

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Multimedia and virtual reality effect on distraction and oral health education in 4-6 year old children

Protocol summary

Study aim

Multimedia and virtual reality effect on distraction and oral health education in 4 to 6 year old children

Design

Clinical trial with parallel groups, without blinding, randomized, on 60 patients. A random number table will be used for randomization.

Settings and conduct

This study will be performed in Tabriz School of Dentistry. Children are randomly divided into four groups. There will be 2 sessions of treatment. In the first session, oral health education will be provided in all groups. Health education will be done using VR glasses in the first group, TV in the second group, tablet in the third group and TSD(Tell-Show-Do) in the last group. In the second session, restorative treatment of the lower alveolar block in all 4 groups of patients will be performed using one of the VR, TV, tablet and TSD methods that the cartoon will broadcast. The level of anxiety and behavior of children will be measured. The plaque index will be re-examined in two follow-up periods one month apart.

Participants/Inclusion and exclusion criteria

Admission: Children 4 to 6 years. No history of dental treatment. Has at least one repairable tooth in the mandible. Withdrawal: Has symptoms of anxiety. Evidence of respiratory disease or Covid disease 19. No need for emergency dental treatment. Lack of parental cooperation. Pulp exposure

Intervention groups

Intervention 1: Health education with VR headset
Second intervention: health education with television
Intervention 3: Health education with tablet
Intervention 4: Health Education with TSD (Tell-Show-Do)

Main outcome variables

Oral health Anxiety Behavior plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210103049926N1**

Registration date: **2021-08-28, 1400/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-28, 1400/06/06**

Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

ozra golsanamlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-20, 1400/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multimedia and virtual reality effect on distraction and oral health education in 4-6 year old children

Public title

The impact of media on children's oral health

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Children should be 4 to 6 years old. Children should not have any dental treatment history. Children should have at least 1 tooth that need restorative treatment.

Exclusion criteria:

Children have major anxiety disorders. Symptoms of respiratory disease or Covid 19 disease are seen in the child. Children need emergency dental treatment.

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 children with inclusion criteria will enter the study. These people will be randomly divided into 4 groups. The method of randomization is simple and its unit is individual. The randomization tool is a table of random numbers. In order to hide the random allocation, sealed envelopes will be used.

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**

Ethnic committee of Tabriz university of medical sciences

Street address

Golgasht Ave., Tabriz city

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2021-06-29, 1400/04/08

Ethics committee reference number

IR.TBZMED.REC.1400.292

Health conditions studied**1****Description of health condition studied**

Oral health

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Oral health promotion that evaluated by plaque index

Timepoint

2 times evaluating oral health promotion at one month intervals

Method of measurement

Plaque index

2**Description**

Anxiety

Timepoint

Evaluating anxiety during tooth restoration

Method of measurement

Faces version of the Modified Child Dental Anxiety Scale questionnaire

3**Description**

Evaluating Behavior

Timepoint

Evaluating behavior during tooth restoration

Method of measurement

Frankel Behavior Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: In the first session, the tools used by the usual method of behavioral control technique will be introduced to children. Also, to determine the initial oral health status of the child, plaque detection pills and plaque index will be calculated. In this group, Brushing with horizontal method will be taught to children and

their parents by using a VR headset and playing a cartoon about How to brush. In the second session, class one or two restoration of the first or second mandibular primary molars with injecting inferior alveolar nerve block will be done using VR method and by playing a part of Tom and Jerry cartoon, and the anxiety and behavior of children Will be assessed. At the end of session the subjects' anxiety will be measured by Faces version of the Modified Child Dental Anxiety Scale and their behavior will be recorded based on the Frankel Classification Scale. The improvement of oral health will be re-examined in two follow-up session by the plaque index.

Category

Behavior

2

Description

Intervention group2: In the first session, the tools used by the usual method of behavioral control technique will be introduced to children. Also, to determine the initial oral health status of the child, plaque detection pills and plaque index will be calculated. In this group, Brushing with horizontal method will be taught to children and their parents by using a television and playing a cartoon about How to brush. In the second session, class one or two restoration of the first or second mandibular primary molars with injecting inferior alveolar nerve block will be done using television and by playing a part of Tom and Jerry cartoon, and the anxiety and behavior of children Will be assessed. At the end of session the subjects' anxiety will be measured by Faces version of the Modified Child Dental Anxiety Scale and their behavior will be recorded based on the Frankel Classification Scale. The improvement of oral health will be re-examined in two follow-up session by the plaque index.

Category

Behavior

3

Description

Intervention group3: In the first session, the tools used by the usual method of behavioral control technique will be introduced to children. Also, to determine the initial oral health status of the child, plaque detection pills and plaque index will be calculated. In this group, Brushing with horizontal method will be taught to children and their parents by using a tablet and playing a cartoon about How to brush. In the second session, class one or two restoration of the first or second mandibular primary molars with injecting inferior alveolar nerve block will be done using tablet and by playing a part of Tom and Jerry cartoon, and the anxiety and behavior of children Will be assessed. At the end of session the subjects' anxiety will be measured by Faces version of the Modified Child Dental Anxiety Scale and their behavior will be recorded based on the Frankel Classification Scale. The improvement of oral health will be re-examined in two follow-up session by the plaque index.

Category

Behavior

4

Description

Control group: In the first session, the tools used by the usual method of behavioral control technique will be introduced to children. Also, to determine the initial oral health status of the child, plaque detection pills and plaque index will be calculated. In this group, Brushing with horizontal method will be taught to children and their parents by using usual method tell-show-do (TSD) and playing a cartoon about How to brush. In the second session, class one or two restoration of the first or second mandibular primary molars with injecting inferior alveolar nerve block will be done using TSD , and the anxiety and behavior of children Will be assessed. At the end of session the subjects' anxiety will be measured by Faces version of the Modified Child Dental Anxiety Scale and their behavior will be recorded based on the Frankel Classification Scale. The improvement of oral health will be re-examined in two follow-up session by the plaque index.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشکده دندانپزشکی دانشگاه علوم پزشکی تبریز

Full name of responsible person

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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ozra Golsanamlou
Position
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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