Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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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 physicall 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

dr Zohreh Estaki

Street address

Enghelab Sq, North Kargar St, after Atomic Energy Organization

City

Tehran

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

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Web page address

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