Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of virtual reality technology on Preoperative anxiety in children

Protocol summary

Summary

The present study will be aimed to investigate the effects of virtual reality technology on pre-operative anxiety in children. As an experimental study, it has a control group with pretests and posttests. Moreover, the statistical population will comprised of all children candidate for surgeries at Dr Mohammad Kermanshahi Hospital in Kermanshah, Iran. Of the whole statistical population, 20 children will selected through the convenience sampling and randomly assigned to two groups (10 in the experimental group and 10 in the control one). Not to mention, the inclusion criteria will be the pre-operative anxiety. The examinees will give the pre-tests, and then the participants in the experimental group will provide with virtual reality. In other words, their eyes will equipped with glasses with a broad field of vision while watching the simulated process of entering the operating room. in control group we will use of intimacy and companion of parents for subjects. In addition, the examinees will given the anxiety questionnaires about two or three hours prior to going into the operating room. Furthermore, the findings in both groups will be compared with each other in the pre and post-test stages. One of the primary outcomes of this therapeutic method is the reduction of the pre-operative anxiety in children.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021525433N3**
Registration date: **2017-04-28, 1396/02/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

Name
Fatemeh Dehghan
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Kermanshah University of Medical Sciences

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2017-05-22, 1396/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual reality technology on Preoperative anxiety in children

Public title
The effect of virtual reality technology on Preoperative anxiety in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:age range of between 8 and 12 years, candidate for abdominal surgery, no history of abdominal

surgery, no mental illness through patient's file or asking from patient's companion. Exclusion criteria: stress or particular problems when using the glasses and virtual reality handset. previous history of using virtual reality instrument.

Age
From **7 years** old to **16 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In the present study we will use closed pocket for random assignment. By asking patients to chose a sheet and then will be assigned to experimental or control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor of Research,No 2 Building , Kermanshah University of Medical Sciences,Martyr Shahid Beheshti, Kermanshahi

City
Kermanshah

Postal code

Approval date
2017-02-14, 1395/11/26

Ethics committee reference number
KUMS.REC.1395.659

Health conditions studied

1

Description of health condition studied
anxiety

ICD-10 code
f41

ICD-10 code description
anxiety disorders, nonorganic or unspecified

Primary outcomes

1

Description
anxiety

Timepoint
Before surgery

Method of measurement
Beak Anxiety Questionnaire

Secondary outcomes

1

Description
Relaxation

Timepoint
Before surgery

Method of measurement
Questionnaire

Intervention groups

1

Description
Control group: Caress

Category
Behavior

2

Description
Intervention group: Virtual reality technology

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr Mohammad Kermanshahi Hospital

Full name of responsible person
Rostam Jalali

Street address
Hilal Ahmar crossroads, Kermanshah

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzai

Street address

Vice President of Research, Building 2, Kermanshah University of Medical Sciences,Martyr Shahed Behesht, Kermanshahi

City

Kermanshah

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 Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Behrooz Hamzeh

Position

Research Assistant

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