Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of coping skill training versus no coping training on pain perception, anxiety and behavior in 3-6 years old children during dental treatment as a clinical trial

Protocol summary

Summary

Aim of this study is evaluating the effect of coping skill training versus no training on pain perception, anxiety and behavior in dental setting. Patients were selected from referred patients to Tabriz Dental Faculty, pediatric dentistry department, from 21/4/2015. Ninety patient were randomized using the website www.randomizer.org in two 45 case and control group. Case group will receive coping skill training before dental procedure whereas control group will not receive any training. Inclusion criteria are: 3-6 year old children, have at least one carious primary mandibular molar, needing inferior alveolar nerve block and physical and psychological health. Exclusion criteria are: children who have physical or psychological disorder, history of major medical or dental procedures and history of stress disorders. In both groups pain perception that is primary outcome and anxiety and behavior that are secondary outcomes, will be recorded by blinded person.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511223168N2**
Registration date: **2016-04-26, 1395/02/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-26, 1395/02/07

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coping skill training versus no coping training on pain perception, anxiety and behavior in 3-6 years old children during dental treatment as a clinical trial

Public title

Effect of coping skill training on pain perception, anxiety and behavior in dentistry

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 3-6 year old children, attending to Department of Pediatric Dentistry of Tabriz University of Medical Sciences, who has at least one carious primary mandibular molar, needing inferior alveolar nerve block, physical and psychological health according to SDQ

(strengths and difficulties questionnaires) test. Exclusion criteria: children under 3 and above 6 year old, children who have physical or psychological disorder, history of hospitalization, history of major medical or dental procedures, history of dental pain and history of stress disorders.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Using the website: www.randomizer.org

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Science

Street address
Tabriz University of Medical Siceinces, Daneshgah Square, Abresan st.

City
Tabriz

Postal code

Approval date
2015-11-09, 1394/08/18

Ethics committee reference number
TBZMED.REC.1394.848

Health conditions studied

1

Description of health condition studied
dental anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain perception

Timepoint
before and immediately after intervention

Method of measurement
Wong baker faces pain rating scale

Secondary outcomes

1

Description
anxiety

Timepoint
before and immediately after intervention

Method of measurement
venham anxiety rating scale

2

Description
behavior

Timepoint
before and immediately after intervention

Method of measurement
frankle scale

Intervention groups

1

Description
Intervention1: 45 patients in first visit received dental prophylaxis or fluoride therapy using Tell-Show-Do technique. In second visit before dental procedure they will receive coping skill training including deep breathing, silence time, muscle relaxation and releasing anxious thoughts in about 20 minutes. Training these skills will be done by a pediatric dentistry resident. Pain perception, anxiety and behavior in first and second visit will be measured by a resident of pediatric dentistry who is blinded to study.

Category
Behavior

2

Description
Intervention2: 45 patients in first visit received dental prophylaxis or fluoride therapy using Tell-Show-Do technique. In second visit they will receive routine dental procedure without any coping training. Pain perception, anxiety and behavior in first and second visit will be measured by a resident of pediatric dentistry who is blinded to study.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Science Faculty of Dentistry

Full name of responsible person
Elahe Molavi

Street address
Tabriz University of Medical Siceinces, Daneshgah Square, Abresan st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences Vice chancellor for research

Full name of responsible person
Elahe Molavi

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Grant name
124202

Grant code / Reference number
10506000

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

Title of funding source
Tabriz University of Medical Sciences Vice chancellor for research

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
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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