Study Protocol

Title

Virtual reality immersion therapy for symptom management in Palliative Care inpatients: feasibility trial.

Investigators

Henrique Nicola

MD

Derek Eng

MBBS, FAChPM

Sampath Kondasinghe

MBBS, FRACP, FAChPM

Emma Hale

CN BSN MCouns MPallCare

Paula Moffat

MBBS, FAChPM

Keiron Bradley

MBBS, FAChPM

Centre

Bethesda Healthcare

Claremont, WA

Background

 Optimising symptom management is part of the core of palliative care medicine practice. Both pharmacological and non-pharmacological are routinely implemented to improve patients comfort, well-being, and minimising symptoms such as pain, anxiety, fatigue, depression, among others. Recently, the use of virtual reality (VR) technology has made its way into the arsenal used to ameliorate these symptoms, and early studies in multiple settings have demonstrated promising results 1-4. However, literature specific to palliative care remains scarce5-9.

 Our study aims to provide refined data, specific to palliative care in-patient setting in order to asses VR technology use acceptability, tolerability, feasibility and initial efficacy in improving symptom control. The data obtained shall be used to provide important insight towards future research on VR technology role in palliative medicine practice.

Objectives

 Primary objective:

 - To establish acceptability, tolerability and feasibility of VR immersion therapy in palliative care in-patients.

 - To determine optimal duration and frequency, aka, “dosing”, of the immersion therapy

 Secondary objectives:

 - To collect data on symptoms incidence plus standard deviation

 - Initial clinical efficacy for symptoms improvement

Methods

 Study setting:

 1 in-patient Palliative Care unit in Perth, Western Australia.

 Design:

 This trial is set to be a prospective interventional non randomised trial.

 Inclusion criteria:

 - adult patient requiring treatment as palliative care in-patient

 - alert and orientated

 - expected to stay in hospital for more than 48 hours.

 Exclusion criteria:

 - one or more episodes of delirium during this hospitalisation

 - non-English speaking

 - contra-indications to using VR device: severe vertigo, seizures, monocular vision, simulation sickness.

Each eligible participant suitable to be part of the trial will be approached by a study investigator who will go through informed consent process, which will include verbal explanation of the trial in plain language and provision of the participant information form.
 Allocation to intervention group vs control group will occur in a 2:1 ratio – for every 2 participants allocated to intervention group, 1 will be allocated to the control group.

 Intervention group:

1 – will answer twice daily Symptom Assessment Scale (SAS) part of the Palliative Care Outcomes Collaboration (PCOC) in order to assess symptom severity (well validated tool for palliative care in-patients) [appendix 1] - this will be applied by either a member of the research group or a part of the healthcare team caring for the patient

2 – will have a choice of VR scenarios and initial duration (3 to 10 minutes) and frequency (once or twice daily).

3 – ongoing sessions duration of each immersion and frequency will be guided by patients’ preferences within the above options. Each participant will be asked daily of his, her or their preference – these sessions and questions will be applied by a member of the research team.

4 – duration of therapy will be up to 14 days or until patient is either: a) discharged home, b) developed a contra-indication or complication of the therapy, c) withdrew wish to continue, d) deceased.

5 - the participant will withdraw from the study should they wish to go a full day without having the therapy.

Visor Immersive was the chosen device due to its portability, ease of use and available software. The headset along with the software were trialed by all members of the research team. Their application is simple and no formal training is required.

Decontamination of the device with disinfectant wipes will be performed before and after each session.

 Participants can withdraw from the intervention at any time.

 Risk management of adverse effects:
 The reported incidence of serious side effects or harm by the literature secondary to the intervention proposed is close to zero.

 Side effects, uncommon and mild, include cyber sickness, vertigo, nausea, anxiety, claustrophobia, fear, discomfort, are quickly resolved immediately by ceasing the therapy/ removing the virtual reality headsets. There is no described long term or prolonged side effect in the literature. Infection control risks will be addressed by approval from infectious control department and careful handling/wiping of the devices before and after each use, as per recommended.

 Given the safe nature of the intervention, our risk management plan consists of excluding patients (as per exclusion criteria) at high risk for developing significant side-effects, explaining possible adverse effects at time of consent and removing device should a significant side-effect occur.

 Levels of discomfort and harm will be subjective and graded by the patient as mild, moderate or severe. If the side-effect is deemed moderate to severe, cessation of the virtual reality therapy will ensue.

In case a side-effect persists after removal of the device, symptomatic treatment will occur at the discretion of the treating clinician.

 Removal of the device in patients with mild side-effects, should they wish to do so, and trial of re-instating the headset after cessation of the side-effect, is allowed should the patient wish and the research team deem appropriate.

 Control group:
 A small control group receiving standard care will also be questioned using SAS PCOC twice daily for the duration of their hospital stay.

 Consent:

 Informed consent will be obtained for each participant.

Should the meet criteria to be a participant in this study, a researcher will approach the potential participant and provide verbal and written information, allowing for questions and reasonable time. Written information will be presented in the form of a participant information form, which covers:

 (a) any alternatives to participation;

 (b) how the research will be monitored;

 (c) provision of services to participants adversely affected by the research;

 (d) contact details of a person to receive complaints;

 (e) contact details of the researchers;

 (f) how privacy and confidentiality will be protected;

 (g) the participant’s right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

 (h) the amounts and sources of funding for the research;

 (i) financial or other relevant declarations of interests of researchers, sponsors or institutions;

 (j) any payments to participants;

 (k) the likelihood and form of dissemination of the research results, including publication;

 (l) any expected benefits to the wider community;

 (m) any other relevant information, including research-specific information required under other chapters of this National Statement.

 Participation is voluntary, and the potential participant must have sufficient information to consent.

Consent will be done in writing.

 Since confusion is an exclusion criteria, consent from next of kin does not apply to this trial.

 Data collection:

 Demographic details (age and gender), diagnosis, reason for admission, length of stay and discharge destination will be collected.

 Acceptability: we will collect eligible participants willingness to use VR therapy and reasons for it. A brief questionnaire will be applied by one of the study investigators to answer these questions separately from the informed consent process as part of the VR questionnaire [appendix 2].

 Feasibility: data on optimal duration and frequency of the VR therapy will be obtained from participants. They will be also questioned about barriers and challenges in the practical applications of the therapy [appendix 2].

 Tolerability: compliance and side effects incidence of VR therapy will be evaluated. Literature has suggested possible side effects might include cyber sickness, vertigo, fear, anxiety and discomfort. Data on incidence and severity of side effects will be recorded, and management of these will be done by the caring physician. Discontinuation of therapy due to side-effects is allowed and will also be recorded. A modified version of Evaluation of Virtual Reality intervention questionnaire5, 10 will be used [appendix 2].

 For assessment of symptom incidence and severity, we will use the well validated symptom assessment scale (SAS) section of the Palliative Care Outcomes Collaboration (PCOC) data collection chart. It consists of a multitude of symptoms which are scored by either patient or family member from 0 (symptom absent) to 10 (the worst possible). Participants will undergo this assessment twice daily [appendix 1]. Pharmacological requirements for symptom alleviation will also be recorded.

 Data will be analysed to answer study’s objectives and interpreted to provide insight into further research on VR therapy usage in palliative care settings.

Sample size

 To estimate participation rate, if we identify 50 eligible subjects, we will be able to estimate a drop-out rate of 50% to a confidence interval of 95% of +/- 13%.

 For a feasibility trial aiming to determine parameters such as incidence and standard deviation, sample sizes between 24 and 50 patients have been recommended by the literature. The control group will consist of 20 to 25 patients.

Ethical considerations

 The protocol will be submitted for ethical approval by the relevant committees of the study centre.

 Informed consent will be required from the participants before they are included in the trial.

 Data will be collected to the structured questionnaires and filled in paper. Data will then be transferred to a digital dataset in .xlsx format.

 Storage:
 The paper questionnaires will be stored in a locked file in the Bethesda Palliative Care department with only access to investigators of the study. Once the data has been transferred to digital format by both scanning the full pages and typing responses, paper questionnaires will be appropriately disposed of to locked confidential bins for shredding.
 The digital dataset will be stored utilising Cloudstor, in order to comply with UWA data management guidelines, for future statistical analysis and paper writing. This will be unidentified and password protected.

 Data retention:
 As a clinical trial is involved, research records will be retained for at least 25 year after the date of publication.
 Data sharing/ access:
 The level of sensitivity is confidential restricted, given medical information is collected. All efforts such as de-identification of participants and collection of only essential information, are taken to ensure confidentiality. Only the trial researchers will have access to the data, which will be password protected.
 Should a participant withdraw from study, the investigators will give the subject the options of 1 - only not further participating in the therapy and questions (data still retained and analysed) versus 2 - having all data erased and not being a part of the study at all.

 Once statistical analysis is completed, paper will be written and reviewed by the investigators. This will be followed by submission for publication to peer reviewed PubMed indexed medical journals.

 Particular attention will be given to chapter 4.3 of the National Health and Medical Research Council (NHMRC) National Statement, which addresses people in dependent or unequal relationships, since healthcare providers will be part of the team of investigators of this study. The group of investigators commits to the Statement’s recommendations of research merit and integrity, justice, beneficence and respect. Study participants might be well known patients of the investigators. To mitigate the risk of unequal relationships interfering in the potential participants choice, the study group will undertake the following measures:

o Allowing time for the participants to make their decision

o Provision of participant information form

o Allowing opportunities for potential participants to discuss with their family/ loved ones

o Allowing for potential participants opportunities to discuss the study with other staff not part of the investigators group

o Ensuring NO disadvantage or negative consequence will result from choosing not to participate on the trial

o Whenever possible, the informed consent process will be done by an independent person of the investigating group, not previously known or caring for the potential participant’s health

o Ensuring confidentiality

Funding

 For this feasibility trial, investigators will use paid clinical and non-clinical times. We have partnered with a Perth company called Visor Immersive, who are providing us with 2 virtual reality devices during this period. No additional funding for this feasibility trial is required.

Timetable

Submission for ethics approval: July/2022

Application for funding: not applicable

Data collection period: Third trimester of 2022 to second trimester of 2023

Data analysis: Third trimester of 2023

Manuscript writing: Third to fourth trimester of 2023

Submission for publication to follow.

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Appendix 1

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| --- | --- |
| S:\CHSD Shared\AHSRI programs\PCOC\PCOC_Logo_Best.PNG | (Please complete or affix Label here)UPI:SurnameFirst name:DOB:  |
| **Symptom Assessment Scale**Please use this form to tell us about the symptoms that bother, worry or distress you. This information will help us to meet your needs.**Moderate****Severe****Mild****Absent**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |

C:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion3.pngC:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion1.pngC:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion5.pngC:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion2.pngC:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion4.pngC:\Users\lthompso\Desktop\SAS drafts\SAS Icons Rooland\PCOC_Emotion0.png1. Write the day or date in the first row.
2. Use the scale above to choose a number between 0 and 10 that shows how bothered, worried or distressed you are.
3. You can add other symptoms in the blank space at the bottom of the list.
 |
| **Day or date** |  |  |  |  |  |  |  |  |  |
| Difficulty sleeping |  |  |  |  |  |  |  |  |  |
| Appetite problems |  |  |  |  |  |  |  |  |  |
| Nausea |  |  |  |  |  |  |  |  |  |
| Bowel problems |  |  |  |  |  |  |  |  |  |
| Breathing problems |  |  |  |  |  |  |  |  |  |
| Fatigue |  |  |  |  |  |  |  |  |  |
| Pain |  |  |  |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |  |  |  |

Appendix 2

**DATA COLLECTION SHEET: Evaluation of the Virtual Reality (VR) intervention**

**Virtual reality immersion therapy for symptom management in Palliative Care inpatients: feasibility trial.**

Participant number:
Age: Sex: Diagnosis: Reason for VR:
Date of assessment:

 **Media chosen**

**Length of time the equipment was used**

0- 5 minutes 6 – 10 minutes 11 – 15 minutes >16 minutes

**Participant’s reaction to VR**

Good Poor Indifferent

Please explain:

**Problems/complications**

Yes No
If yes please state:

**Other comments:**



**Questions for the participant**

**What did you think of the VR experience?**

**What did you like?**

**Can you tell me about any part of the VR experience you didn’t like?**

**Would you want to use this again? What are the reasons for this choice?**

**What could we do differently next time to improve the experience?**