Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Smartphone application vs virtual reality effect on 5-8years old children fear & anxiety in first dentistry operation

Protocol summary

Study aim
Kids fear & anxiety control in dentistry
Design
Double-blind randomised , phase 3 , parallel clinical trial without control group
Settings and conduct
A double-blind randomized clinical trial with 42 patients divided into 4 groups by 4 blocks and the type of intervention inside the sealed envelopes was determined: First group use dentist bling application before dentistry operation Second group use virtual reality in dentistry operation
Participants/Inclusion and exclusion criteria
Inclusion criteria: co-operative / first dentistry operation Exclusion criteria: Indication of pulpectomy / extraction / abscess /restoration Systemic disease
Intervention groups
One group is given the dentist bling game application, which is a dental game to learn about dentistry, and the other group is given virtual reality glasses in which animation is played to distract the child.
Main outcome variables
Investigating the effect of dental game applications in controlling children's fear, investigating the effect of dental game applications in children's anxiety, investigating the effect of virtual reality glasses in controlling children's fear, investigating the effect of virtual reality glasses in controlling children's anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220123053803N1**
Registration date: **2022-07-02, 1401/04/11**
Registration timing: **registered_while_recruiting**
Last update: **2022-07-02, 1401/04/11**
Update count: **0**
Registration date
2022-07-02, 1401/04/11

Registrant information
Name
Arman Khosravi Nejad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2277 6304
Email address
armankhosravinezhad@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2022-08-23, 1401/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Smartphone application vs virtual reality effect on 5-8years old children fear & anxiety in first dentistry operation

Public title
Application vs virtual reality effect on kids fear & anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Co-operative kids (not in group Frankl's class 1 and in group 2-3-4) First dentistry operation 5-8years

Exclusion criteria:

Pulpectomy / extraction / Restoration / abscess indication Systemic disease

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done with 4 random blocks and this process is done by someone other than the operator. In this process, Excel software is used and finally the information of each group (virtual reality or application) is placed in closed envelopes and these envelopes are opened only when the operator wants to perform the treatment. There are also possibilities for both types of treatment and it is not clear in advance which treatment is to be performed and the envelopes are numbered in the same order in which they are randomized.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding the person who fills in the questionnaires with the child after the treatment and also the person who is responsible for evaluating the questionnaire data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tehran University of Medical Sciences

Street address

تهران، اتوبان نواب، ابتدای خانی آباد نو، خیابان ماهان(شهید زلفی)، روبروی پارک شریعتی، دانشکده دندانپزشکی پردیس بین الملل

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.186

Health conditions studied

1

Description of health condition studied

Fear

ICD-10 code

F40.23

ICD-10 code description

Blood, injection, injury type phobia

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Comparison of virtual reality and application on anxiety index

Timepoint

While first dentistry operation

Method of measurement

Facial Anxiety Scale / Modified Child Dental Anxiety Scale

2

Description

Comparison of virtual reality and applications on the fear index

Timepoint

While first dentistry operation

Method of measurement

Dental Subscale Children's Fear Survey Schedule

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group is the group that uses virtual reality glasses during the first dental treatment and an animation is played inside the virtual reality glasses so

that the child does not get distracted from the surrounding environment and also reduces fear and anxiety during the treatment.

Category

Treatment - Devices

2

Description

The other group are children who are given the dentist bling game application before the treatment session to play, and this program makes the child familiar with the dental environment and tools so that he experiences less fear and anxiety during the treatment session.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

International Campus of Tehran University of Dentistry

Full name of responsible person

Arman Khosravi Nejad

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In front of Shariaty Park , Mahan St , KhaniAbad No , Tehran

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dentistyic@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Javad Kharazifard

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In front of shariaty Park , Mahan St , KhaniAbad No , Tehran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Arman Khosravi Nejad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available