

Contents lists available at ScienceDirect

**Contemporary Clinical Trials Communications** 



journal homepage: www.elsevier.com/locate/conctc

# The *Tandem VR*<sup>TM</sup> protocol: Synchronized nature-based and other outdoor experiences in virtual reality for hospice patients and their caregivers

O. McAnirlin<sup>a,\*</sup>, J. Thrift<sup>b,a</sup>, F. Li<sup>a</sup>, J.K. Pope<sup>c</sup>, M.H.E.M. Browning<sup>a</sup>, P.P. Moutogiannis<sup>d</sup>, G. Thomas<sup>e</sup>, E. Farrell<sup>f</sup>, M.M. Evatt<sup>g</sup>, T. Fasolino<sup>f</sup>

<sup>a</sup> Virtual Reality and Nature Lab, Department of Parks, Recreation and Tourism Management, Clemson University, 170 Sirrine Hall, 515 Calhoun Dr, Clemson, SC, 29634, USA

<sup>b</sup> School of Nursing, Clemson University, 605 Grove Road, Greenville, SC, 29605, USA

<sup>c</sup> Hospice of the Foothills, Prisma Health System, 701 Grove Rd., Greenville, SC, 29605, USA

<sup>d</sup> Palliative Medicine, Prisma Health System, 701 Grove Rd., Greenville, SC, 29605, USA

<sup>e</sup> Department of Genetics and Biochemistry, Clemson University, D153 Poole Agricultural Center, Clemson, SC, 29634, USA

<sup>f</sup> School of Nursing, Clemson University, 414 Edwards Hall, Epsilon Zeta Dr., Clemson, SC, 29634, USA

<sup>8</sup> Medical Student (M2), University of South Carolina School of Medicine Greenville, 607 Grove Rd, Greenville, SC, 29605, USA

ARTICLE INFO

Keywords: Virtual reality Protocol Hospice Caregivers Tandem VR <sup>TM</sup>

#### ABSTRACT

*Background:* Nature-based and other outdoor 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. However, the psychological distress of the patient-caregiver dyad is interconnected and highlights the interdependence and responsiveness to distress as a unit. Hospice care services and healthcare need strategies to help patients and informal caregivers with EOL transitions.

*Methods:* Our study uses the synchronized *Tandem* VR<sup>TM</sup> approach where patient-caregiver dyads experience immersive nature-based and other outdoor VR content. This mixed methods study will recruit 20 patient-caregiver dyads (N = 40) enrolled in home hospice services nearing EOL. Dyads will experience a personalized nature-based and other outdoor VR experience lasting 5–15 min. Self-reported questionnaires and semi-structured interviews will be collected pre/post the VR intervention to identify the impacts of *Tandem* VR<sup>TM</sup> experiences on the QOL, pain, and fear of death in patient-caregiver dyads enrolled with hospice services. Additionally, this protocol will determine the acceptance of *Tandem* VR<sup>TM</sup> experiences by dyads as a non-pharmacological modality for addressing patient and caregiver needs. Acceptance will be quantified by the number of dyads accepting or declining the VR experience during recruitment.

*Discussion:* Using personalized, nature-based and other outdoor VR content, the patient-caregiver dyads can simultaneously engage in an immersive encounter may help alleviate symptoms associated with declining health and EOL phases for the patient and the often overburdened caregiver. This protocol focuses on meeting the need for person-centered, non-pharmacological interventions to reduce physical, psychological, and spiritual distress. *Trial registration:* NCT06186960.

#### 1. Introduction

Virtual Reality (VR) is increasingly utilized by palliative and hospice care worldwide to help bring meaning, joy, healing, and closure to patients at the end of their lives [1]. Immersive, 360-degree VR experiences have the potential to aid existential suffering for patients whose functional decline prevents them from experiencing their new or loved locations due to sickness, frailty, and weakness [2].

Nature-based and other outdoor 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 [1,3]. Being outdoors in natural environments can activate the parasympathetic nervous system and brain regions associated with physiological relaxation [4]. Evidence suggests that nature-based and other outdoor VR content can similarly reduce physical and psychological symptom burden [1,5–7]. Symptom burden impacts functional

https://doi.org/10.1016/j.conctc.2024.101318

Received 28 January 2024; Received in revised form 15 May 2024; Accepted 1 June 2024 Available online 22 June 2024 2451-8654/© 2024 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/bync-nd/4.0/).

<sup>\*</sup> Corresponding author. 170 Sirrine Hall, 515 Calhoun Dr., Clemson, SC, 29634, USA. *E-mail address:* Omcanir@clemson.edu (O. McAnirlin).

status, leading to isolation, loneliness, and poor quality of life (QOL) [8]. In a recent study by the authors [9], patients with end-stage severe chronic obstructive pulmonary disease (COPD) showed improved shortness of breath and comfort during a personalized experience with nature-based and other outdoor VR content. Additionally, results from two studies, Pardini et al. [10,11] found that offering some choice in their VR content to both non-clinical participants and patients with cognitive impairments increased their engagement and relaxation in the virtual environment, which could be a benefit that transfers to the patient-caregiver dyad.

Informal caregivers like spouses, partners, or friends may also benefit from nature-based or other outdoor VR experiences. Informal caregivers are crucial in hospice patients' physical, emotional, and practical care [12]. These caregivers deliver an estimated 66 h per week of care and are intimately involved in the EOL phases [13]. Providing this amount of care requires significant physical and emotional sacrifices [14]. Caregivers' 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 [12]. While caregivers survive beyond the patient, reducing their physical and psychological impact offers long-term benefits for their well-being and bereavement process [15]. Hospice care services and healthcare need strategies to help reduce burnout and the impact of caregiving on informal caregivers.

Given the progressive nature of serious illnesses, patient and caregiver dyads have missed opportunities to engage in meaningful experiences. Family picnics or hiking in familiar outdoor spaces often hold valuable memories. Nature-based and other outdoor VR experiences can be personalized through 360-degree videos and audio for each dyad. Personalizing these VR experiences allows patients to revisit familiar and non-threatening spaces where memorable experiences occur. Implementing such a personalized, technologically advanced intervention among dyads enrolled in hospice is expected to significantly mitigate stressors associated with EOL events by bringing joy and closure to dyads.

Therefore, *Tandem VR*<sup>*TM*</sup> may provide the needed strategy for the well-being of the patient and caregiver dyad by allowing them to engage in meaningful experiences simultaneously through VR. Tandem VR<sup>*TM*</sup> was invented by lead author, Olivia McAnirlin, Copyright © 2020–2024, Dr. Olivia McAnirlin. All rights reserved. In *Tandem VR*<sup>*TM*</sup>, the dyad concurrently experiences memorable nature and other outdoor experiences. Providing stimuli of panoramic views with high-resolution audio is critical in distraction techniques that can reduce the symptom burden during EOL phases. Evidence supports using distraction techniques through VR, with one study reporting a 33–60% reduction in pain scores [16]. *Tandem VR*<sup>*TM*</sup> offers hospice teams a person-centered strategy for the patient's well-being and the psychological needs of informal caregivers.

#### 1.1. Primary objectives

We propose a single-arm, non-randomized clinical trial that utilizes a pre- and post-test design to test the impact and acceptance of *Tandem VR*<sup>TM</sup> in the hospice home-based setting. This study seeks to: (1) Identify the impacts of personalized nature-based and other outdoor *Tandem VR*<sup>TM</sup> experiences on the QOL, pain, and fear of death in patient-caregiver dyads enrolled with hospice services through questionnaire data and semi-structured interviews; (2) Determine the acceptance of personalized nature-based and other outdoor *Tandem VR*<sup>TM</sup> experiences by dyads as a non-pharmacological modality for addressing the needs of dyads, as measured by the number of dyads accepting or declining the VR experience during recruitment.

#### 1.2. Hypothesis

Our central hypothesis is that both members of the patient-caregiver

dyad will increase QOL and decrease pain and fear of death after viewing their personalized *Tandem VR*<sup>TM</sup> experience.

#### 2. Methods

#### 2.1. Setting, recruitment, and eligibility criteria

This study was approved by Prisma Health Ethics Committee and Clemson University's Institutional Review Board. A hospice Care Facility (the "Facility") will be utilized for recruitment and data collection for this multi-site study. This organization offers hospice and bereavement services to Upstate South Carolina, USA residents. The average length of stay for patients is 70 days.

We aim to recruit 20 patient-caregiver dyads (40 people total) enrolled in home hospice services through convenience sampling from the Facility. The sample size was based on pragmatic reasons such as the availability of eligible patients at participating sites over the study period, site workload, and available VR devices. Additionally, 20 patient-caregiver dyads are about 20% of the patients at any given time on the roster due to the high patient turnover experienced for in-home hospice services at the Facility. The dyads will receive the Tandem  $VR^{TM}$  intervention from the research assistants implementing the treatment modality. Dyads will be primarily recruited using word-ofmouth by the research assistants who work/volunteer at the Facility. The research assistants will use the inclusion/exclusion criteria to identify viable dyads that they feel will be able/willing to participate in the study. Recruitment and data collection will be conducted over 8-16 weeks. Research assistants will track the number of dyads who accept or decline to participate in the Tandem VR<sup>TM</sup> experience.

The research recruiters, hospice-affiliated social workers, and other hospice personnel will screen, determine eligibility with the research team, and implement and evaluate the Tandem VR<sup>TM</sup> intervention with the dyads. Each dyad must consist of one patient and one self-identifying informal caregiver in order to enroll in the Tandem VR TM intervention. An informal caregiver may be a spouse, partner, family member or friend who supports the needs of the patient [17]. Inclusion criteria for the patient and caregiver include: 1) English speaking; 2) projected life expectancy of <6 months (established by the Facility; and 3) cognitively intact (has sufficient judgment, planning, organization, and self-control) as evaluated by staff at the Facility. Exclusion criteria for the patient and caregiver include: 1) cognitive impairment affecting participation; 2) condition that interferes with VR usage, including but not limited to seizures, facial injury precluding safe placement of headset; 3) prognosis of hours or actively dying at the time enrollment; 4) motion sickness; 5) claustrophobia, 6) visual and/or hearing impairments; and 7) inability to speak English.

#### 2.2. Theoretical framework

The Theory of Unpleasant Symptoms addresses three elements impacting the experience of patients with serious illness: 1) symptoms, 2) influencing factors, and 3) consequences of the experience [18]. This theory provides a framework for understanding how symptoms cluster so that healthcare providers can implement non-pharmacological interventions into treatment plans [18,19]. Individuals diagnosed with serious illness struggle with symptom management that impacts their functional status and QOL. Caregivers also experience psychological and physical distress when caring for their loved ones, which heightens their stress responses. This study addresses the symptom cluster of pain and fear of death on the QOL for the patient and caregiver dyad through self-reported outcomes.

# 2.3. Study outcomes

The study will collect patient-caregiver-reported outcomes, including QOL, pain, and fear of death. Investigators will also measure

the acceptability and impact of *Tandem VR*<sup>TM</sup>. Both quantitative data with surveys and qualitative data with interviews will be collected before and after the dyads' *Tandem VR*<sup>TM</sup> experience to understand perceived impacts, preferences, thoughts, and feelings about the intervention. We propose *Tandem VR*<sup>TM</sup> as an effective non-pharmacologic treatment for improving QOL, pain, and fear of death at EOL for dyads.

#### 2.4. Unique hospice considerations

Special considerations will be taken for patients and families where the prognosis is guarded, and these patients, caregivers, and families will not be asked to participate in the *Tandem VR<sup>TM</sup>* protocol. Rarely there are hospice patients who do not wish to know their prognosis or hospice status. This study will only include participants who are openly aware that they are currently on hospice support with a terminal diagnosis so that we can accurately measure any potential effects VR may have on existential pain.

Psychospiritual support is a cornerstone of high-quality hospice care. The experience of the dying human being can be emotional and difficult for many patients. To ensure continued excellence in hospice care, social workers will be present during the VR intervention to help address any psychological distress or emotions that the VR experience may evoke.

## 2.5. Tandem VR TM protocol

# 2.5.1. Recruitment, screening, and consenting to Tandem VR $^{TM}$

Verbal recruitment will be conducted face-to-face by the research assistants, staff members, and volunteers with hospice care. This will occur during admission to the Facility. Interested dyads will be screened to participate by the research assistants to ensure eligibility based on inclusion/exclusion criteria. Dyads will complete the consent and *Tandem VR*<sup>TM</sup> Intake forms. The *Tandem VR*<sup>TM</sup> Intake form (Supplemental Information) helps guide dyads to the personalized VR content they may want to experience. Personalized, immersive, 360-degree, nature-based and other outdoor VR content will be co-created by the research recruiter, research assistant, and the dyad with the VR Intake Form. Besides the optional patient advisory council, the remaining intervention steps occur during one home visit.



- Recruitment by research assistants (RA), staff, or volunteers during hospice admission.
- Screening of interested dyads for eligibility based on inclusion/exclusion criteria.
- Completion of consent and intake form by Dyads..

Recruitment, Screening, and Consenting to Tandem VR<sup>TM</sup>



- RA will collect demographic information, MQOL-E, BPQ, FOD.
- RA will select, edit, and compose personalized 360-degree VR experiences for Dyads on *EchoSphere*.
- RA will deploy the experience to VR HMDs and prepare for Tandem VR<sup>TM</sup> intervention.

Pre-Tandem VR<sup>TM</sup> Preparation

# 2.5.2. Pre-Tandem VR TM

The *Tandem VR*<sup>TM</sup> intervention will be carried out in the patientcaregiver dyad's home setting, with the research assistants implementing the experience and providing support when needed (Fig. 1). Research assistants will collect demographic information from the dyad. Additionally, each member of the dyad will complete a paper copy of the McGill Quality of Life Questionnaire-E (MQOL-E), Wisconsin Brief Pain Questionnaire (BPQ), and Collet-Lester Fear of Death (FOD) Scale before beginning the *Tandem VR*<sup>TM</sup> experience [20–22].

# 2.5.3. Tandem VR $^{TM}$ intervention

After the surveys are completed, the research assistants will share a personalized library of immersive, 360-degree, nature-based and other outdoor VR experiences for the dyads to choose from based on their VR Intake Form. Once the dyad has determined their desired experiences from the library, the research assistant will assist the dyads in wearing a VR head-mounted display (HMD). The research assistants will ensure the safety of the patient and caregiver while using these devices. The HMDs used were the Pico Neo 3 (642g) with 4K resolution (3664x1920), 72Hz refresh rate, and  $98^{\circ}$  field of view.

The research assistants will then initiate the *Tandem VR*<sup>TM</sup> experience using the *EchoSphere* system to synchronize the playback of the personalized, nature-based and other outdoor VR content. *EchoSphere* was independently developed by one of the authors, Fu Li, as a synchronized VR experience system consisting of a controller tablet, VR HMDs, content server, and specialized software (Fig. 2). The research assistants will select, edit, and compose the personalized 360-degree VR experiences for dyads via the tablet and deploy the experience to the VR HMDs via a wireless local area network (WLAN). The benefits of the *EchoSphere* system include the ability for research assistants to seamlessly create a personalized VR experience for 2+ users and deploy the VR content without the users needing to press buttons or use controllers with the HMD. The research assistants will manage the entire VR creation and deployment process. The duration of the *Tandem VR*<sup>TM</sup> experience will last 5–15 min.

# 2.5.4. Post-Tandem VR $^{TM}$

Upon completion of the *Tandem VR*<sup>TM</sup> experience, the dyad will complete the MQOL-E, BPQ, and FOD for a second time. After completing these surveys, a semi-structured interview will be conducted



- During home visit, RA helps Dyads put on the HMD to ensure safety during session.
- RA starts the Tandem VR<sup>TM</sup> synchronized experience using EchoSphere.
- Tandem VR<sup>TM</sup> experience lasts between 5-15 minutes.



- Dyads complete MQOL-E, BPQ, and FOD surveys post-VR intervention.
- Research team will conduct a semi-structured interview with the Dyads.
- Dyads are eligible for the Patient Advisory Council.

TM Preparation Tandem VR<sup>TM</sup> Intervention Post-Tandem VR<sup>TM</sup>

**Home Visit** 

**Pre-Home Visit** 

Fig. 1. Sequence to provide dyads with Tandem VR  $^{TM}$ .

Contemporary Clinical Trials Communications 40 (2024) 101318



Fig. 2. EchoSphere consists of a tablet and software system to deploy Tandem VRTM to multiple HMDs for synchronized viewing.

by a phone call set up by the research assistants, with trained interviewers within the research team to alleviate the burden on the research assistants on site. The semi-structured interview will utilize a six-question interview guide specifically crafted for the dyad to answer in the Post-*Tandem*  $VR^{TM}$  phase of data collection (see Section 2.8). The interviewers will take field notes during each interview to provide context during the quantitative analysis and interpretation stages.

The anticipated total time for a home visit involving the *Tandem VR*<sup>TM</sup> experience is 60 min. As a participant in the study, each member of each dyad will receive a \$10 electronic gift card and be eligible to participate in a Patient Advisory Council (PAC) to share their perspectives on the *Tandem VR*<sup>TM</sup> experience with the research team.

#### 2.6. Patient advisor council (PAC)

We will assemble a Patient Advisory Committee (PAC) of dyads either enrolled in hospice services who have participated in *Tandem VR*<sup>TM</sup> or who have participated in another affiliated research program involving VR while enrolled in hospice services. The PAC will enable the research team to gather their unique and invaluable perspectives on the clinical use of *Tandem VR*<sup>TM</sup> in the home setting. All dyads will have been exposed to a personalized VR experience before being asked to join the PAC. Dyads will be chosen if they want to discuss ways to improve the *Tandem VR*<sup>TM</sup> experience through open-ended interviews and/or focus groups with the research team.

The PAC will allow us to work firsthand on bettering our personcentered approach to care. The PAC will be a dedicated working group of patients and caregivers who will advise the research team on expanding the person-centered approach of the *Tandem*  $VR^{TM}$  protocol. PACs empower patients and caregivers to meet regularly as equal partners with the research team to advance the Tandem  $VR^{TM}$  protocol with a person-centered research approach. The post-Tandem  $VR^{TM}$ interview data will be de-identified and shared with the PAC as the first step of empowering the PAC to represent the wide-ranging patient and caregiver dyad perspective. There will be up to 3 PAC sessions, lasting up to 30 min per session, with either a patient, a caregiver, or a dyad to facilitate conversations that extend beyond the post-Tandem  $\textit{VR}^{\textit{TM}}$ interview focus. The PAC will meet with the research team to discuss three domains: technological aspects of VR, value-added intervention, and ongoing integration. The PAC session topics may range from suggestions by the PAC for overcoming technical issues, content availability, perceived impacts, scalability, utility for other patient populations, and the importance/value of getting an HMD covered by insurance. Each participant in the PAC will be compensated \$50 (\$100 per dyad) per PAC meeting for up to three sessions, which will be hosted after the completion of Tandem VR TM data collection.

# 2.7. Role of hospice personnel and volunteers in research

Hospice personnel or volunteers at the Facility (i.e., social workers)

will play an important role within the research team and work alongside student researchers and trained researchers overseeing the *Tandem*  $VR^{TM}$  protocol. Research assistants will assist with consenting dyads and offer expert insights on using the intervention as a non-pharmacological modality. Additionally, research assistants will support the home visits involving *Tandem VR* <sup>TM</sup>. Research assistants will be on hand in the unexpected occurrence of reportable adverse events regarding the *Tandem VR* <sup>TM</sup> experience or other times during the protocol, such as recruitment and screening. Ongoing dialogue between the research assistants 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.

#### 2.8. Data collection and measures

Data will be collected through the pre- and post-intervention surveys and post-intervention semi-structured interviews explained above. The surveys will evaluate well-being, perceived change in pain, and perceived fear of death for both members of the dyad. Additionally, demographic data will be collected from all participants. Both the patient and caregiver will complete the same pre- and post-intervention demographics, surveys, and interview questions. We are interested in the utilization of *Tandem VR<sup>TM</sup>* as a tool to potentially improve quality of life (QOL), perception of fear of death, and perceived change in pain for both the patient and caregiver as a dyad and individually. Although the patient may seem like the obvious choice to look for pre-post-changes, informal caregivers are often overburdened and have their own unique experiences that influence their OOL, fear of death, and pain.

Demographic data will include birth year, gender, racial group, ethnicity, primary diagnosis for admittance to hospice, and length of time in hospice. In addition, the clinicians on the research team will review participants' electronic medical records (EMR), collecting the medical record number (MRN), type of diagnosis, and life expectancy. Due to the sensitivity of the data and IRB regulations, this information will be stored and used only by the clinicians on the research team. All dyads will be assigned randomized IDs to allow as much anonymity as possible within the research team and when reporting study findings.

Well-being will be measured with the McGill Quality of Life Questionnaire (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 [21]. The 16-item questionnaire uses a 0–10 response scale and was developed specifically to assess the QOL for patients facing end-of-life transitions [23]. The MQOL-E has been shown to have strong reliability and validity in various palliative and hospice care populations [24–26].

Perceived change in pain will be assessed with the Wisconsin Brief Pain Questionnaire (BPQ). The BPQ is the precursor for the Brief Pain Inventory (BPI), another well-known scale used extensively [20,27]. Patients will rate their pain from 0 = no pain to 10 = worst pain imaginable in response to items such as "average pain," "worst pain," "least pain" over the last seven days, and "pain right now." The survey will automatically conclude per the BPI instructions for patients and caregivers who indicate no pain for the first four questions on the BPI. The average of all items will be used to create a single pain severity score. This measure shows strong reliability and validity in palliative care populations [28].

Changes in perception of fear of death will be measured by the Collett-Lester Fear of Death Scale (CL-FODS), which has 28 items [22]. The CL-FODS uses a 5-Likert scale ranging from 1 = not to 5 = very for how disturbed or anxious a person is by different aspects of death and dying (i.e., shortness of life, lack of control over dying, and feeling lonely; [29]). The CL-FODS has four subsections: death of self, death of others, dying of self, and dying of others [22]. The means of each subsection and total scale scores illustrate the degree of anxiety about death and dying, with higher values indicating the greater severity [29]. The CL-FODS was developed and tested by those working in healthcare and is valid when compared to other scales that measure anxiety related to perceptions about death [29].

The semi-structured interviews will reveal the perceived benefits and value of the *Tandem VR*<sup>*TM*</sup> experience. This information will be used to evaluate the likelihood of integrating this intervention as a treatment modality for future dyads. Each dyad will be asked the following questions from an interview guide to reflect on their experience.

- What is the relationship between yourself and the patient?
- Tell us about your experience in Tandem VR TM
- What was it like being together in the *Tandem VR*<sup>TM</sup> experience?
- Was there anything about the *Tandem VR*<sup>TM</sup> experience that helped you?
- Was there anything about the *Tandem VR*<sup>TM</sup> experience you feel could be improved?
- Were there any unusual sensations such as dizziness, lightheadedness, or disorientation while you were in the *Tandem VR*<sup>TM</sup> experience? If so, please explain.

# 2.8.1. Establishing minimally clinically important differences (MCID) thresholds

Historically, the impact of clinical interventions focuses on statistical significance, such as p-values, from the collected data. However, this approach may not reflect the value of the intervention within the clinical setting and associated patient outcomes. To bridge the gap between research and clinical relevance, the minimal clinically important difference (MCID) provides a strategy to detect the slightest difference in scores within a domain or outcome that "patients can perceive as beneficial or harmful and that it would require-in the absence of troublesome side effects and high costs-a change in the management of patient health care" ([30], p.1). The MCID varies by patient population, context, and methods of determination and, therefore, lacks a universal definition. To our knowledge, the MCID thresholds of the MQOL, BPI, and FOD are not currently established for patient and caregiver dyads facing EOL transitions. Therefore, the MCID thresholds will be established as an additional outcome of this protocol to evaluate the outcomes of the *Tandem* VR<sup>TM</sup> experience on dyads.

The MCID thresholds of the MQOL, BPI, and FOD may be determined through distribution methods that rely on statistics or correlation with changes on an external "anchor" that also measures clinical change [31]. In *Tandem VR*<sup>TM</sup>, we will use an 11-point Global Rating of Change (GRC) scale paired with an instrument-specific question for determining the MCID of the MQOL, BPI, and FOD within our sample. The GRC has high face validity, sensitivity to change, test-retest reliability, and strong correlation when used as an external anchor for various domain-specific health report measures of pain or disability [32].

To determine the MCID for each instrument (MQOL, BPI, FOD), an instrument-specific question will be presented to each member of the dyad. For example, for the FOD scale, we would ask, "With respect to your fear of death, how do you feel after the *Tandem VR*<sup>TM</sup> experience?" The patient will then respond using an 11-point GRC scale of -5 to +5. A score of -5 will indicate "much worse." A score of 0 will indicate "no change." A score of +5 will indicate "much better." Those who score greater than 0 will be considered responders. Those who score less than or equal to 0 will be considered non-responders. The change difference (CD) method will then determine the MCID. The difference between the average instrument score for responders and non-responders is considered the MCID using this method [31].

# 2.8.2. Data analysis

Participants ' descriptive statistics and demographic characteristics will be reported for each outcome measured on the surveys. Changes resulting from the *Tandem VR*<sup>TM</sup> experience will be statistically tested with mean/median comparisons (i.e., paired sample t-tests or Mann-Whitney U). Statistical significance will be determined by a *p*-value <0.05. Semi-structured interview data will be examined using a thematic analysis to capture the perceived benefits and value of *Tandem VR*<sup>TM</sup>. We will also triangulate quantitative and qualitative data outcomes to investigate why some dyads may have responded differently to the *Tandem VR*<sup>TM</sup> than others. We are interested in data analysis that will meaningfully capture both the patient and caregivers as individuals, as well as an interconnected dyad; however, flexibility in data analysis is warranted for a sample size of 20 dyads.

### 3. Discussion

Based on a growing body of evidence on the value of VR for patients with serious illnesses, we propose a *Tandem VR*<sup>TM</sup> as an innovative approach at the forefront of scientific and clinical transformative care. Using personalized, nature-based and other outdoor VR experiences, patient-caregiver dyads can simultaneously engage in immersive experiences that may help alleviate symptoms associated with declining health and EOL phases. A mainstay of this protocol is its person-centered approach, supporting both patients and caregivers through co-created personalized immersive experiences. Additionally, this protocol facilitates applied research for patients through an internal hospice care and volunteer team network, which is promising for implementation in future hospice care facilities.

We predict that data collected during this protocol will demonstrate *Tandem VR*<sup>TM</sup> as an effective non-pharmacologic treatment for increasing QOL, and decreasing perceptions of pain and fear of death for dyads. Moreover, we predict *Tandem VR*<sup>TM</sup> will be safely deployed in home settings. This intervention will also likely show improved dyad interactions through experiencing *Tandem VR*<sup>TM</sup>. However, we acknowledge that at this time there are no results that support these claims because this study is currently in active data collection. The outcomes from this study will be used to improve the acceptance and impact of *Tandem VR*<sup>TM</sup>. The results will also inform and refine future design guidelines and best practices for implementing *Tandem VR*<sup>TM</sup> for dyads in the hospice home setting.

As with all protocols, there are limitations to the *Tandem VR*<sup>TM</sup> protocol. We have built a diverse, wide-ranging library of 360-degree, nature-based and other outdoor VR experiences for dyads to pick from when co-creating their personalized experience. This library will continue to grow as the research team travels and records new videos. However, there may be a desired nature location or outdoor experience we cannot find or curate for a given dyad. In that case, we will offer a "best fit" experience that most closely matches their desired experience. Some dyads may choose not to participate if they are not interested in this "best fit" VR experience. By using the VR Intake form, we plan to mitigate disinterest in "best fit" experiences as much as possible but recognize that *Tandem VR*<sup>TM</sup> may require such an extensive library of content that licensing from other creators outside of the research team may be required for the success of this protocol. Tracking the number of

dyads that choose not to be recruited for *Tandem VR*  $^{TM}$  will enable us to assess this potential limitation.

#### 4. Conclusion

This study extends the need for person- and caregiver-centered, nonpharmacological interventions to reduce physical, psychological, and spiritual distress. Inspired by the mission of Prisma Health to transform the healthcare experiences for patients and families, the *Tandem VR*<sup>*TM*</sup> intervention may help patients and their caregivers deal with EOL concerns. Our team is committed to inspiring a new treatment modality, providing patients with an experience that is personalized, inspiring, and practical in its implementation.

#### Ethics and dissemination

This study was approved by Prisma Health IRB (2079177-1) and Clemson University's IRB (IRB2023-0604). This research will be disseminated through peer-reviewed publications, conference proceedings, and presentations.

#### Disclosure of the use of generative AI

During the preparation of this work, the authors used *MidJourney* to generate illustrations of the research process scenarios for Figs. 1 and 2. After using this tool/service, the authors reviewed and edited the content as needed and took full responsibility for the publication's content.

#### Funding

This research is supported by Prisma Health Seed Grant. The funding source had no involvement in study design, in the collection, analysis, and interpretation of data, in the report's writing, and in the decision to submit the article for publication.

#### CRediT authorship contribution statement

**O. McAnirlin:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Conceptualization. **J. Thrift:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition. **F. Li**: Writing – review & editing, Visualization, Software, Resources, Methodology. **J.K. Pope:** Project administration, Methodology, Funding acquisition. **M.H.E.M. Browning:** Writing – review & editing, Resources. **P.P. Moutogiannis:** Methodology. **G. Thomas:** Writing – original draft, Validation. **E. Farrell:** Validation. **M.M. Evatt:** Methodology. **T. Fasolino:** Writing – review & editing, Supervision, Methodology, Funding acquisition.

# Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Data availability

No data was used for the research described in the article.

#### Acknowledgements

The authors would like to thank facility staff and volunteers for all their time and effort collecting data. We would also like to thank in advance the patients and families who will be participating in our study.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101318.

#### References

- H. Carmont, S.J. McIlfatrick, Using virtual reality in palliative care: a systematic integrative review, Int. J. Palliat. Nurs. 28 (3) (2022) 132–144, https://doi.org/ 10.12968/ijpn.2022.28.3.132.
- [2] H.L. Amonoo, J.H. Harris, W.S. Murphy, J.L. Abrahm, J.R. Peteet, The physician's role in responding to existential suffering: what does it mean to comfort always? J. Palliat. Care 35 (1) (2020) 8–12, https://doi.org/10.1177/0825859719839332.
- [3] P.P. Moutogiannis, J. Thrift, J.K. Pope, M.H.E.M. Browning, O. McAnirlin, T. Fasolino, A rapid review of the role of virtual reality in care delivery of palliative care and hospice, Rapid Reviews 25 (6) (2023) 300–308, https://doi.org/10.1097/ NJH.00000000000983.
- [4] M.F. Norwood, A. Lakhani, A. Maujean, H. Zeeman, O. Creux, E. Kendall, Brain activity, underlying mood and the environment: a systematic review, J. Environ. Psychol. 65 (2019) 101321, https://doi.org/10.1016/j.jenvp.2019.101321.
- [5] L. Appel, E. Appel, O. Bogler, M. Wiseman, L. Cohen, N. Ein, H.B. Abrams, J. L. Campos, Older adults with cognitive and/or physical impairments can benefit from immersive virtual reality experiences: a feasibility study, Front. Med. 6 (2020) 329, https://doi.org/10.3389/fmed.2019.00329.
- [6] M.H.E.M. Browning, K.J. Mimnaugh, C.J. van Riper, H.K. Laurent, S.M. LaValle, Can simulated nature support mental health? Comparing short, single-doses of 360degree nature videos in virtual reality with the outdoors, Front. Psychol. 15 (10) (2019) 2667, https://doi.org/10.3389/fpsyg.2019.02667.
- [7] M.P. White, N.L. Yeo, P. Vassiljev, R. Lundstedt, M. Wallergård, M. Albin, M. Lõhmus, A prescription for "nature" – the potential of using virtual nature in therapeutics, Neuropsychiatric Dis. Treat. 14 (2018) 3001–3013, https://doi.org/ 10.2147/ndt.s179038.
- [8] Y. Schenker, S.Y. Park, K. Jeong, J. Pruskowski, D. Kavalieratos, J. Resick, J. S. Kutner, Associations between polypharmacy, symptom burden, and quality of life in patients with advanced, life-limiting illness, J. Gen. Intern. Med. 34 (4) (2019) 559–566, https://doi.org/10.1007/s11606-019-04837-7.
- [9] O. McAnirlin, Reflections on co-creating nature-based virtual reality experiences for adults living with severe COPD, All Dissertations 3292 (2023). https://tigerpr ints.clemson.edu/all\_dissertations/3292.
- [10] S. Pardini, S. Gabrielli, M. Dianti, C. Novara, G.M. Zucco, O. Mich, S. Forti, The role of personalization in the user experience, preferences and engagement with virtual reality environments for relaxation, Int. J. Environ. Res. Publ. Health 19 (12) (2022) 7237, https://doi.org/10.3390/ijerph19127237.
- [11] S. Pardini, S. Gabrielli, L. Gios, O.M. Dianti, L. Appel, S. Olivetto, A. Torres, P. Rigatti, E. Trentini, L. Leonardelli, M. Bernardi, M. Lucianer, S. Forti, C. Novara, Customized virtual reality naturalistic scenarios promoting engagement and relaxation in patients with cognitive impairment: a proof-of-concept mixedmethods study, Sci. Rep. 13 (1) (2023) 20516, https://doi.org/10.1038/s41598-023-47876-1.
- [12] R. Jacops, C.S. Hopkins, T. Fasolino, Patient-Caregiver dyad: a systematic review informing a concept analysis, Int J Nurs Health Care Res 5 (1298) (2022), https:// doi.org/10.29011/2688-9501.101298.
- [13] Y. Rhee, H.B. Degenholtz, A.T. Lo Sasso, L.L. Emanuel, Estimating the quantity and economic value of family caregiving for community-dwelling older persons in the last year of life, J. Am. Geriatr. Soc. 57 (9) (2009) 1654–1659, https://doi.org/ 10.1111/j.1532-5415.2009.02390.x.
- [14] J.J. Adashek, I.M. Subbiah, Caring for the caregiver: a systematic review characterising the experience of caregivers of older adults with advanced cancers, ESMO open 5 (5) (2020) e000862, https://doi.org/10.1136/esmoopen-2020-000862.
- [15] C.G. Pottie, K.A. Burch, L.P. Thomas, S.A. Irwin, Informal caregiving of hospice patients, J. Palliat. Med. 17 (7) (2014) 845–856, https://doi.org/10.1089/ jpm.2013.0196.
- [16] T. Jones, T. Moore, J. Choo, The impact of virtual reality on chronic pain, PLoS One 11 (12) (2016) e0167523, https://doi.org/10.1371/journal.pone.0167523.
- [17] Family Caregiver Alliance. (n.d.). Definitions. Retrieved from https://www.care giver.org/resource/definitions-0/, last accessed 5/July/2024.
- [18] G.L.L. Gomes, F. M. R. L. de Oliveira, K.T.F. Barbosa, A. C. T. de Medeiros, M. Fernandes, G.M. das, M. M. L. da Nobrega, Theory of unpleasant symptoms: critical analysis, Texto & Contexto- Enfermagen 28 (2019) e20170222, https://doi. org/10.1590/1980-265X-TCE-2017-0222.
- [19] E.R. Lenz, L.C. Pugh, R.A. Milligan, A. Gift, F. Suppe, The middle-range theory of unpleasant symptoms: an update, ANS. Advances in nursing science 19 (3) (1997) 14–27, https://doi.org/10.1097/00012272-199703000-00003.
- [20] C.S. Cleveland, The brief pain inventory user guide, Retrieved from, https://www. mdanderson.org/documents/Departments-and-Divisions/Symptom-Research/ BPI\_UserGuide.pdf, 2009. (Accessed 1 September 2024).
- [21] S.R. Cohen, B.M. Mount, M.G. Strobel, F. Bui, The McGill quality of life questionnaire: a measure of quality of life appropriate for people with advanced disease. A preliminary study of validity and acceptability, Palliat. Med. 9 (3) (1995) 207–219, https://doi.org/10.1177/026921639500900306.
- [22] D. Lester, The Collett—Lester fear of death scale, in: R.A. Neimeyer (Ed.), Death Anxiety Handbook: Research, Instrumentation, and Application, Taylor & Francis, 2015, pp. 45–60.

#### O. McAnirlin et al.

- [23] L. Axelsson, A. Alvariza, N. Carlsson, S.R. Cohen, R. Sawatzky, K. Årestedt, Measuring quality of life in life-threatening illness - content validity and response processes of MQOL-E and QOLLTI-F in Swedish patients and family carers, BMC Palliat. Care 19 (1) (2020) 40, https://doi.org/10.1186/s12904-020-00549-6.
- [24] P.L. Lua, S. Salek, I. Finlay, C. Lloyd-Richards, The feasibility, reliability and validity of the McGill Quality of Life Questionnaire-Cardiff Short Form (MQOL-CSF) in palliative care population, Qual. Life Res. 14 (2005) 1669–1681, https:// doi.org/10.1007/s11136-005-2817-8.
- [25] G. Myring, P.M. Mitchell, W.G. Kernohan, S. McIlfatrick, S. Cudmore, A. M. Finucane, L. Graham-Wisener, A. Hewison, L. Jones, J. Jordan, L. McKibben, D. H.L. Muldrew, S. Zafar, J. Coast, An analysis of the construct validity and responsiveness of the ICECAP-SCM capability wellbeing measure in a palliative care hospice setting, BMC Palliat. Care 21 (1) (2022) 1–10, https://doi.org/ 10.1186/s12904-022-01012-4.
- [26] S. Porter, T. McConnell, L. Graham-Wisener, J. Regan, M. McKeown, J. Kirkwood, M. Clarke, E. Gardner, S. Dorman, K. McGrillen, J. Reid, A randomised controlled pilot and feasibility study of music therapy for improving the quality of life of hospice inpatients, BMC Palliat. Care 17 (1) (2018) 125, https://doi.org/10.1186/ s12904-018-0378-1.

- [27] J. Stanhope, Brief pain inventory review, Occup. Med. 66 (6) (2016) 496–497, https://doi.org/10.1093/occmed/kqw041.
- [28] K. Huen, C. Huang, H. Liu, L. Kwan, S. Pannell, A. Laviana, J. Saucedo, K. Lorenz, C. Bennett, J. Bergman, Outcomes of an integrated urology-palliative care clinic for patients with advanced urological cancers: maintenance of quality of life and satisfaction and high rate of hospice utilization through end of life, Am. J. Hospice Palliat. Med. 36 (9) (2019) 801–806, https://doi.org/10.1177/ 1049909119833663.
- [29] T. Rosenberg, Critical synthesis package: Collett-Lester fear of death scale, MedEdPORTAL 9 (9572) (2013), https://doi.org/10.15766/mep\_2374-8265.9572.
- [30] J.a.S. Apaza, J.V.A. Franco, N. Meza, E. Madrid, C. Lóćzar, L. Garegnani, Minimal clinically important difference: the basics, Medwave 21 (3) (2021) e8149, https:// doi.org/10.5867/medwave.2021.03.8149.
- [31] Y. Mouelhi, É. Jouve, C. Castelli, S. Gentile, How is the minimal clinically important difference established in health-related quality of life instruments? Review of anchors and methods, Health Qual. Life Outcome 18 (1) (2020), https:// doi.org/10.1186/s12955-020-01344-w.
- [32] S.J. Kamper, C.G. Maher, G. Mackay, Global rating of change scales: a review of strengths and weaknesses and considerations for design, J. Man. Manip. Ther. 17 (3) (2009) 163–170, https://doi.org/10.1179/jmt.2009.17.3.163.