

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of visual distraction on children's anxiety during dental treatment: A cross over randomized clinical trial

Protocol summary

Summary

The aim of this survey is to evaluate the effect of visual distraction on dental anxiety(measured by Venham picture test and pulse rate) of children while receiving dental treatment under local anesthesia The participants are selected from 4-5 years old patients that presented for treatment at the pediatric department of the school of Dentistry, Tehran University of Medical Science. The inclusion criteria for the patients are: (1) general health, (2) no previous dental experience involving local anesthetic administration for the last 2 years and (3) pulpotomy and ssc treatment plan required for primary molars in lower quadrants. exclusion criteria:1) previous unpleasant experience in dental setting (2)mental or physical disability 3) sound lower primary molars with minimal treatment needs. sample size: 28 intervention: In the first group after local anesthesia administration, treatment procedure is done while a silent cartoon is playing on the monitor in front of each child. The second visit in this group is without any distraction aid and the procedure is carried out under normal dental setup using conventional Tell- show- Do method. The second group experience the first visit with no distraction and conventional Tell- show- Do is used as a behavior guidance method. Visual distraction in this group is implemented in the second visit using a silent cartoon playing on the monitor . Treatment procedures are similar in both groups during two sessions including inferior alveolar nerve block as local anesthesia, pulpotomy and stainless steel crown treatment of lower primary molars. primary outcomes:In both groups preoperative and postoperative anxiety level is rated with Venham Picture Test (VPT) at the beginning and the end of each session respectively, as well as pulse rate(PR). Patient behavior is scored using Frankl Behavior Rating Scale in each appointment time of intervention :9 am

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080135434N1**

Registration date: **2017-08-11, 1396/05/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-11, 1396/05/20

Registrant information

Name

Zohreh Estaki

Name of organization / entity

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

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

dental school

Expected recruitment start date

2017-09-10, 1396/06/19

Expected recruitment end date

2017-12-10, 1396/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of visual distraction on children's anxiety during dental treatment: A cross over randomized clinical trial

Public title

effect of cartoon on dental anxiety in children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:(1) general good health, (2) no previous dental experience involving local anesthetic administration for the last 2 years and (3) pulpotomy and ssc treatment required for primary molars in lower quadrants. exclusion criteria:1) previous unpleasant experience in dental setting (2)mental or physical disability 3) sound lower primary molars with minimal treatment needs

Age

From **4 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of school of dentistry, Tehran
University of Medical Sciences

Street address

Enghelab Sq, North Kargar St, after Atomic Energy
Organization

City

Tehran

Postal code

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1396.2849

Health conditions studied

1

Description of health condition studied

dental anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

pulse rate

Timepoint

before and after dental procedure

Method of measurement

with tactile sensation

2

Description

anxiety level

Timepoint

before and after dental procedure

Method of measurement

by venham picture test

3

Description

child behaviour

Timepoint

before, during and after dental procedure

Method of measurement

by frankl behaviour iscale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: visual distraction by playing a silent cartoon during dental procedure control group: conventional behaviour guidance method (tell- show - do) is used during dental procedure

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

pediatric department of dental school ,Tehran

University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Dentistry, Tehran University of Medical
Sciences

Full name of responsible person

Dr Sara Ghadimi

Street address

Enghelab Sq, North Kargar St, after Atomic Energy
Organization

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

School of Dentistry, Tehran University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

pediatric department of dental school, Tehran
University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty