Study Protocol with Statistical Analysis Plan

Official Title:

Effectiveness of Augmented Reality as a Distraction Technique for Reducing Pain and Anxiety in Pediatric Dental Extractions: A Parallel-Group, Double-Blind Randomized Controlled Trial

NCT Number: NCT06954883

Unique Protocol ID: 17-2024-0004

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1. Administrative Information

Principal Investigator: Ahmed Kamel Abdel Naser

Institution: Faculty of Dentistry, Assiut University Dental Hospital

Trial Registration: ClinicalTrials.gov (NCT06954883)

Unique Protocol ID: 17-2024-0004

2. Background and Rationale

Pediatric dental anxiety and pain are common barriers to care.

Augmented Reality (AR) may reduce distress by immersive distraction.

Hypothesis: AR distraction will reduce pain and anxiety vs. Tell–Show–Do.

3. Objectives

Primary: To evaluate the effect of AR distraction on pain (Wong-Baker FACES).

Secondary: To evaluate effect on anxiety (CFSS-DS) and heart rate.

4. Study Design

Randomized, controlled, parallel-group, single-blind trial.

Setting: Pediatric Dentistry Clinic, Assiut University Dental Hospital.

5. Participants

Eligibility: Children aged 6–10 years, requiring tooth extraction, ASA I.

Exclusion: Visual/hearing impairment, neurological disorders, traumatic dental history.

6. Interventions

AR group: 30 children wore AR headset during anesthesia and extraction.

Control group: 30 children received Tell–Show–Do technique.

7. Outcomes

Primary: Pain (Wong-Baker FACES, 0–10).

Secondary: Anxiety (CFSS-DS, 15–75), Heart rate (bpm).

8. Sample Size Calculation

Based on 2-point difference in Wong-Baker scale, power 80%, alpha=0.05.

25 per group needed, increased to 30 per group (N=60).

9. Randomization and Blinding

Block randomization, sealed envelopes for allocation concealment.

Outcome assessors blinded to group allocation.

10. Statistical Analysis Plan

Analysis: Intention-to-treat. Significance $p<0.05$, two-sided.

Continuous data: Mean ± SD, compared with t-tests (independent/paired).

Effect size (Cohen's d) calculated. Missing data <5% complete case.

Secondary outcomes analyzed similarly. Sensitivity analysis: per-protocol.

11. Ethics and Dissemination

Approved by Institutional Review Board, informed consent obtained.

Trial conducted per Declaration of Helsinki. Results to be published.