

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of pain and anxiety rate in children in the aged 3 to 7 years during dental procedures using two different behavioral guidance techniques, conversation distraction and "prize-distraction"

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of conventional distraction and prize distraction behavioral guidance methods on reducing pain and anxiety in children during dental procedures.

Design

Randomized cross-over and single blinded clinical trial in which 60 children will be divided into two groups of 30 people using SPSS software(group AB and group BA)In the first session, treatment is performed for each child in the presence of one of the behavioral guidance methods on the left or right. In the next session, the treatment is performed in the presence of another method and on the opposite side, for each child.

Settings and conduct

The study is performed on children in need of dental treatment in Dr. Hamid Sarlak's private office. Behavioral guidance techniques are used during anesthesia injection, the level of children's pain is measured by Sound Eye Motor and Face Pain Rating scale and the level of their anxiety is measured based on " pulse rate per minute" and is recorded by the dental assistant.

Participants/Inclusion and exclusion criteria

Children in 3 to 7 years old, completely healthy, with no history of dental treatment and hospitalization. Children who need pulpotomy and Stainless Steel Crown treatment of maxillary D teeth bilaterally and cooperate well with their dentist.

Intervention groups

"Prize distraction" is a technique in which the clinician engages with the child in a reward-oriented manner and, by increasing motivation, encourages the child to reward positive behavior. This method is used immediately before applying painful stimuli. In "Conversation distraction" the dentist defines the "story of the tooth germ." My friend, When we eat sweets, if we do not brush well, the germs nest on the teeth and slowly eat

our teeth and cause pain in them.

Main outcome variables

The study outcome in all individuals is measure of pain and anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054300N1**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Maryam Rahmati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of pain and anxiety rate in children in the aged 3 to 7 years during dental procedures using two different behavioral guidance techniques, conversation distraction and "prize-distraction"

Public title
Effect of prize distraction technique on reducing children's pain and anxiety in dentistry

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children in 3 to 7 years old. Children who are genetically, systemically and physically healthy. All children in need of pulpotomy and SSC treatment of maxillary first primary molars bilaterally. Children without any history of dental treatment and hospitalization. Children with a positive or definitely positive status based on Frankl's cooperation criteria.
Exclusion criteria:

Age
From **3 years** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method will be used to randomize the patients participating in the study. For this purpose, size 4 blocks will be selected and according to them, the randomization sequence of patients will be determined (AB or BA). Also, to select the maxillary quadrant in the first treatment session, 60 completely similar envelopes are used, half of them have the letter L and the other half have the letter R inside. In the first treatment session, the envelopes are turned upside down several times to change the place of all of them, then one envelope will be selected for each child, if it is the letter R, the treatment is done on the right and if it is the letter L, the treatment is done on the left.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study is a single blind. In this study, the statistical analyzer is unaware of how individuals are assigned to groups and the type of intervention performed in each session to treat individuals. The observer, as the scorer of the Sound Eye Motor(SEM)

scale and the number of Pulse Rate per minute(PR/min) and the recorder of them, can not be blinded because he is necessarily aware of the type of behavioral guidance by listening to the dentist.

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

No. 37 , Dastgheib Cross.,Behzisti St., Daneshgah Ave., Arak Town

City

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Province

Markazi

Postal code

3817953173

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.ARAKMU.REC.1400.353

Health conditions studied

1

Description of health condition studied

Pain and anxiety in children during dental procedures that lead to non-cooperative behavior and difficulty in treating them.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in Sound Eye Motor criteria

Timepoint

During the local anesthesia process

Method of measurement

1.Sound Eye Motor (SEM) This scale will be scored as an objective criterion for measuring the amount of pain. , The child's eyes and body condition will be determined and recorded by a trained dental assistant who is aware of this criterion, these scores will be compared with the scores of the next treatment session that uses another

method of behavioral guidance. 2. Face Pain Rating Scale (FPR): This scale is used as a subjective criterion for measuring pain, which will be scored by the child himself using Wong-Baker images after local anesthesia, and the score is determined by the score. The next session is compared

Secondary outcomes

1

Description

Anxiety level based on pulse rate per minute

Timepoint

1- Three minutes after the child sits on the unit at the beginning of the treatment session 2- When using the behavioral guidance method during local anesthesia injection

Method of measurement

Pulse oximeter device: One of the symptoms of anxiety is an increase in heart rate. To measure the level of anxiety, the number of pulses per minute (Pulse rate / min) can be used. Positioning the device probe on the index finger of the child's left hand will be used and the score recorded in the two sessions will be compared.

Intervention groups

1

Description

"Intervention group 1": treatment of pulpotomy and stainless steel crown of maxillary D teeth similarly on the right and left side with the presence of one of the behavioral guidance methods (prize distraction) on one side of the maxilla and in the presence of another method (Intervention 2) is performed on the opposite side. The "prize distraction" technique begins about 20 seconds before picking up the local anesthetic syringe and continues for 1 minute to 20 seconds after the local anesthetic is injected (about 100 seconds in total). Local anesthesia is performed by an experienced dentist with the infiltration technique, without showing the anesthetic syringe to the child. In this technique, the dentist uses reward-oriented sentences to distract the child from the painful stimulus. The dentist speaks as slowly as possible so that the child's attention is fully absorbed by the dentist and the sentences are visualized in his mind.

Category

Behavior

2

Description

"Intervention group 2": Pulpotomy and treatment of stainless steel crown of maxillary D teeth performed in the presence of one of the behavioral guidance methods (conversation distraction) In "conversation distraction", the dentist defines the "story of the tooth germ". this technique begins about 20 seconds before picking up the local anesthetic syringe and continues for 1 minute to 20 seconds after the local anesthetic is injected (about 100

seconds in total). Local anesthesia is performed by an experienced dentist with the infiltration technique, without showing the anesthetic syringe to the child. The dentist speaks as slowly as possible so that the child's attention are fully aware of him and the sentences are visualized in his mind.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Hamid Sarlak's private office

Full name of responsible person

Hamid Sarlak

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Mirahmad Building., corner of Azod St., Abbas Abad St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available