

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Trial Study on the Impact of Virtual Reality in Reducing Children's Dental Pain, Fear, and Anxiety

Protocol summary

Study aim

Investigating the effect of virtual reality in reducing pain, fear and anxiety in children during dental procedures

Design

A randomized clinical trial, with a parallel control group, without blinding, a sample size of 60. Randomization using Minitab 17 software.

Settings and conduct

The research location is a dental office in Kerman city. To compare the effectiveness of using virtual reality (VR) therapy versus usual care for patients. The control group will receive the standard care without any VR content while the intervention group will be treated with VR therapy. Pain, anxiety, and fear levels will be measured through self reports from patients, observations from researchers, and interviews with parents before, during, and after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No auditory, visual, or speech impairments, require routine dental care. Exclusion criteria: nausea and dehydration, mental disorders, unstable physical or mental health, fear, under four years of age, manifest anxiety, unwilling to participate in the investigation.

Intervention groups

During the dental procedure, the intervention group will engage with virtual reality glasses that feature an animation portraying a benevolent woodland lion whose dentition emits mellifluous melodies as it traverses through the arboreal landscape during the seasons of spring, autumn, and winter. Control group: routine care.

Main outcome variables

Pain, fear and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210710051836N3**

Registration date: **2023-05-14, 1402/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-14, 1402/02/24**

Update count: **0**

Registration date

2023-05-14, 1402/02/24

Registrant information

Name

Hamed Riyahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3246 0284

Email address

h.ehtemam@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial Study on the Impact of Virtual Reality in Reducing Children's Dental Pain, Fear, and Anxiety

Public title

The Impact of Virtual Reality in Reducing Children's

Dental Pain, Fear, and Anxiety

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 No vision problems No hearing problem No speech problems The need for routine dental treatment
Exclusion criteria:
 The child displays a heightened level of anxiety Age under four years The child and her parents exhibited a lack of willingness to partake in the study Having symptoms such as nausea Having symptoms such as dehydration Use of sedatives Psychopathy Unstable state of physical or mental health Fear

Age
From **4 years** old to **15 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
 The process of random assignment, whereby participants are divided into control and intervention groups without bias, was facilitated through the use of Minitab 18 software. This program generates a series of random numbers which we utilized to allocate individuals to their respective groups. The aim of this approach is to prevent any predictions regarding the type of intervention received by both the company providers and researchers. We enter a series of numbers as the number of sample size in the first column and after the Calc tab, we click the sample from column option and we say, give us the numbers we entered in a random form, which does this by sampling without placement. In order to achieve the random order of entry of people into each of the groups under study, first in the software and in the first column, we create an arithmetic sequence of numbers starting from 1 and ending at 60 (the number of the required sample size). Then, because the ratio of people in both groups is equal, through the mentioned path, we inform the software that the number of 50% or half of the numbers in the first column is placed in the two columns with the names of the control group and the intervention group. In this way, we have two sets of random numbers that can be used in the order in which people enter each group, for example, the column of the intervention group has random numbers 3, 4, and 7, which means it is the third. The fourth and seventh patients who refer to the office are included in the intervention group.

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
 Kerman University of Medical Sciences
Street address
 Deputy of Research, Jahad Blvd, Kerman
City
 Kerman
Province
 Kerman
Postal code
 7619813159
Approval date
 2023-03-15, 1401/12/24
Ethics committee reference number
 IR.KMU.REC.1401.549

Health conditions studied

1

Description of health condition studied
 Palpectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Pain
Timepoint
 Since the inception of the research investigation
Method of measurement
 Wong-Baker FACES (WBS) Pain Rating Scale

2

Description
 Fear
Timepoint
 Since the inception of the research investigation
Method of measurement
 The Child Fear Scale (CFS)

3

Description
 Anxiety
Timepoint
 Since the inception of the research investigation

Method of measurement

Faces version of Modified Child Dental Anxiety Scale (MCDAS (f)), SCARED (parent version) and The Children's Anxiety Meter-State (CAM-S)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is scheduled to utilize virtual reality headsets during their dental operation. These devices are designed specifically for children and feature a captivating animation depicting a benevolent woodland predator, whose dentition produces melodious sounds as it traverses through the seasonal transitions of autumn, spring, and summer.

Category

Rehabilitation

2

Description

Control group: The control group experiences the dental procedure without virtual reality glasses.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentist's office

Full name of responsible person

Elham Farokh Gisoor

Street address

Esteghlal Ave, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3243 5531

Email

h.ehtemam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Davood Kalantar Neyestanaki

Street address

Research Deputy, Jihad Blvd, Kerman

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3787

Email

h.ehtemam@gmail.com

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

Kerman University of Medical Sciences

Full name of responsible person

Houriyeh Ehtemam

Position

Principal Investigator

Latest degree

Bachelor

Other areas of specialty/work

Medical Informatics

Street address

Haft Bagh Alavi

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

003431325415

Email

h.ehtemam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Houriyeh Ehtemam
Position
Principal Investigator
Latest degree
Bachelor
Other areas of specialty/work
Medical Informatics
Street address
Haft Bagh Alavi
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5415
Email
h.ehtemam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Houriyeh Ehtemam
Position
Principal Investigator
Latest degree
Bachelor
Other areas of specialty/work

Medical Informatics
Street address
Haft Bagh Alavi
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5415
Email
h.ehtemam@gmail.com

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

Not applicable

Data Dictionary

Not applicable