Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Virtual Reality versus Standard Care for Pain Management in Children 6-12 Years Old: A Randomized Controlled Trial

Protocol summary

Study aim

Evaluation of the effect of virtual reality on pain levels in children aged 6 to 12 years during dental procedures

Design

Randomized controlled clinical trial, with parallel groups and a 1:1 allocation ratio, on 36 children aged 6 to 12 years. A block method (block size 4) was used for randomization. Due to the nature of the intervention, blinding of participants and dentist was not possible, but the data analyst was blinded to group allocation.

Settings and conduct

This study was conducted in at Labkhand Dental Clinic, Kashan, on children aged 6 to 12 years. After screening and assessment with the SCARED questionnaire, participants were randomly assigned to two intervention and control groups. The intervention included the use of a virtual reality headset for 10 to 15 minutes simultaneously with local anesthetic injection. no Blinding

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age 6–12 years 2.Healthy (ASA I or II) 3.No prior VR experience 4.SCARED score ≥ 25 (no significant anxiety) 5.Parental consent and child assent Exclusion criteria: 1.History of seizures, epilepsy, or heart disease 2.Motion sickness, nausea, or vomiting 3.Psychiatric or developmental disorders 4.Active infection, inflammation, or nocturnal pain 5.Wearing eyeglasses 6.SCARED score < 25 (significant anxiety)

Intervention groups

Virtual reality group (18 people): Use of VR headset along with conventional behavioral techniques and local anesthetic gel. Control group (18 people): Conventional behavioral techniques and local anesthetic gel, without use of VR.

Main outcome variables

Primary outcome: Pain level during local anesthetic injection, measured using the Wong-Baker Faces Pain Scale (WBFPS) – self-report. Secondary outcomes: Heart rate (HR) and blood oxygen saturation (SpO_2) measured via pulse oximetry at multiple stages; anxiety measured using SCARED questionnaire at baseline.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260601069600N1**
Registration date: **2026-07-14, 1405/04/23**
Registration timing: **prospective**

Last update: **2026-07-14, 1405/04/23**
Update count: **0**

Registration date

2026-07-14, 1405/04/23

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-16, 1405/04/25

Expected recruitment end date

2026-10-17, 1405/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Virtual Reality versus Standard Care for Pain Management in Children 6-12 Years Old: A Randomized Controlled Trial

Public title
Effect of Virtual Reality on dental pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 6 to 12 years, classified as American Society of Anesthesiologists (ASA) physical status I or II (indicating a healthy patient or one with mild systemic disease). 3.Absence of visual or auditory impairments. Good general physical health. Absence of visual or auditory impairments. No documented history of epilepsy, seizures, or cardiovascular conditions. No cognitive impairments, balance disorders (e.g., vertigo), or active conditions such as nocturnal pain, infection, or inflammation. No prior history of sedative injections, or a history where the most recent injection occurred more than six months before the study. No previous experience with virtual reality (VR) headsets. No documented history of anxiety disorders. A score of 25 or above on the Screen for Child Anxiety Related Disorders (SCARED) questionnaire, suggesting the absence of clinically significant anxiety. Written informed consent provided by a parent or legal guardian, along with assent from the child participant.

Exclusion criteria:
History of motion sickness, nausea, or vomiting. Current treatment for psychiatric disorders (e.g., psychosis, post-traumatic stress disorder) or developmental/intellectual disabilities. A known history of epilepsy or seizures. A known history of cardiovascular disease. Presence of nocturnal pain, active infection, or inflammation. Any prior use of VR headsets. Patients presenting for tooth extraction or treatment of dental infections who had no history of prior invasive medical or dental procedures. A score below 25 on the SCARED questionnaire, indicating potential anxiety disorders. Current treatment for psychiatric disorders (e.g., psychosis, PTSD) or developmental/intellectual disabilities. Use of eyeglasses, due to potential interference with the VR headset fit and visual experience.

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: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to either the intervention group (sedation with virtual reality [VR] distraction) or the control group (sedation without VR distraction) using a block randomization method with a fixed block size of four. The allocation sequence will be generated by an independent statistician and will be maintained by a third party to ensure allocation concealment. Investigators and clinical personnel responsible for participant recruitment will be blinded to the allocation sequence throughout the enrolment process. Group assignments will be revealed only after participant enrolment has been completed, thereby minimizing the risk of selection bias. Due to the nature of the intervention, blinding of participants and the treating clinician will not be feasible, as the use of the VR headset will be readily identifiable during the procedure. However, statistical analyses will be conducted by a blinded data analyst, and group allocations will be coded before analysis to reduce the potential for analytical bias.

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 Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Hekmat Street, Qotb e Ravandi Boulevard, Kashan, Isfahan Province, Iran

City
Kashan

Province
Isfehan

Postal code
8715973449

Approval date
2026-06-28, 1405/04/07

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1405.016

Health conditions studied

1

Description of health condition studied
Tooth caries and pulpotomy and root canal treatment

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Dental Pain

Timepoint

During anesthesia injection (during the intervention)

Method of measurement

Wong-Baker Faces Pain Scale (WBFPS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group (Virtual Reality Group): Participants in the intervention group received standard care in addition to a virtual reality (VR) intervention using the Shinecon VR G02ED headset connected to an iPhone 12. The VR equipment was first introduced to the child and parent using the Tell–Show–Do technique. Each child then selected one of three animated films (Finding Nemo, Kung Fu Panda 3, or Despicable Me 2) and watched it for 5 minutes before and during the administration of the local anesthetic injection. The total duration of VR exposure was 10–15 minutes. Standard care included behavioral management techniques (storytelling, singing, watching cartoons on a screen, and playing with toys) together with the application of a topical anesthetic gel before the injection. Heart rate and oxygen saturation were monitored using a pulse oximeter before VR use, after VR initiation, during the injection, and after the injection. All local anesthetic injections were administered by the same pediatric dentist. Following completion of the injection, the VR headset was removed and the dental treatment proceeded as planned. Following the treatment, the children's self-reported pain levels during the local anesthetic injection procedure were assessed using the Wong-Baker Faces Pain Scale (WBFS).

Category

Behavior

2

Description

Control Group: Participants in the control group received standard care only, which consisted of conventional behavioral management techniques (storytelling, singing, watching cartoons on a screen, and playing with toys) together with the application of a topical anesthetic gel before the local anesthetic injection. No virtual reality headset was used in this group. All local anesthetic injections were administered by the same pediatric dentist. Heart rate and oxygen saturation were monitored using a pulse oximeter before the injection, during the injection, and after the injection. After completion of the injection, dental treatment continued according to the routine clinical protocol. Following the treatment, the children's self-reported pain levels during the local anesthetic injection procedure were assessed using the Wong-Baker Faces Pain Scale (WBFS).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Labkhand Dental Clinic

Full name of responsible person

Amene Taghdisi Kashani

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Labkhand Dental Clinic, Goli Alley, Beheshti Street, Kashan

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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
Kashan 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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Deidentified individual participant data (IPD) will not be shared in order to protect participant confidentiality and in accordance with the ethical approval of the study and institutional policies. Furthermore, the informed consent process did not include a plan for sharing individual participant-level data with external researchers.
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
Not applicable
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Study documents, including the study protocol, the statistical analysis plan (SAP), and the informed consent form template. These documents describe the study design, methodology, outcome measures, statistical

methods, and ethical procedures used in the trial. No deidentified individual participant data (IPD) or participant-level datasets will be shared.

When the data will become available and for how long

The study documents will become available upon publication of the primary study results in a peer-reviewed journal and will remain available for five years. Approved documents will be provided electronically upon reasonable request to eligible researchers.

To whom data/document is available

The study documents (including the study protocol, the statistical analysis plan, and the informed consent form template) will be available only to qualified researchers affiliated with recognized academic or research institutions. Requests must be submitted using a valid institutional email address and sent directly to the corresponding author. Applicants should clearly describe the purpose of their request. The documents may be used solely for scientific research and educational purposes. Commercial use, including use by pharmaceutical companies, medical device manufacturers, or other commercial organizations, is not permitted. Recipients must agree not to redistribute the documents to third parties without prior written permission. A response will normally be provided within 14 working days after receipt of a complete request.

Under which criteria data/document could be used

The study documents (including the study protocol, the statistical analysis plan, and the informed consent form template) may be used exclusively for scientific research, educational purposes, systematic reviews, meta-analyses, and methodological research. Access will be granted only after review and approval of a written request by the corresponding author. Applicants must provide a clear description of the intended use of the requested documents and agree to use them solely for non-commercial purposes. Redistribution of the documents to third parties or any attempt to identify study participants is strictly prohibited. No deidentified individual participant data (IPD) will be shared.

From where data/document is obtainable

The study documents (including the study protocol, the statistical analysis plan, and the informed consent form template) can be obtained by contacting the corresponding author via email. Approved documents will be provided electronically upon request. Correspondence should be directed to the corresponding author: Dr. Leila Shokrizadeh Arani, Assistant Professor, Health Information Management Research Center, Kashan University of Medical Sciences, Kashan, Iran. Email: shokrizadeh-l@kaums.ac.ir

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

Researchers requesting access to the study documents (including the study protocol, the statistical analysis plan, and the informed consent form template) should submit a written request by email to the corresponding author. The request should include the applicant's full name, institutional affiliation, institutional email address, and a brief description of the intended use of the requested documents. The corresponding author will review the request to ensure that it is consistent with the study objectives and ethical requirements. If approved, the requested study documents will be provided electronically within 7–14 business days. No individual participant data (IPD) or any information that could identify study participants will be shared.

Comments