Official Study Title: *The Effect of Virtual Reality on Pain and Patient Satisfaction in Adults Receiving Genicular Nerve Radiofrequency Ablation*

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Study Protocol

Study Title

The Effect of Virtual Reality on Pain and Anxiety in Adults Receiving Genicular Nerve Radiofrequency Ablation

Principal Investigator

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1. Background and Rationale

This study aimed to investigate whether Virtual Reality (VR) therapy could reduce procedural pain and anxiety in adults undergoing genicular nerve radiofrequency ablation (GNRFA). The study utilized the SootheVR system, a medically curated immersive VR device, during the procedure. VR therapy has emerged as a promising non-pharmacologic adjunct for managing procedural discomfort and anxiety.

2. Study Objectives

Primary Objective:
- To evaluate the effect of VR therapy on post-procedural pain levels using the Visual Analog Scale (VAS).

Secondary Objectives:
- To assess pre- and post-procedure anxiety scores.
- To measure patient satisfaction with the procedure.
- To assess provider satisfaction and perception of patient pain.
- To determine the use of additional local anesthetic.

3. Study Design

This was a randomized, non-blinded, single-site interventional study. Participants undergoing GNRFA were randomized to either receive standard care alone or standard care plus VR therapy using the SootheVR headset. Surveys were administered before and after the procedure to collect pain, anxiety, and satisfaction scores. Data were entered via Qualtrics.

4. Eligibility Criteria

Inclusion Criteria:
- Adults ≥18 years
- Undergoing genicular nerve radiofrequency ablation
- Ability to consent

Exclusion Criteria:
- Need for sedation during procedure
- Cognitive impairment
- Neurological contraindications (e.g., epilepsy)
- Refusal or intolerance to VR headset
- Pregnancy
- Motion sickness, visual/auditory impairments affecting headset use

5. Study Procedures

Participants were screened and consented on the day of the procedure. Baseline pain, anxiety, and prior VR experience were recorded via survey. Participants were then randomized to either VR or control group. Standard GNRFA was performed using fluoroscopy guidance. The VR group used the SootheVR headset during the procedure. Post-procedure, surveys captured outcome data including pain, anxiety, and satisfaction metrics.

6. Statistical Analysis Plan

Data were analyzed using descriptive statistics and comparative tests. Paired t-tests or Wilcoxon signed-rank tests were used to evaluate changes in pain and anxiety scores. Group comparisons were conducted using independent t-tests or Mann-Whitney U tests where applicable. Significance was set at $p < 0.05$.

7. Data Management

Data were entered into Qualtrics and exported to secure institutional drives for analysis. No protected health information was stored outside of secure UCI systems. Only authorized personnel had access to the data. Surveys and raw data were retained for IRB compliance and results reporting.

8. Ethics and Oversight

This study was reviewed and approved by the University of California, Irvine Institutional Review Board (IRB #2020-6207). All participants gave informed consent. Data confidentiality was maintained throughout the study. The study was minimal risk and included monitoring for adverse reactions to VR technology.

9. Study Status

The study has been completed. Enrollment and data collection are finalized. Results analysis is underway and will be submitted to ClinicalTrials.gov.