Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of augmented reality (AR) technology in reducing pediatric pain and anxiety in dentistry

Protocol summary

Study aim
Investigating the Effect of Augmented Reality Technology in Reducing Pain and Anxiety in Pediatric Dentistry

Design
A randomized clinical trial with a control group, parallel-group design, and no blinding, conducted on 32 patients. Randomization was performed using sealed envelopes.

Settings and conduct
It will be conducted on 32 children aged 6 to 12 years who are visiting the pediatric dentistry department for the first time. Each participant will undergo two dental visits, and one tooth will receive local anesthesia in each session. In one visit, augmented reality (AR) will be applied using Meta Quest 3 headset, while in the other visit, no AR will be used. Study location: Kerman Dental School – Department of Pediatric Dentistry

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Children aged 6 to 12 years, Requiring local dental anesthesia, No systemic diseases (e.g., cardiovascular or severe anxiety disorders),Mentally and communicatively capable, No allergy to local anesthetic drugs, Written informed consent obtained from the parents. Exclusion Criteria: History of severe dental phobia, Visual or neurological impairments preventing use of AR glasses, Use of analgesics within the previous 48 hours, Previous dental treatment experience, Significant behavioral management problems impeding study participation.

Intervention groups
Local anesthesia will be administered by a pediatric dentistry resident under faculty supervision using Lidocaine 1:80000 (Darou Pakhsh, Iran). In the intervention group, the Meta Quest 3 AR headset (Meta, USA) will be used during injection, while the control group will receive the injection without any distraction device.

Main outcome variables
Pain score; Anxiety level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250712066454N1**
Registration date: **2025-09-04, 1404/06/13**
Registration timing: **prospective**

Last update: **2025-09-04, 1404/06/13**
Update count: **0**

Registration date
2025-09-04, 1404/06/13

Registrant information

Name
Mojtaba Madadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of augmented reality (AR) technology in reducing pediatric pain and anxiety in dentistry

Public title
the effect of augmented reality glasses in reducing pain and anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged between 6 and 12 years. Requiring bilateral local anesthetic injection for dental procedures. No systemic diseases such as cardiovascular conditions or severe anxiety disorders. Mentally capable of communication. No known allergy to local anesthetic agents. Written informed consent obtained from the child's parents.
Exclusion criteria:
History of severe dental fear or phobia. Visual or neurological impairments preventing the use of AR glasses. Use of analgesic medications within 48 hours prior to treatment. Previous dental treatment experience. History of significant behavioral management issues that hinder clinical cooperation.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant (child aged 6 to 12) serves as a split-mouth experimental unit. This means each child must have two similar teeth requiring local anesthesia, treated during two separate visits:1. First visit: Injection with the use of augmented reality glasses (Meta Quest 3), 2. Second visit: Injection without augmented reality. Thus, each child provides two dental samples (one with AR, one without), allowing for intra-individual comparison.
Randomization (investigator's opinion)
Randomized
Randomization description
Before the treatment begins, written informed consent is obtained from the parents. Participants are randomly assigned to two groups. For randomization, sealed envelopes are prepared. Treatment Envelope 1: The first visit involves local anesthesia with the use of Meta Quest 3 headset, during which the child is fully immersed in a virtual environment. The second visit involves anesthesia without the headset. Treatment Envelope 2: The first visit involves local anesthesia without the headset, and the second visit involves anesthesia with the Meta Quest 3 headset and full immersion in the virtual environment. The envelopes are sealed and placed in a box. A clinic secretary who is unaware of their contents randomly selects one envelope for each participant. The assigned intervention is then registered and performed by a pediatric dentistry resident. The second visit is conducted by the same resident two weeks after the first visit.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman university of medical sciences
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Kerman University of Medical Sciences, Shafa crossroad, Jomhuri Eslami Blvd.
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kerman
Province
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Approval date
2025-06-21, 1404/03/31
Ethics committee reference number
IR.KMU.REC.1404.192

Health conditions studied

1

Description of health condition studied
Pain and anxiety caused by dentistry
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain Level
Timepoint
Immediately after the intervention
Method of measurement
Wong-Baker Scale, Face, Legs, Activity, Cry, Consolability Scale

2

Description
Physiological Anxiety (Heart Rate)
Timepoint
Before the intervention, During the intervention, Immediately after the intervention
Method of measurement
Fingertip Pulse Oximeter

3

Description
Dental Anxiety (DAS Score)
Timepoint
On the same day following the intervention
Method of measurement
Dental Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: The local anesthetic injection for all teeth will be administered by a pediatric dentistry specialist resident under the supervision of the relevant professor. The treatment steps and the use of the Meta Quest 3 augmented reality headset (Meta, USA) will be thoroughly and precisely explained to the resident. Before the treatment session begins, the use of the headset will be explained to the child in simple terms for 3 minutes, and they will be allowed to interact with it to feel comfortable. The child will wear the headset 2 minutes before the injection to acclimate to the virtual environment. A 3D animation titled 'Jungle Quest,' specifically designed to reduce anxiety and featuring nature and jungle animals, will be played. This animation is free of stressful content and includes calm, relaxing music. While immersed in this augmented reality environment, a 1.5 mL local anesthetic injection of Lidocaine 1:80000 (Perzocaine, Darou Pakhsh Company, Tehran, Iran) will be administered using a 30-gauge needle. The headset will remain on the child's head for 1 minute after the injection is complete. The total duration of headset use will be approximately 5 minutes for each injection. Other medical equipment includes an A3 model pulse oximeter (made in China), which will be placed on the child's finger solely for monitoring vital signs.
Category
N/A

2

Description
Control Group: Local anesthesia for all teeth will be administered by a pediatric dentistry specialist assistant under the supervision of the relevant professor. The treatment steps will be thoroughly and precisely explained to the assistant; however, no Meta Quest 3 augmented reality headset (Meta, USA) or any other distraction tool will be used.The procedure will be as follows: Before the injection, the child will be seated in the dental unit. An A3 fingertip pulse oximeter (CN, China) will be placed on the child's index finger, and their heart rate will be recorded prior to the intervention. No headset or distraction device will be applied. Local anesthesia will be administered using lidocaine 1:80000 (Perzocaine, Darou Pakhsh Company, Tehran, Iran).During the injection, a trained observer will record the child's pain using the FLACC scale. The child's heart rate during the injection will be recorded using the A3 fingertip pulse oximeter (CN, China). After the injection, the child's heart rate will again be recorded with the A3 fingertip pulse oximeter (CN, China). The child will then self-report their pain level using the Wong-Baker scale. Treatment will proceed afterward. At the end of the session, the child will complete the DAS questionnaire to assess their level of anxiety.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman university of medical sciences, Faculty of dentistry
Full name of responsible person
Elham Faroukh Ghisor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Associate Professor of pediatric dentistry
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document

Only a portion of the data is shared, such as the original outcome information.

When the data will become available and for how long

Access period begins 6 months after results are published.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

For researchers

From where data/document is obtainable

Faroukh@kmu.ac.ir; Dr.mojtaba.madadi@gmail.com

What processes are involved for a request to access data/document

1 month

Comments