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@sbmu.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
City
Tehran
Province
Tehran
Postal code
1983969411
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
Fateme Kalantari
Street address
Daneshjou Boulevard, Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 935 914 4941
Email
fa.kalantari1995@sbmu.ac.ir
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

Street address
Daneshjou Boulevard, Velenjak

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5351

Email
fa.kalantari1995@gmail.com

Person responsible for scientific 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

Street address
Shahid Beheshti University of Medical Science, Daneshjou Boulvard, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5351

Fax

Email
fa.kalantari1995@sbmu.ac.ir

Person responsible for updating data

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

Street address
Shahid Beheshti University of Medical Science, Daneshjou Boulvard, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5351

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