

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of using game application on anxiety before surgery in children aged 5-11 years

Protocol summary

Study aim

Determining the effect of using game software on the score of anxiety before surgery in children aged 5-11 years

Design

In this clinical trial, 70 children who are candidates for surgery in the first stage are easily selected and available through the list of surgeries, and in the next stage, they are randomly placed in one of two control or test groups. Study is a blind.

Settings and conduct

The study site is the operating room of Imam Hossein Hospital in Isfahan. The research is a single blind that the statistical analyst does not know about the study groups.

Participants/Inclusion and exclusion criteria

Entry requirements: At least one parent of the child is present. No history of surgery in the past. Have the necessary vigilance to the extent that it does not prevent research. Physical ability to play with game and educational software. No history of disease (mental, epilepsy, Down syndrome, mental disability). Complete consent to participate in the study. Do not take anti-anxiety drugs based on the doctor's instructions in the file. No entry conditions. The child's unwillingness to play with the software. Severe pain before intervention. Emergency surgery.

Intervention groups

Children aged 5-11 years are considered as candidates for surgery and according to the inclusion criteria, they are randomly assigned to one of the two control and test groups. Children in the intervention group play for 15 minutes, half an hour before surgery, and children in the control group play with toys and do not play with software. Anxiety levels are measured before and after the intervention (5 minutes before the child is transferred from the waiting room to the operating room).

Main outcome variables

Anxiety score before surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150715023216N10**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Said Amini Rarani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3522 6158

Email address

ghadami@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-25, 1400/08/03

Expected recruitment end date

2021-11-24, 1400/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using game application on anxiety before surgery in children aged 5-11 years

Public title

The effect of using game application on anxiety before surgery in children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Child 11-5 years At least one parent of the child is present No history of surgery in the past Have the necessary vigilance to the extent that it does not prevent research Physical ability to play with game and educational software No history of disease (mental, epilepsy, Down syndrome, mental disability) Complete consent to participate in the study Do not take anti-anxiety drugs based on the doctor's instructions in the file

Exclusion criteria:

The child's unwillingness to play with the software Severe pain before intervention Emergency surgery

Age

From **5 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the available samples are selected from the list of surgeries according to the inclusion criteria, and then the block randomization method is used. Blocking to balance the number of samples assigned to groups. The size of the blocks is equal and will be in the form of six blocks. We use random location software for randomization. In this method, random sequences created by random location software are recorded on the cards and the cards are placed in black letter envelopes and on the outer surface of the envelopes, the number of people entering the study is written and then In the order in which they enter the study, the envelopes are opened to determine which group they belong to.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst is unaware of which group each sample belongs to

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing, Management and Rehabilitation - Isfahan University of Med

Street address

Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.125

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

In this study, anxiety scores are measured in two groups of control and test.

Timepoint

Before and after the intervention

Method of measurement

Yale Modified Children Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After admission to the operating room, children in the intervention group while in the waiting room (half an hour before surgery) in addition to receiving routine and standard care with the help of

parents and researchers for 15 minutes, with the simulated game software It is from the operating room environment and in addition to entertaining the child is effective in training and familiarity with the operating room. This researcher-made Iranian game software is installed on one of the parents' mobile phones. Anxiety scores are measured immediately after admission to the operating room (before the intervention) and 5 minutes immediately before the child is transferred from the waiting room to the operating room (after the intervention).

Category

N/A

2

Description

Control group :The children in the control group receive routine and standard care after being admitted to the operating room, in the waiting room, and play with toys according to the routine, and do not receive games with software. Anxiety scores are measured immediately after admission to the operating room (before the intervention) and 5 minutes immediately before the child is transferred from the waiting room to the operating room (after the intervention).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hossein hospital

Full name of responsible person

Ahmad Ghadami

Street address

Hazarjerib Street

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Esfahan

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Isfahan

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8174675731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Isfahan University of Medical Sciences, Hezarjerib

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Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Ghadami

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences
Full name of responsible person
Ahmad Ghadami
Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Individual participant data collected for the primary outcome measures

When the data will become available and for how long

After publication for one year

To whom data/document is available

For all those who request information

Under which criteria data/document could be used

Any analysis on the data is allowed, but printing the article on the data is prohibited

From where data/document is obtainable

Corresponding author of article

What processes are involved for a request to access data/document

After requesting the data, the data will be sent by email to the responsible author after a maximum period of one week

Comments