

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial to evaluate the effectiveness of using computer games with role playing method in reducing children situational anxiety in dental treatment

Protocol summary

Summary

Objectives: To determine the effect of play therapy in reducing dental anxiety of children. Study design: A randomized clinical trial with a parallel design carried out on 40 children aged between 6 and 8 years to ascertain the comparative efficacy of role playing with dentist games on tablet in reducing the dental anxiety of children during dental treatment. In this double blind study, Children separately and without linking together are treated and evaluator is blind too. The phase of this study is 2-3. Setting and conduct: Forty children were randomly divided into two groups: Control (Holst technique), role playing (Holst technique and playing with dental games). Holst technique is done in both groups but in case group, computer games are used too and children are done role playing. All the children experienced treatment with or without role playing and the anxiety was assessed using MCDAS test(is for evaluate the anxiety of children in School age and has high reliability and validity) before and after treatment. Participants including major eligibility criteria: Inclusion criteria are nothing systemic disease and developmental and mental disorders and cooperative children. It was confirmed that they have no previous experience of hospitalization and dental visit. Had caries lesion in one of the primary mandibular molars and needed a pulpotomy with restoration treatment. Also exclusion criteria are Children with Frankel 1, 2. Children that did not play dental games at home and anti-cooperative parent. Intervention: The first group was control and in the intervention group, role playing was done. Main outcome measures: Primary outcome variable was severity of anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011217935N6**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Zahra Bahrololoomi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 1624 0691

Email address

zbahrololoom@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2016-01-25, 1394/11/05

Expected recruitment end date

2016-02-24, 1394/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effectiveness of using computer games with role playing method in reducing children situational anxiety in dental treatment

Public title

Efficacy of role playing in reduce anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The children with no systemic disease and developmental and mental disorders and cooperative children. It was confirmed that they have no previous experience of hospitalization and dental visit. Had caries lesion in one of the primary mandibular molars and needed a pulpotomy with restoration treatment. Exclusion criteria: Children with Frankel 1, 2. Children that did not play dental games at home and anti-cooperative parent.

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Children was divided into two groups according to the table of random numbers. Double blind: Children separately and without linking together are treated and evaluator is blind too.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Emam street, faculty of Dentistry, Dahe Fajr Blvd, Yazd

City

Yazd

Postal code**Approval date**

2015-10-14, 1394/07/22

Ethics committee reference number

IR.SSU.REC.1394.93

Health conditions studied**1****Description of health condition studied**

Management of anxiety during dental treatment

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes**1****Description**

Severe of anxiety

Timepoint

Before and immediate after treatment

Method of measurement

MCDAS test

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: In the control group ,the dentist introduces children with only dentistry instruments

Category

Behavior

2**Description**

Intervention group: dentist introduces instruments and also uses video games.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental Faculty of Shahid Sadoughi University of Medical Sciences of Yazd

Full name of responsible person

Maryam Ebrahimian

Street address

Emam street, faculty of Dentistry, Dahe Fajr Blvd,

Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shahid Sadoughi
University of Medical Sciences of Yazd

Full name of responsible person

Dr. Fateme Ezoddini Ardakani

Street address

Emam street, faculty of Dentistry, Dahe Fajr Blvd,
Yazd

City

Yazd

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 of Shahid Sadoughi
University of Medical Sciences of Yazd

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

Dental Faculty of Shahid Sadoughi University of
Medical Sciences of Yazd

Full name of responsible person

Maryam Ebrahimian

Position

Postgraduate student of pediatric dentistry

Other areas of specialty/work

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Position

Associate professor of Pediatric Dentistry

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Postgraduate student of pediatric dentistry

Other areas of specialty/work

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Phone

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Email

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