

# 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