

A trial on the use of virtual reality in children during dental local anesthesia

Submission date 13/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 11/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/10/2026	Condition category Oral Health	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Many children feel anxious or experience pain when receiving a local anaesthetic injection during dental treatment. Anxiety and pain can make dental visits more difficult for children, parents, and dental professionals. Virtual reality (VR) technology may help distract children during medical and dental procedures, reducing their discomfort and fear. This study aims to find out whether using a VR headset during a dental injection can reduce pain, anxiety, and distress in children compared with standard care.

Who can participate?

Children aged 4 to 10 years who are generally healthy, have not had dental treatment or visited a dental setting in the previous six months, and whose parent or guardian agrees to participation can take part.

What does the study involve?

After parents or guardians provide consent, participating children are randomly allocated to one of two groups. One group receives local anaesthetic injections while wearing a VR headset, while the other group receives the injection without VR. Before treatment, measurements are taken including pulse rate and behaviour scores. Additional measurements are recorded during and after the injection. Researchers assess anxiety using pulse oximeter readings, behaviour using validated behavioural scales, and pain using a child-friendly pain rating scale. The results from the two groups are compared to determine whether VR reduces anxiety, pain, and distress during dental injections.

What are the possible benefits and risks of participating?

Children using VR may experience less anxiety and discomfort during the dental procedure. The study may help identify effective ways to improve children's experiences of dental treatment in the future. Risks are expected to be minimal and are mainly related to the routine dental injection. Some children may find the VR headset uncomfortable or may not wish to use it.

Where is the study run from?

Faculty of Dental Medicine, Alaa Redwan, Umm Al-Qura University, Makkah, Saudi Arabia.

When is the study starting and how long is it expected to run for?

The study started recruiting participants in March 2024. Recruitment was completed in May 2025 and the study finished in May 2025.

Who is funding the study?

Faculty of Dental Medicine, Alaa Redwan, Umm Al-Qura University, Makkah, Saudi Arabia.

Who is the main contact?

Dr Alaa Redwan, akredwan@uqu.edu.sa

Contact information

Type(s)

Principal investigator, Scientific, Public

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Study information

Scientific Title

Virtual reality for pain and anxiety control during local anesthesia in a pediatric dental teaching clinic: a randomized controlled trial

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 01/01/2024, The Biomedical Research Ethics Committee at Umm Al-Qura University (Umm Al-Qura University Makkah P.O.Box 715, Makkah, 24381, Saudi Arabia; +966125280347; cscenterQuqu.edu.sa), ref: HAPO-02-K-012-2024-01-1940

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Health services research, Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Pain and anxiety during local anesthesia in pediatric dentistry

Interventions

Participants were randomly allocated to treatment groups using numbered, opaque, sealed envelopes to ensure allocation concealment. The first group received local anesthesia while using the VR device (intervention group) while the other received local anesthesia without the VR device (control group). The VR was placed for about 4-5 minutes depending on the child and the operator and that was only once during the LA insertion.

Intervention Type

Device

Phase

Phase II

Drug/device/biological/vaccine name(s)

Virtual Reality (VR)

Primary outcome(s)

1. Anxiety measured using pulse oximeter at before, during and after LA administration
2. Behavior measured using the Visual Analogue Scale (VAS) at before, during and after LA administration
3. Behavior measured using FLACC (Face, Legs, Activity, Cry, Consolability) scale at during LA administration
4. Pain measured using the Wong-Baker Pain Scale (WBPS) at after LA administration

Key secondary outcome(s)

Completion date

08/05/2025

Eligibility

Key inclusion criteria

1. No prior exposure to the dental setting or treatment procedures during the past 6 months
2. Classified as ASA I or II
3. Willing to participate in the study

Healthy volunteers allowed

Yes

Age group

Child

Lower age limit

4 Years

Upper age limit

10 Years

Sex

All

Total final enrolment

85

Key exclusion criteria

Children or parents who refused participation in the study

Date of first enrolment

21/03/2024

Date of final enrolment

08/05/2025

Locations

Countries of recruitment

Saudi Arabia

Sponsor information

Organisation

Umm Al-Qura University

Funder(s)

Funder type

Funder Name

Umm Al-Qura University

Alternative Name(s)

UQU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/09/2026	No	Yes
Protocol file			21/09/2026	No	No