Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of simulated dental game on the children′s pain and anxiety in the first session of dental treatment

Protocol summary

Summary

(1)The effect of simulated dental game on the children′s pain and anxiety in the first session of dental treatment (2)This clinical trial was performed on 50 children aged 4-7 years old who were referred to a private clinic in 2 groups(n=25) (3).At the examination session Wong-Baker FACES Pain Rating Scale test and heart rate were measured.then simulated dental game was given to the study group. The children were randomly divided into two groups (n=25), study (game) and control. At the treatment session, heart rate was measured in 5 stages. At the end of treatment WBS test was measured again (4) No previous experience of dental visit (5)Simulated dental game was given to the children of study group (6)Pain and anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120531236N1**
Registration date: **2017-07-19, 1396/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-19, 1396/04/28

Registrant information

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Name of organization / entity
Dentistry Student
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of simulated dental game on the children′s pain and anxiety in the first session of dental treatment

Public title

The effect of simulated dental game on the children′s pain and anxiety4-7 years old in the first session of dental treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: They have no previous experience of hospitalization and dental visit; At least need to the same elective treatment in the mandibular. Exclusion criteria: Necessity for using aggressive behavior management technique; Necessity for parental presence.

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundi shapur University of Medical Science, Ethics Committee
Street address
Ground floor, Department of Development Research and Technological University of Medical Sciences and Health Services Ahvaz, City University
City
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61357-15794
Approval date
2016-04-16, 1395/01/28
Ethics committee reference number
IR.AJUMA.REC.1395.11

Health conditions studied

1

Description of health condition studied
The Relation Between Dental Simulation and Dental Anxiety in Children at First dental Session
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Before treatment. After treatment
Method of measurement
WBS test

2

Description
Anxiety
Timepoint
Before treatment,Sitting on dentistry unit, Injection, Using turbine, Using angle, End of treat ment
Method of measurement
Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group : Simulated dental game given children of study group
Category
Prevention

2

Description
Control group : No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Pediatrics, School of Dentistry
Full name of responsible person
Street address
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Rearch and Technological Development Jundishapur University of Medical Science
Full name of responsible person
Mohsen Safi
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City
Ahvaz
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Rearch and Technological Development Jundishapur University of Medical Science
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

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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