

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### A comparative evaluation of audial and visual behavioral management techniques on the anxiety of 6-12 year old children undergoing dental treatment: a clinical trial

#### Protocol summary

##### Study aim

Determining the effect of audial and visual behavioral control methods on the level of anxiety of children undergoing dental treatment

##### Design

Clinical trial with control group, with 2 parallel groups, double-blind, randomized allocation, on 90 patients.

##### Settings and conduct

Patients referred to the pediatric dentistry department of Shahid Beheshti University are randomly assigned to one of the three groups: control (usual behavioral control including tell-show-do), audial group (play music) and visual group (play cartoons by tablet). All treatments will be performed by one dentist (pediatric resident). The child's anxiety will be checked according to MCDAS (child's self-report), heart rate and blood oxygen level (pulse oximetry), the level of acceptance of the child by asking her/him and will be confirmed by the relevant instructor. The data is collected by a person who is not aware of the treatment steps and then checked and compared in spss software.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The age of the child is between 6 and 12 years Lack of previous experience in dentistry Dental treatments that require anesthesia. Absence of mental and systemic diseases Non-entry criteria: .Complex and time-consuming treatment · Unusual non-cooperation of the child · dissatisfaction of the patient's parents to participate in the study

##### Intervention groups

Control group: tell-show-do Intervention groups: audial group, visual group the child's favorite story, poem or song is played by handsfree. and child's favorite cartoon will be played without sound for the child.

##### Main outcome variables

Child's anxiety level by MCDAS; heart rate and blood oxygen level by pulse oximetry; child acceptance level

#### General information

##### Reason for update

##### Acronym

MCDAS (Faces version of Modified child dental anxiety scale)

##### IRCT registration information

IRCT registration number: **IRCT20230106057065N1**

Registration date: **2023-01-11, 1401/10/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-11, 1401/10/21**

Update count: **0**

##### Registration date

2023-01-11, 1401/10/21

##### Registrant information

##### Name

Fateme Kalantari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4434 1610

##### Email address

fa.kalantari1995@sbfmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-16, 1401/09/25

##### Expected recruitment end date

2023-05-15, 1402/02/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

A comparative evaluation of audial and visual behavioral management techniques on the anxiety of 6-12 year old children undergoing dental treatment:a clinical trial

**Public title**

A comparative evaluation of audial and visual behavioral management techniques on the anxiety of children undergoing dental treatment:a clinical trial

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The age of the child is between 6 and 12 years No previous experience in dentistry Dental treatments that require anesthesia Absence of mental and systemic diseases

**Exclusion criteria:**

Complex and time-consuming treatment Unusual non-cooperation of the child Dissatisfaction of the patient's parents to participate in the study

**Age**

From **6 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation rule According to the sample size, 3 intervention groups are placed inside balls in a lottery container, and referring patients randomly remove the balls from the container without replacement.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Informed consent was obtained from the patient's parents to participate in the 3 groups: tell-show-do, audio, video randomly selected by their child. Collection of physiological information pulse rate and oxygen saturation level of blood (pulse oximetry) and information related to the child's anxiety level (MCDAS) and her level of acceptance are collected by a person who is not aware of the intervention and study. The collected data is also analyzed by a person who is not aware of the study. It should be noted that the intervention is performed by one person, who is a pediatric dentistry resident.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid beheshti University of Medical Sciences

**Street address**

Faculty of Dentistry, Shahid Beheshti University, Daneshjou Boulevard, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2022-12-11, 1401/09/20

**Ethics committee reference number**

IR.SBMU.DRC.REC.1401.088

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

The level of anxiety of children undergoing dental treatment

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

MCDAS: The child's anxiety level is reported by the emoticons shown by the child.

**Timepoint**

Before-during-after treatment

**Method of measurement**

by emoticons and MCDAS questions

**2****Description**

Pulse rate

**Timepoint**

Before-during-after treatment

**Method of measurement**

pulse oximeter

### 3

**Description**

Blood oxygen saturation level

**Timepoint**

Before-during-after treatment

**Method of measurement**

pulse oximeter

### 4

**Description**

Child acceptance rate

**Timepoint**

After treatment

**Method of measurement**

by 3 questions that are asked by the blinded person and the last question includes a visual analog scale that is reported by the child.

### 5

**Description**

Age of the patient

**Timepoint**

Before treatment

**Method of measurement**

Demographic information sheet

### 6

**Description**

gender of the patient

**Timepoint**

Before treatment

**Method of measurement**

Demographic information sheet

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Control group: Tell-show-do, In this method, all the tools used are explained to the child before the treatment.

**Category**

Behavior

### 2

**Description**

Intervention group: Audial group, In this method, the child's favorite story, poem, song or music is played by hands-free.

**Category**

Behavior

### 3

**Description**

Intervention group: Visual group, in this method, the child's favorite cartoon is played without sound.

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Shahid Beheshti Faculty of Dentistry

**Full name of responsible person**

Fateme Kalantari

**Street address**

Daneshjou Boulevard, velenjak

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**Phone**

+98 21 2217 5351

**Email**

fa.kalantari1995@sbmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fateme Kalantari

**Position**

Resident of pediatric dentistry

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident of pediatric dentistry

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Medical doctor

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**Fax**

**Email**

fa.kalantari1995@sbmu.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

The data collected from the study and analysis can be published without mentioning the names of the participants.

**When the data will become available and for how long**

Beginning of the access period after 1402

**To whom data/document is available**

Collected data without mentioning the names of the participants will be provided to the researchers for reference if needed to conduct other studies.

**Under which criteria data/document could be used**

To conduct other studies

**From where data/document is obtainable**

To access the data, send a message to the email of Fateme Kalantari.

**What processes are involved for a request to access**

**data/document**

After receiving the email, the data will be sent with permission from the relevant instructor.

**Comments**