

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of effectiveness of Adiou Distraction Methods on Pain and Anxiety of 4-8 years old Paediatric Patient During Dental Treatment

Protocol summary

Study aim

The purpose of this study is the comparison effectiveness of audio distraction methods on pain and anxiety of 4-8 years old children during dental treatment

Design

Clinical trial with two groups of intervention with control group, with cross sectional groups, single blind, randomized

Settings and conduct

This study will be conducted at the private clinic of Hamid Sarlak, a pediatric dentistry specialist in Arak. For each patient, according to the groups assigned, pulpotomy and SSC treatment will be done in the presence of one of the audio distraction in one side and in the next treatment session, the treatment will be performed in the presence of a other method on the opposite side. In the treatment sessions at a specific time, pain and anxiety levels are measured with heart rate, SEM, and FPR.

Participants/Inclusion and exclusion criteria

60 children 4 to 8 years old, at children's dentistry office in Arak city in 99-98 candidates for double sided pulpotomy and stainless steel crown (SSC) in the first or second primary maxillary molars of the same type They are healthy genetically, systemic and learning ability They have no history of dental treatment and hospitalization In Frankel cooperation scale should be in positive or definitely positive position Existence of severe pain or obvious need for treatment on a side earlier of opposite side that excludes the study from random state, prevent entry.

Intervention groups

Group 1: First session Audio story Second session Music
Group 2: First session Music Second session Audio Story

Main outcome variables

Pain; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190702044077N1**

Registration date: **2019-09-29, 1398/07/07**

Registration timing: **prospective**

Last update: **2019-09-29, 1398/07/07**

Update count: **0**

Registration date

2019-09-29, 1398/07/07

Registrant information

Name

Maedeh Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3372 1472

Email address

dr_maedehsadeghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of effectiveness of Adiou Distraction Methods on Pain and Anxiety of 4-8 years old Paediatric Patient During Dental Treatment

Public title

Effect of Adiou Distraction Methods on Pain and Anxiety During Dental Treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients should be candidates for double sided pulpotomy and stainless steel crown (SSC) in the first or second primary maxillary molars of the same type They are genetically, systemic and able to learn healthy They have no history of dental treatment and hospitalization In Frankel cooperation scale should be in positive or definitly positive position

Exclusion criteria:

Existence of severe pain or obvious need for treatment on one side earlier of opposite side that excludes the study from a random state Lack of cooperation for attending medical sessions

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Child with first or second primary molars simillary on both sides of the maxilla, that require pulpotomy and stainless steel crown

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization Unit: Individual Randomization tool: software will be used to place persons in two groups based on the preference and delay of the method and in the third session for selection the maxillary quadrant, 60 very similar envelopes, half of which are zero and half of which are one, are used. In the first treatment session, move the envelopes, then select one envelope for each child, if the number is zero, treatment on the right and if the number is one treatment on the left will be done. The concealment is carried out by envelopes of a black and same shape that are not clearly identified.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single blind study. In this study, the assistant dentist who records the indices is unaware of how individuals are assigned to the groups and the type of intervention performed at each session to treat individuals. According to the present study, since the

intervention of all participants during the treatment is to listen to the audio story or music, it is not possible to keep the participants blind and the participants will notice What kind of media do they listen to either way. The present study is a preventive study and participants' blindness did not have a clear effect on the results.

Placebo

Not used

Assignment

Crossover

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

2019-07-28, 1398/05/06

Ethics committee reference number

IR.ARAKMU.REC.1398.120

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

Heart rate at first and second sessions once and for all treatment sessions (third and fourth sessions) three times is measured and recorded by the dentist's assistant. 1. One minute after the start of the method of distraction 2. During injection Local anesthetic 3. During pulp exposure

Method of measurement

To determine the heart rate, the digital electronic device OXY300 (Microlife AG, Widnau, Switzerland) will be used by placing the probe on the child's left hand finger.

2

Description

Face pain rate

Timepoint

After starting the distraction method

Method of measurement

The subjective evaluation of pain is performed by the FPR scale after the starting distraction method which is recorded by the child using its scoring image, and determined score by the next session in the presence of another distraction method are compared.

3

Description

Evaluation of pain by eye, movement and sound (SEM)

Timepoint

After starting the distraction method

Method of measurement

The Objective scale used to measure pain is a SEM scale that evaluates the status of the child's sound, eyes, and movements according to the score table. The score for this scale is recorded by the dentist's assistant after the start of the specific method of distraction. The score is compared with the score of the next session in the presence of the another distraction method.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Playing the audio story, in this study three audio stories for a total of 30 minutes with the voice of Ms. Pegah Razavi, from a MP3 player model of the RM-1101 by JBL wired headset during treatment for the child, is used.

Category

Prevention

2

Description

Intervention group: Music playing, In this study, both kind of relaxed and happy childish music will be used as a 30-minute package. which is distributed by a MP3 player model of the RM-1101 by JBL wired headset during treatment for the child.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Hamid Sarlak's office Pediatric Dentistry

Full name of responsible person

Hamid Sarlak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arjmandzadegan

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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

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

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

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Latest degree

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Other areas of specialty/work

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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 university 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