

# 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,  
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**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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Dental Faculty of Shahid Sadoughi University of  
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**Full name of responsible person**

dr. Zahra Bahrololoomi

**Position**

Associate professor of Pediatric Dentistry

**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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**Fax**

**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*