Study Protocol

Official Title:
The Effects of Virtual Reality with Debriefing on Patients with Chronic Pain

ClinicalTrials.gov ID (NCT number):
NCT04236804

Protocol Date:
2024-12-20

Scientific Background

Chronic musculoskeletal pain, defined as persistent or recurrent pain lasting more than three months, is a disabling condition with significant physiological and psychosocial implications. Unlike acute pain, chronic pain serves no adaptive purpose, as it often persists after the original precipitating event (e.g., fracture, sprain, trauma) has resolved.

Immersive Virtual Reality (IVR) has shown potential as a treatment for acute pain, but its use for chronic pain remains underexplored. IVR enables individuals to immerse themselves in a three-dimensional environment, promoting normal movement patterns by distracting them from their pain. This study examines the effects of IVR combined with occupational therapy (OT) to determine whether it reduces chronic pain and associated symptoms more effectively than OT alone.

Study Objectives

- Primary Objective: To evaluate changes in Morphine Milligram Equivalent (MME) use from baseline to three months in patients receiving OT with or without IVR.
- Secondary Objectives:
  - To assess changes in chronic pain intensity using the Numeric Pain Rating Scale.
  - To evaluate self-efficacy, fear of movement, and functional participation using validated scales, including the Pain Self-Efficacy Questionnaire, the Tampa Scale of Kinesiophobia, and the Goal Attainment Scale.
  - To assess changes in patient-reported outcomes such as sleep disturbance, physical function, and emotional well-being using PROMIS measures.

Study Design & Methods

- Study Type: Interventional
- Allocation: Randomized
- Interventional Model: Parallel Assignment
- Masking: None (Open Label)
- Primary Purpose: Treatment

Arms and Interventions:

1. Active Comparator: Occupational Therapy (OT)
   - Participants receive six 1-hour outpatient OT sessions tailored to chronic pain management, including education, exercises, stress management, and daily activity planning.
2. Experimental: Occupational Therapy + Virtual Reality (OT+VR)
   - Participants receive a combination of OT and 10–30 minutes of IVR during each session. IVR sessions include interactive exercises and games, followed by therapist-led debriefing.

Measurements:

- Participants complete surveys before and after each therapy session.
- Additional bi-weekly online surveys are administered for the study duration.

Eligibility Criteria

Inclusion Criteria:

- Adults aged 18 years or older.
- Referred for chronic pain OT at UPMC Centers for Rehab Services.

Exclusion Criteria:

- History of seizure disorders or recent VR intervention.
- Sensory insensitivity or contagious facial disorders incompatible with VR headset use.
- Insufficient cognitive ability or physical coordination for IVR use.

Statistical Considerations

This study was designed to evaluate the effects of occupational therapy with or without immersive virtual reality on MME and patient-reported outcomes over an 8-week period. Following consultation with study clinicians, the primary outcome was revised to focus on patient-reported changes in MME from baseline to 8 weeks, ensuring alignment with the study's therapeutic goals.

Primary Analysis:

- Within-group changes in MME and PROMIS measures from baseline to 8 weeks will be analyzed using paired t-tests or Wilcoxon signed-rank tests (for non-normally distributed data).
- Between-group differences will be assessed using independent t-tests or Mann-Whitney U tests.

Secondary Analysis:

- Changes in PROMIS measures (e.g., pain intensity, fatigue, and depression) will be analyzed using similar methods. Adjustments will be made for baseline values in secondary outcomes using linear regression.

Handling Missing Data:

- Missing data will be addressed using multiple imputation under the assumption that data are missing at random. Sensitivity analyses will compare results from imputed datasets with complete-case analyses.

Adjustment for Covariates:

- Analyses will adjust for baseline MME, PROMIS scores, and demographic factors (age, gender) where appropriate.

Challenges Due to Small Sample Size:

- The study's small sample size (n=20) limits statistical power, increasing the risk of Type II error and reducing the ability to detect small-to-moderate effect sizes. This limitation may affect the robustness of statistical inferences. Findings should be interpreted with caution and viewed as exploratory in nature.

Software:

- All statistical analyses will be performed using R (version 4.3.1). Detailed analysis scripts will be maintained to ensure reproducibility.

Subgroup and Sensitivity Analyses:

- Subgroup analyses will examine treatment adherence and baseline PROMIS scores. Sensitivity analyses will explore the impact of different imputation methods for missing data.