Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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

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

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2

Recruitment center

Name of recruitment center

Emam Reza Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
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4

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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School Of Nursing and Midwifery
Full name of responsible person
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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

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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