

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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

Name

Fateme Alidadi

Name of organization / entity

Dentistry Student

Country

Iran (Islamic Republic of)

Phone

+98 917 641 8110

Email address

alidadi.f@ajums.ac.ir

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

Ahvaz

Postal code

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 treatment

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 Research and Technological
Development Jundishapur University of Medical
Science

Full name of responsible person

Mohsen Safi

Street address

Ground floor, Department of Development Research
and Technological University of Medical Sciences and
Health Services Ahvaz, City University

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 Research 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

Contact

Name of organization / entity

Faculty of Dentistry, Ahvaz University of Medical Sciences

Full name of responsible person

Dr Leila Basir

Position

Professor of Pediatric Dentistry, Professor and Head of Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Dental Student

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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