

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of different methods of multimedia distraction on pain and anxiety of 5-9 years old children during dental treatment

Protocol summary

Study aim

The purpose of this study is Comparison of the effect of different methods of multimedia distraction on pain and anxiety of 5-9 years old children during dental treatment

Design

Clinical trials with control group, with parallel, non-random groups

Settings and conduct

This study will be conducted at the private clinic of Hamad Sarlak, a pediatric dentistry specialist in Arak. For each patient, according to the groups designated in a meeting, the cartoon is silently or soundly distributed and in the other session the patient is considered as a control. In the treatment sessions at certain times, the level of anxiety is measured by heart rate, SEM, and FAS.

Participants/Inclusion and exclusion criteria

The criteria for entering this study will be that the participants in this project should be genetically and systemically healthy and have no adverse history of dentistry, and in terms of cooperation in the positive or Definitely positive status. Frankl's position. All patients Need for Bilateral Palpotomy D or E Maxillary Teeth. The exclusion criteria are the lack of patient collaboration for attending the third and fourth sessions of treatment

Intervention groups

First Intervention:Spoken Cartoon, Second Intervention:Silent Carton, Third Intervention (Control): No Cartoon Playing

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190224042820N1**

Registration date: **2019-05-08, 1398/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

Sara Jafari mofrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3272 2483

Email address

s_jafari73@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-13, 1398/01/24

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of different methods of multimedia distraction on pain and anxiety of 5-9 years old children during dental treatment

Public title

effect of different methods of multimedia distraction on pain and anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Genetically and systemically healthy Do not have a bad history of dentistry In terms of cooperation, positive or Definitely Positive is to be categorized by Frankl Need for Bilateral Palpotomy D or E Maxillary Teeth

Exclusion criteria:
Lack of cooperation for attending medical sessions

Age

From **5 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Arak University of Medical Sciences

Street address

Academic Complex of the Great Prophet, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.ARAKMU.REC.1397.259

Health conditions studied

1

Description of health condition studied

The amount of pain and anxiety of a child during dental

treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pulse rate

Timepoint

The pulse rate in each treatment is measured three times and recorded by the dentist's assistant. 1 minute after the start of the method of disturbing the senses. 2. During local anesthetic injection. 3. At pulp exposure.

Method of measurement

To measure the heart rate and oxygen saturation, Microlife AG, Widnau, Switzerland (OXY 300) will be used by placing the probe on the left hand side of the baby's finger.

2

Description

faces pain rating

Timepoint

The FPR criterion is measured at the end of treatment

Method of measurement

The FPR is scored and recorded by the child using the FPR image.

3

Description

Sound Eye Motor pain(SEM)

Timepoint

The SEM criterion is measured and recorded at the time of anesthetizing injection

Method of measurement

The SEM criterion evaluates the status of the sounds, eyes, and child movements according to the SEM table and recorded by the dentist's assistant.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: spoken cartoon, a 30-minute cartoon Tom and Jerry on a 17-inch LCD display on the dental unit's arm, about 120 cm from the patient's eyes

Category

Prevention

2

Description

Intervention group: silent cartoon, a 30-minute cartoon Tom and Jerry on a 17-inch LCD display on the dental

unit's arm, about 120 cm from the patient's eyes

Category

Prevention

3

Description

Control group: In this study, each person is considered as a controller and receives one session of one of the interventions and the other session does not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Hamid Sarlak's office Pediatric Dentistry

Full name of responsible person

Hamid Sarlak

Street address

Fifth Floor, Mir Ahmad Building, Azod Corner, Shahid Beheshti Street

City

Arak

Province

Markazi

Postal code

3813634159

Phone

+98 86 3222 3794

Email

Dr.hamidsarlak@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Arjmandzadegan

Street address

Academic Complex of the Great Prophet, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3645

Email

mmatinam81@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hamid Sarlak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Fifth Floor, Mir Ahmad Building, Azod Corner, Shahid Beheshti Street

City

Arak

Province

Markazi

Postal code

3813634159

Phone

+98 86 3222 3794

Email

Dr.hamidsarlak@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Sara Jafari Mofrad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Narges Hostel, Basij Square, Sardasht

City

Arak

Province

Markazi
Postal code
3819693345
Phone
+27 6632722486
Email
S_jafari73@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Sara Jafari Mofrad
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Narges Hostel, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 66 3272 2483
Email
S_jafari73@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Not applicable

Title and more details about the data/document

All data are publishable

When the data will become available and for how long

one year after publishing results

To whom data/document is available

All researcher in universities and research centers

Under which criteria data/document could be used

There are no conditions

From where data/document is obtainable

Dr Hamid Sarlak

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

Request a person by email Investigating university affiliation of the requesting person Send information via email The maximum time of this process is one month.

Comments