

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### effect of video games on preoperative anxiety in children aged 3-6 years old undergoing elective surgery

#### Protocol summary

##### Summary

The aim of this study is determining effect of video games on preoperative anxiety among 3-6 years old children. This study is a random clinical trial containing both intervention group and control group that is carried out in pediatrics hospitals. Children are located in either control group or intervention group at random. For the intervention group, anxiety test is performed before entering the waiting room by means of m-Yale PAS tool; and then the children play the video game for twenty minutes. After that, children are injected with 0.5 mg/kg Midazolam and transferred to the operation bed. In the control group, children wait twenty minutes in the waiting room instead of playing the video game. The second anxiety test is carried out after transferring to the operation bed. In order to perform a blind study, trained nurses who measure anxiety are not aware whether intervention is carried out or not. Each group contains 45 children without any background in surgery or hospitalization. Children should not have any chronic degenerative disease and their parents should not be a hospital member. In the intervention group, children should be familiar with video game and play more than fifteen minutes. In this research, primary outcome measure is preoperative anxiety.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112631114N1**

Registration date: **2017-04-30, 1396/02/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-30, 1396/02/10

#### Registrant information

##### Name

Elham Rostami

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8888 2885

##### Email address

e.rostami.77@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

School of Nursing and Midwifery-Nursing Care Research Center

#### Expected recruitment start date

2016-12-21, 1395/10/01

#### Expected recruitment end date

2017-07-21, 1396/04/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

effect of video games on preoperative anxiety in children aged 3-6 years old undergoing elective surgery

#### Public title

effect of video games on preoperative anxiety

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

Entrance criteria: Neither chronic degenerative disease nor mental disorders; should not be observed based on both parents' statements and the patient background file; None of parents should not be a hospital personnel;

The child should not have been hospitalized before this study. Exit criteria: The child don't play until fifteenth minutes of time; The child is not familiar with video games.

#### 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

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences, School of Nursing and Midwifery

##### Street address

Rashid Yasemi St. Valiasr St. Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2016-11-08, 1395/08/18

#### Ethics committee reference number

IR.IUMS.REC 1395.9311687005

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

Acute stre

#### ICD-10 code description

Acute stress reactionF43.0

### 2

#### Description of health condition studied

anxiety

#### ICD-10 code

Anxiety di

#### ICD-10 code description

Anxiety disorder, unspecified F41.9

## Primary outcomes

### 1

#### Description

Preoperative Anxiety

#### Timepoint

Pre intervention-Post intervention

#### Method of measurement

modified yale preoperative anxiety scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the control group, children will stay in holding area for 15-20 minutes.

#### Category

N/A

### 2

#### Description

In this research, the intervention is video game. In the intervention group, children will play with video game verified by pediatric psychiatrist, in holding area.

Duration of the intervention is 15-20 minutes.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

DR.M.Kermanshahi Hospital

##### Full name of responsible person

Elham Rostami

##### Street address

D.R Kermanshahi Hospital, Helal-e-Ahmar Crossroads

##### City

Kermanshah

### 2

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

**Full name of responsible person**

Elham Rostami

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**3**

**Recruitment center**

**Name of recruitment center**

Emam Khomeyni Hospital

**Full name of responsible person**

Elham Rostami

**Street address**

Emam Khomeini Hospital, Naqhlieh Street

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**Recruitment center**

**Name of recruitment center**

Bisotoon Hospital

**Full name of responsible person**

Elham Rostami

**Street address**

Bisotoon Hospital, Keyhanshahr Boulevard

**City**

Kermanshah

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

School Of Nursing and Midwifery

**Full name of responsible person**

Dr.Nahid Akbari

**Street address**

Rashid Yasemi St. Valiasr St. Tehran- Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

School Of Nursing and Midwifery

**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**

DR.M.Kermanshahi Hospital

**Full name of responsible person**

Elham Rostami

**Position**

nurse

**Other areas of specialty/work**

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**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*