Role of Virtual Reality (VR) in Decreasing Pain and Anxiety in Patients with Sickle Cell Disease (SCD) and Cancer

Protocol Summary

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1. Protocol Title: Role of Virtual Reality (VR) in Decreasing Pain and Anxiety in Patients with Sickle Cell Disease (SCD), Cancer, and Bone Marrow Transplant (BMT) Patients

2. Purpose of the Study: We propose implementing a feasibility study of the use of VR in patients with SCD, cancer, and bone marrow transplant patients. We plan to assess pain as well as anxiety and depressive symptoms prior to the session as well as following the session for inpatients and outpatients with SCD, malignancy, and patients undergoing/who underwent BMT. The sessions will include a ten-minute relaxation response introductory narrative segment (deep breathing and mindfulness) followed by a ten-minute narrated and immersive VR. **We hypothesize the use of VR will not only be feasible, but will also decrease pain, anxiety and depressive symptoms in hospitalized patients and outpatients with SCD, cancer, and BMT patients.**

3. Background & Significance: Pain, anxiety and depression contribute significantly to health care visits and subsequently contribute substantially to the cost of the healthcare system. In 2009-2010, visits related to mental health as primary concern accounted for over 63 million visits in the outpatient setting.[1] Patients with sickle cell disease (SCD) often have complicated courses while hospitalized and often deal with pain, anxiety, and depression. SCD is a chronic blood disorder with patients typically experiencing daily pain with frequent hospital admissions for worsened acute pain. Cancer and BMT patients also commonly deal with pain related to primary malignancy, side effects of chemotherapy, transplant complications, etc. They may also have symptoms of anxiety and depression in the setting of chronic illness.

Therapy is often focused on pharmacologic therapies, which are often not adequate and have side effects such as sedation. An increasing focus has therefore been placed on non-pharmacologic therapies. The scope of non-pharmacologic interventions has developed over the last several years with innovations in technology. Advances in the field of technology provide potential avenues for innovative and improved care models for our patients. Virtual reality (VR) has been recently utilized to improve anxiety and pain in a variety of patient populations including children undergoing elective surgery[2] and children experiencing intravenous cannulation in the Emergency Department.[3] Patients with SCD, cancer, and BMT patients are groups of patients that can benefit from VR as part of their care as VR has shown effectiveness in providing remarkable non-pharmacologic therapy.

4. Design & Procedures: We will perform a feasibility and pilot study evaluating relaxation response (narration leading through deep-breathing, mindfulness, and other relaxation techniques) followed by VR in patients with sickle cell disease (SCD), cancer, and BMT patients. The VR headset (Dynamic Virtual Viewer or similar device) used will be compatible with an iPhone application titled Provata VR. The devices are provided by the study personnel. The virtual reality headset is commercially available. Different VR headsets have been used in prior studies, some compatible with computer programs and other compatible with a Samsung

device. The VR session will be narrated by Jon Seskevich, RN, and the image through the Provata VR mobile application has been chosen by the study team.

They will then listen to a ten-minute relaxation response recording by Jon Seskevich, RN on an iPhone. Following this, the image on Provata VR will be opened, the narration of the VR image by Jon Seskevich, RN will be started on the iPhone, and the VR headset secured. The patient should be sitting or lying down for the VR portion of the session to decrease the risk of injury. The audio narration will play while the patient is viewing the VR image. The study team will be supervising the patient while the headset is in use. No patient data will be stored on the iPhone, it simply allows the patient to view the VR image through the VR headset with narration by Jon Seskevich, RN. During the entire session, patients will also wear an Apple iWatch to passively record objective data such as heart rate through the Health app. For 30 minutes prior to and following the session, patients will also wear the Apple iWatch.

The patients will first be provided a consent form and consented. They will have the opportunity to ask questions prior to and following consent. They will subsequently fill out a GAD-7 (Generalized Anxiety Disorder) and PHQ-9 (Patient Health Questionnaire) form. They will complete the session described above. Patients will also provide an initial pain score and answer questions through the TRU-Pain app. Following this, patients will complete another GAD-7, PHQ-9, pain score, Presence Questionnaire, Feasibility Questionnaire, Patient's Global Impression of Change (PGIC) form, and answer questions in the TRU-Pain app. Patients will then be able to ask questions/provide further feedback.

5. Selection of Subjects: A total of 60 subjects, including inpatients and outpatients with SCD, malignancy, and patients undergoing/who underwent BMT. Approximately half of these patients will be inpatient and half will be outpatient. These patients must have a diagnosis of chronic or acute pain (current pain or baseline pain score >0) or have at least one symptom of anxiety or depression as measured by the GAD-7 or PHQ-9 questionnaires (positive response to any question).

6. Subject Recruitment & Compensation: Admitted patients with SCD, malignancy, or BMT patients for malignant or non-malignant disorders on the Hematology/Oncology and Bone Marrow Transplant Services in addition to outpatients with SCD, malignancy, and BMT patients for malignant and non-malignant reasons will be eligible for participation. This study will be known to Hematology, Oncology, and Bone Marrow Transplant providers. Personnel from this study will present to clinic and assess with other providers if certain patients being seen that day would fit the inclusion criteria for the study. The patient's primary care team alerts study personnel of their possible eligibility and interest. No further recruitment will likely be needed. Patients will not be compensated and the study/session involves minimal risk to the patient. As per Duke University protocol, there will be no "cold contact" whereby a patient is approached by the research team without the study having been introduced by a person known to the patient before.

7. Consent Process: Risks/benefits will be explained to the patient as well as their parent(s)/guardian(s) as part of the consent process and they will have the ability to review the consent form. As much time as needed will be given for the adult patients, and the minor patients along with their parents, to make an informed decision. All questions and concerns will be answered to the potential subject's satisfaction and will verbalize understanding prior to signing the consent form.

8. Subject's Capacity to Give Legally Effective Consent: Individuals (or parents of minors) that cannot read and/or understand the requirements, and "no guarantee" of benefit of the study will not be eligible for participation. The protocol of this study targets populations that are unlikely to have impaired decisional capacity. If there is a concern for impaired capacity during the clinical interview, that patient will be excluded from the study. Parents of minors are expected to provide consent, but may be excluded from providing consent and thereby the patient excluded from the study if the parent is unable to read, cannot speak or understand English, or has impaired capacity to give legally effective consent.

9. Study Interventions: A 30 minute session with ten-minute relaxation response and ten-minute narrated VR with surveys before and after session. Patients will wear an Apple iWatch to passively record objective data. Patients will also wear an Apple iWatch for 30 minutes prior to and 30 minutes following session to record objective data passively.

10. Risk/Benefit Assessment: This study involves minimal risk given the imagery/narrative used will likely either be seen in a neutral or positive light. Loss of PHI and breech of patient confidentiality are possible risks. The potential benefits include improvement in anxiety and/or depressive symptoms. The results of this study will be critical as feasibility and pilot analysis to use for power analysis and future grant submissions with additional collaborators. Minimal risk to using TRU-Pain app given the data gathered is de-identified.

11. Costs to the Subject: The subjects will not have any costs associated with the study other than the utilization of approximately 90 minutes of their time for the session.
Routine medical care will be charged to the subject ore their insurance company.

12. Data Analysis & Statistical Considerations: The endpoints of the study are feasibility of 30-minute VR sessions and change in pain, GAD-7, and PHQ-9 scores. Study personnel with assistance of Duke statistician if needed will analyze the data to determine if any significant change in GAD-7 and PHQ-9 was noted in any group with the study intervention. This data/outcome of the study will be used to power future studies.

A sample size of approximately 60 is appropriate given this is a feasibility study. Within 1 year, these patients hopefully will be reached.

13. Data & Safety Monitoring: The data will be obtained with the use of Duke Box to maximize the protection of each patient's data. Objective data collected on the Apple iWatch

will be uploaded to Citrix Sharefile via the TRU-Pain HKO app and will subsequently be transferred to Duke Box. Data gathered from the TRU-Pain app will be sent to Citrix Sharefile and Duke Box as well. There will not be an independent data monitoring committee for this study. The PI will review and sign off on all adverse events and any problems. These will be reported to the IRB in accordance with HRPP policies.

14. Privacy, Data Storage & Confidentiality: Patient privacy will be maximized by allowing only the patient, their parent(s)/guardian(s) and the study personnel during the session. Data will be stored with the use of Duke Box and Citrix Sharefile to maximize patient confidentiality. All subjects are assigned a unique study number when enrolling. Study staff will follow all HIPPA guidelines when enrolling and explaining the study to subjects and their parents. All doors will be kept closed and all human traffic into the area kept to a minimum. All study related documents are kept in a locked file in the research offices in Hanes House, Room 273. No PHI will leave DUHS. All computer databases are password protected. Only staff involved with the study have access to the study data. All study related documents will be kept per requirements for 6 years after the close of the study.

Bibliography

[1] National Center for Health Statistics: Mental Health. CDC. https://www.cdc.gov/nchs/fastats/mental-health.htm

[2] Chow, C.H., et. al. Systematic Review: Audiovisual Interventions for Reducing Preoperative Anxiety in Children Undergoing Elective Surgery. Journal of Pediatric Psychology. 2016:41(2):182-203.

[3] Miller, K., et. al. A Prospective Randomized Controlled Trial of Nonpharmacological Pain Management During Intravenous Cannulation in a Pediatric Emergency Department. Pediatric Emergency Care. 2016:32(7):444-451.