

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of Virtual Reality distraction on pain and anxiety during dental Treatment in children

Protocol summary

Study aim

Determining the effect of Virtual Reality distraction on pain and anxiety during dental treatment in children

Design

Clinical trial with control group, no blinded, randomized , on 30 patients

Settings and conduct

We will examine 30 children aged 4 to 12 years referring to dental offices and clinics affiliated to Shahrekord University of Medical Sciences. These children will be randomly divided into two control and experimental groups, and a one-session pulpotomy will be considered for them. In the control group, the Tell-Show-Do behavioral guidance method will be used. In the study group, a virtual reality headset with the ability to play cartoons and movies in 3D will be used to distract the child. Finally, in both groups, the level of pain will be recorded and compared through the Wong-Baker Faces pain scale and the level of anxiety through the MCDAS scale (f) and using a pulse oximetry device and the effectiveness of using virtual reality. , will be measured.

Participants/Inclusion and exclusion criteria

Inclusion: Good cooperation, child and parent satisfaction, and the child's physical and mental is healthy Exclusion: children who were not sensitive to flash light or had not accidents in the eyes, face, and neck

Intervention groups

In the control group, the Tell-Show-Do behavioral guidance method will be used. it means that every dental procedure that is going to be performed for a child, the child should be well informed about it. In the studied group, a virtual reality headset is used, which will play the movie from the screen of the phone.

Main outcome variables

Pain score;Anxiety score;The level of dissolved oxygen in the blood heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058670N1**

Registration date: **2023-11-17, 1402/08/26**

Registration timing: **prospective**

Last update: **2023-11-17, 1402/08/26**

Update count: **0**

Registration date

2023-11-17, 1402/08/26

Registrant information

Name

Sajedeh Saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 392 6170

Email address

saberisajede78@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Virtual Reality distraction on pain and anxiety during dental Treatment in children		Shahrekord
Public title		Province
The effect of Virtual Reality on pain and anxiety during dental treatment in children		Chahar-Mahal-va-Bakhtiari
Purpose		Postal code
Education/Guidance		8814874595
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2023-10-09, 1402/07/17
Children with Frankl's behavior 3 and 4 Children who are free from any psychological as well as systemic illness		Ethics committee reference number
Children without any anxiety disorders		IR.SKUMS.MED.REC.1402.053
Exclusion criteria:		Health conditions studied
Children whose parents were not willing to give consent to the study sensitivity to the motion or flash light or having accidents in the eyes, face, neck, or arms		1
Age		Description of health condition studied
From 4 years old to 12 years old		Investigating distraction through virtual reality
Gender		ICD-10 code
Both		ICD-10 code description
Phase		Primary outcomes
N/A		1
Groups that have been masked		Description
No information		Anxiety score on the scale Faces version of the Modified Child Dental Anxiety Scale
Sample size		Timepoint
Target sample size: 30		Before and after the intervention
Randomization (investigator's opinion)		Method of measurement
Randomized		Questionnaire of Faces version of the Modified Child Dental Anxiety Scale
Randomization description		2
In order to randomly assign patients, the permutation block method will be used with a volume of 6. For this purpose, 5 blocks with a volume of 6 will be prepared by the RA software and will be available to the researchers. Each block will include 6 patients who will be divided into 2 intervention and control groups by one of the following modes: A: control group B: intervention group AAABBB, AABABB,ABABAB,BBBAAA,...		Description
Blinding (investigator's opinion)		Wong-Baker Faces pain scale
Not blinded		Timepoint
Blinding description		After the intervention
Placebo		Method of measurement
Not used		Questionnaire of Wong-Baker faces pain scale
Assignment		Secondary outcomes
Parallel		1
Other design features		Description
		The level of dissolved oxygen in the blood
Secondary Ids		Timepoint
empty		Before the intervention and after the intervention
Ethics committees		Method of measurement
		Pulse oximetry device
1		2
Ethics committee		Description
Name of ethics committee		heart rate
Ethics committee of Shahrekord University of Medical Sciences, Shahrekord, Iran		Timepoint
Street address		Before the intervention and after the intervention
Yeganeh St., 105 Alley, Sub 9, No. 27		Method of measurement
City		Pulse oximetry device

Intervention groups

1

Description

Intervention group: In the studied group, a virtual reality headset is used, which will play the movie from the screen of the phone. The children of the study group were asked to watch the film for 5 minutes before starting the dental treatment and after a little rest, watch the continuation of the film during the dental treatment. After the completion of the treatment, the headset will be removed. Clinical examination and radiographic evaluation will be performed for these children, and the milk molar teeth that require a single-session pulpotomy in the upper and lower jaws will be determined. Teeth with deep caries but Without symptoms, those who do not have swelling, abscess and fistula related to teeth, as well as laxity and movement in clinical examinations, are selected. Also, no periapical radiolucency should be seen in the radiograph. In pulpotomy, when the coronal pulp is removed, the bleeding should be easy to control and the bleeding should stop within 5 minutes after using a pressure pack.

Category

Treatment - Devices

2

Description

Control group: In the control group, the traditional TSD behavioral guidance method will be used. The TSD method is one of the most common methods of behavioral management techniques, and it means that every dental procedure that is going to be performed on a child, the child must be well informed about it, so a demonstration is given to him using a simulator can be.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office in shahrekord

Full name of responsible person

Doctor Fatemeh Naderi

Street address

Yeganeh St., 105 Alley, Sub 9, No. 27

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814874595

Phone

+98 910 392 6170

Email

Saberisajede78@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Doctor Elham Raesi

Street address

Yeganeh St., 105 Alley, Sub 9, No. 27

City

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Province

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Sajedeh-Saberi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Shahre-kord University of Medical Sciences

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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

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

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

The clinical study report will be reported as an article.

When the data will become available and for how long

The access period starts immediately after the results are printed

To whom data/document is available

Access is open to the public

Under which criteria data/document could be used

For more information

From where data/document is obtainable

Yeganeh St., 105 Alley, Sub 9, No. 27 Saberi-Sajedeh
09103926170 saberisajede@gmail.com

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

The clinical study report will be made available to the public immediately after publication. For more information, send an email to
saberisajede78@gmail.com.

Comments