

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effectiveness of psychologic intervention (cognitive-behavioural) on dental anxiety during pulpotomy in 7-10 years old children

Protocol summary

Study aim

Evaluation the effectiveness of psychologic intervention (cognitive-behavioural) on dental anxiety during pulpotomy in 7-10 years old children

Design

Randomised controlled clinical trial with double blinded and a parallel group design of 30 patient enrolled between october and march2018

Settings and conduct

In first session the child undergo prophylaxis and fluoride therapy in dental school clinic and child with clinical dental anxiety diagnosis according to Modified Child Dental Anxiety Scale enter to study .Child with random allocation is assigned in two intervention or control groups. In the intervention group ,the cognitive-behavioural interventions is taught to the child .Also parent are provided with a video recording of a cooperative child under pulpotomy for showing at home to their child. In control group routine behavioral guidance techniques are applied. In second session ,pulpotomy is done and child cooperation level during treatment is scored with Venham Clinical Cooperation Scale. After pulpotomy treatment ,again ,child clinical anxiety level is determinated.

Participants/Inclusion and exclusion criteria

7-10 years old children with one mandibular primary molar teeth need pulpotomy,without mental and systemic and general anxiety problems,without previous dental treatment experience ,with clinical dental anxiety
Exclusion criteria:The child`s inability to learn techniques

Intervention groups

Cognitive- behavioural interventions consist of education the Benson's relaxation technique (breathing with benson technique, gradual muscles expansion and constriction/combination of these two technique)/imagination and distraction. Also parent are provided with a video recording of a cooperative child

under pulpotomy for showing at home to their child . In control group routine behavioral guidance techniques are applied

Main outcome variables

Child anxiety Child cooperation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181024041441N1**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Marziyeh Shokravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-20, 1397/07/28

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of psychologic intervention (cognitive-behavioural) on dental anxiety during pulpotomy in 7-10 years old children

Public title

Evaluation the effectiveness of psychologic intervention (cognitive-behavioural) on dental anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

7-10 years old children Child with no mental and systemic and genetic disturbance Child with no previous dental treatment experience Child with no anxiety disorder according to SCARED scale Presence of clinical dental anxiety according to MCDAS scale in child Presence one mandibular primary molar tooth that need to pulpotomy and inferior alveolar nerve block injection in child

Exclusion criteria:

Child inability for psychologic intervention learning

Age

From **7 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

persons are assigned to the control and intervention groups with simple randomisation according to statistical software(Random Allocation Software).

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome is evaluated by a person other than the clinical investigator and caregiver in random numbers and she is blind to the intervention received. the results of each sample are delivered to the analyzer in the form of a number.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of medical sciences, Bahonar Blvd

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Postal code

15315_34199

Approval date

2018-10-17, 1397/07/25

Ethics committee reference number

IR.QUMS.REC.1397.161

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

dental anxiety in 7-10 years old children

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

child dental anxiety level

Timepoint

Before intervention and again one week after intervention

Method of measurement

Modified child dental anxiety scale

Secondary outcomes**1****Description**

Child cooperation level during pulpotomy

Timepoint

One week after intervention according to child behavior recording video during pulpotomy

Method of measurement

Venhem Clinical Cooperation Rating Scale

Intervention groups

1

Description

Psychologic intervention (cognitive- behavioral) that is taught to the child in three sessions including following stages: First session:Communication establishment with the child /Giving explanation about the treatment procedure and its effects/ introducing the treatment environment/brushing and fluorid therapy Second session :Training the child about the Benson's relaxation technique (gradual muscles relaxation and constriction/combination of these two techniques /breathing technique)/ imagination and distraction training Finally: Parents are provided with a video recording of a cooperative child under pulpotomy to play at home for their child. The treatment appointment is planned one week later and 30 minutes before the treatment begins, intervention stages are practiced again with the child. During the treatment, routine behavioral guidance techniques such as tell-show-do are applied.

Category

Behavior

2

Description

Control group: During treatment routine behavioral guidance techniques such as tell- show- do are applied.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences, School of Dentistry,Department of Pediatric Dentistry

Full name of responsible person

Marziyeh Shokravi

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Sponsors / Funding sources

1

Sponsor

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Marziyeh Shokravi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not 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

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available