. Each patient's name will be transposed into a unique (random) study identification number by the PRR/PRT: year of birth, gender, racial group, ethnicity, primary diagnosis for enrollment into hospice, length of time in hospice care services.

Participant-level data. When participants give consent and are enrolled in the study, each will be assigned a unique (random) study identification number by the PRR/PRT. This ID number will be associated with all participant data that are collected, entered, and analyzed for the study. The link between participants' names and study ID numbers will be kept in a separate electronic file on the computer of the PRR/PRT PI on a password protected computer that is kept in locked office, ensuring that all data prepared for analysis are de-identified. Directly identifying information will never be maintained in the same files. All paper data (pre- post- intervention) will be stored in locked file cabinet that will be accessible only to research staff at the Prisma Health Hospice of the Foothills site. The paper data will only be labeled with the participant's study ID. During the active project period (while data are being collected, coded, and analyzed), data from participants will be entered into the data spreadsheet (included for review) by the PRR/PRT into the Clemson University's secure BOX storage (box.clemson.edu), which is a highly secure online file-sharing system.

Participants' study ID numbers will be associated with the data entered into BOX. Data will be downloaded from BOX for analysis onto password protected computers and saved only on secure Clemson University servers.

Patient-level data retrieved from EHR by the Tandem VR Team

All data to be used in the proposed study will be obtained from the PRR/PRT; only completely de-identified data will be logged into the EXCEL spreadsheet. Data collected by the Research Recruiters will occur in a secure location within the practice office location (701 Grove Road, Greenville, SC 29605).

Types of data

The EXCEL Spreadsheet contains the specific variable list that will be used in the proposed study that will be collected by the Tandem VR Team. While the data involves human subjects, only completely de-identified data will be available and used in the proposed study. Secondary data use is expected to be limited to the specific variables listed in the excel spreadsheet.

Data sharing agreement

Data sharing will occur upon approval of the data management plan submitted to Prisma Health System.

Data repository/sharing/archiving

A long-term data sharing, and preservation plan will be used to store beyond the life of the project. The de-identified data will be deposited into the CLEMSON University secure BOX folder.

Roles and Responsibilities

PRR/PRT will be responsible for ensuring de-identified data are "active" (i.e., during data collection, coding, analysis, and publication phases of the project), and will be responsible for documenting and managing the data throughout the period of the research study.

Additional non-Prisma project personnel (Clemson researchers and undergraduate/graduate research assistants to be determined) will receive human subjects and data management training and will also be responsible for adhering to the data management plan described above. These additional project personnel will not have access to any PRISMA HEALTH electronic records.

PRT will develop study-specific protocols and will train all PRR handling identifiable data and de-identified data using protocols for naming, organizing, and sharing files and entering and downloading data. We will also develop a directory that lists all types of data and where they are stored and entered. For the CU team, we will designate the PI (Jason Thrift) to ensure that these protocols are followed, and documentation is maintained.

The PRT will establish the guideline for managing confidentiality of the single data file containing the participants' names and study ID numbers. At the end of the grant and publication processes, the data will be archived. The CU team, under the direction of the PI (JT) will follow the guidelines for handling de-identified data and archived data.

Expected schedule for data access

The complete dataset stored at CLEMSON U Box folder (all de-identified) is expected to be accessible after the study and all related publications are completed and will remain accessible to the research team for at least 5 years. The PIs and Co-Investigators acknowledge that an annual report will be collected and contain information about the data accessed during that time period.

Dataset documentation

Our final data file will include (a) raw item-level data (where applicable to recreate analyses) with the variable and value labels outlined above, (b) all computed variables created during setup and scoring, and (c) scores for the

demographic and assessment data. These data will be the de-identified and individual- or aggregate-level data used for the analyses.

Dataset documentation will consist of electronic codebooks documenting the following information: (a) a description of the research questions, methodology, and sample, (b) a description of each specific data source (e.g., measures, observation protocols), and (c) a description of the raw data and derived variables, including variable lists and definitions. To assist in the final dataset documentation, we will maintain a log of how data were collected, when, and where throughout the project. Additionally, we will log decisions related to coding, methods, and analysis (including software,) where data and corresponding are stored, and next steps for research projects and plans (including follow up grant submissions/publications).

6. Data and Specimen Banking

Data from this study will be stored in HIPAA compliant Box software. The Co-PIs, Co-Is, and the research assistants will have password protected access to the Box. All the information will be stored in an encrypted database. Electronic communication with outside collaborators will involve only unidentifiable information. Only the primary investigators and members of the research team that will contact the participants will have access to information linked to participant identifiers. Long-term plans for archiving data, samples, and other research products, and preservation of access will be undertaken by Keais Pope, MD and Jason R. Thrift, PhD, RN, CHSE. The Co-PIs and Co-Is will maintain their parts of the data on the Box platform. The data will be retained at least three years after the conclusion of the study. Other electronic backup media and surveys will also be stored to ensure long-term availability of data. Should the Co-PI leave Prisma Health prior to completing the research, the data will be moved either to the relocating Co-PI's new institution, the Co-I's location, and/or to a site maintained by another member of the research community involved with the project. Data from this study will be retained to assist in development of future studies with larger patient populations, multi-site studies and also to aid in application for extramural funding.

7. Statistical Analysis

Differences in outcomes between pre and post intervention data will be statistically tested to determine if Tandem VR impacted primary outcomes. Independent sample t-tests will compare outcomes and changes in symptoms (i.e., pain). We will also triangulate quantitative and qualitative data outcomes with adjustments for sociodemographic characteristics to understand experiences for both the patient and informal caregiver following conclusion of the intervention.

V. ETHICAL CONSIDERATIONS

A. RISKS AND POTENTIAL BENEFITS TO PARTICIPANTS

1. Risks to Participants

The risks associated with participation in this study are no greater than those typically encountered in normal day activities. Certain aspects of the participant's demographics will be collected for this study. Loss of privacy may lead to problems with insurability or social stigmatization. In terms of privacy, participant's data and associated records will be kept in a secure encrypted, password-protected database. Confidentiality of participant information and study activities will also be emphasized to all research personnel. These risks are considered to be minimal and are addressed in the protocol and consent form.

Participants may develop VR-related symptoms such as motion sickness effect, nausea, and headache, often referred to as cybersickness. Measures will be taken to assess if any symptoms of cybersickness occur and discontinue the intervention immediately. The greatest risk is the possible release of your personal health information. The study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure patient data is deidentified. Some of the questions in the surveys/questionnaires are personal and may be upsetting to some participants. The study doctor or staff 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.

In case patients or patient caregivers become emotional during the Tandem VR experience, a Hospice care on-call social worker will be providing real-time and immediate counseling.

2. Potential Benefits to Participants

We expect that this study will demonstrate Tandem VR is an effective non-pharmacologic treatment for the management of physiological distress of patient-caregiver dyads; moreover, we expect Tandem VR will be feasibly and safely deployed in home settings. The expected outcomes from this study include reduction in pain, reduced fear of death and improved quality of life for participants. This intervention is also likely to show improved interactions between patient-caregiver dyads through the imagery used in Tandem VR. The outcomes from this study will be used

to optimize Tandem VR to user satisfaction. The results will also be used to inform and refine future design guidelines and practices for the implementation of Tandem VR for patient-caregiver dyads in the hospice home setting.

B. PARTICIPANT CONFIDENTIALITY AND PRIVACY

1. Participant Confidentiality

We will do everything we can to protect the participant's privacy. Collected data will be stored securely with access limited to the investigators. Paper forms will be kept in a double-locked storage and access to the storage will be restricted to the research team. Confidentiality of participant information and study activities will also be emphasized to all research personnel. Participant's identity will not be revealed in any publication that might result from this study. Limited demographic data will be collected. Data will be handled in a confidential manner to prevent loss of privacy. Electronic files will be stored in an encrypted and password protected database on a secure server. Only the primary investigators and members of the research team who contact the subjects will have access to information linked to subject identifiers.

2. Provisions to Protect the Privacy Interests of Participants

Under federal privacy laws, participants' study records cannot be used or released for research purposes unless the participant agrees. If the participant signs the consent form, he/she agrees to the use and release of health information. If not, the participant will not be able to participate in this study. Once health information has been released, federal privacy laws may no longer protect it from further release and use. The right to use health information for research purposes does not expire unless the participant withdraws agreement. The participant has the right to withdraw from the agreement at any time. This can be done by giving written notice to the study investigators. If the agreement is withdrawn, the participant 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. The participant has the right to review health information that is created during participation in this study. After the study is completed, this information may be requested.

C. VULNERABLE POPULATIONS

N/A

D. CONSENT PROCESS

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

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.

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.

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 your personal health information. Your 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 you 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 you have a concern or problem. You do not have to answer any questions that you do not want to answer. Should any aspect of the experience be distressing or feel negative in any way, you 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 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.

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:
Participation in the study will provide you and your caregiver with a $10 gift card each (total value $20) as a thank you for working within the study.

Participation in the study will allow you to be on the Patient Advisory Council (PAC) where you and your caregiver can assist the researchers with your perspective on the experience in Tandem VR. The payment you 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 you 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 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 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. 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 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.
- Participating investigators at Clemson University.

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 agree 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 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: 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

E. PARTICIPANT ECONOMIC BURDEN/COMPENSATION & OTHER STUDY DETAILS

1. Economic Burden to Participants
There is no economic burden to participants. The study is conducted in the convenience of the patient's home at no cost to the patient.
2. Compensation for Research-Related Injury

Prisma Health 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, 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.

3. Debriefing Participants

Under federal privacy laws, participants' study records cannot be used or released for research purposes unless the participant agrees. If the participant signs the consent form, he/she agrees to the use and release of health information. If not, the participant will not be able to participate in this study. Once health information has been released, federal privacy laws may no longer protect it from further release and use. The right to use health information for research purposes does not expire unless the participant withdraws the agreement. The participant has the right to withdraw from the agreement at any time. This can be done by giving written notice to the study investigators. If the agreement is withdrawn, the participant 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. The participant has the right to review health information that is created during participation in this study. After the study is completed, this information may be requested.

4. Community-Based Participatory Research

We will also assemble a Patient Advisory Committee (PAC) of patients and caregivers enrolled in home-based hospice to gather their unique and invaluable perspectives on clinical use in that setting. The PAC will support our future grant submission to the Patient-Centered Outcomes Research Institute. Each participant in the PAC will be compensated with $50 per person per meeting for a total of 3 meetings.

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VII. APPENDICES

Tandem VR Intake Form Patient ID:

*Disclaimer: We will do our best to fulfill your VR requests, but unfortunately some VR experiences do not have adequate quality or are not yet available. The study calls for participants to engage in nature-based experiences within the Tandem VR Environment. These experiences need to be appropriate for all viewers. Explicit content such as inappropriate language, discriminatory actions, nudity, sexual content, and acts of violence will be excluded. Thank you for your understanding and cooperation."

1.) What kind of virtual reality experiences would you like to have? (Enjoying a relaxing beach, a mountain stream, visiting a foreign place, going skydiving, etc.)

2.) What are your 2 favorite places in the Upstate that you would like to visit again?

3.) Are there any items on your “bucket list” that you would like to try and experience?

4.) Is there anywhere in the world where you have always wanted to go to or to experience?

5.) Is there any place you would like to re-visit? If so, where?

6.) Is there a particular address you would like to visit? (such as your childhood home) If available, what address would you like to visit?

7.) Have you experienced virtual reality before?

8.) Are you prone to motion sickness? (ex. Do you get sick while riding in a car?)

9.) Questions, comments, concerns?

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

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.

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, complete the intake form, and photo consent release form for images that may be identifiable. 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 your personal health information. Your 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 you 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 you have a concern or problem. You do not have to answer any questions that you do not want to answer. Should any aspect of the experience be distressing or feel negative in any way, you 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 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.

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:
Participation in the study will provide you and your caregiver with a $10 gift card each (total value $20) as a thank you for working within the study.

Participation in the study will also allow you to be on the Patient Advisory Council (PAC) where you and your caregiver can assist the researchers with your perspective on the experience in Tandem VR. The payment you 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 you 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 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 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. 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 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.
- Participating investigators at Clemson University.

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 agree 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 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: 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

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