

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of interactive playing on the intensity of anxiety before orthopedic surgery in children 4 - 6 year

Protocol summary

Study aim

Determining the effect of interactive playing on the intensity of anxiety before orthopedic surgery in children 4 - 6 year

Design

The third phase of the clinical trial with a control group with a parallel group design, which will be conducted with a sample size of 60 people (30 subject in each of the intervention and control groups) and with a gender block.

Settings and conduct

This study is carried out by implementing an interactive playing scenario designed by the research team on children with non-dominant lower or upper extremity closed fractures of 4-6 years old children at the time of entering the operating room corridor of Shafa yahyaian Hospital and in the presence of the child's mother. The control group will not receive any intervention.

Participants/Inclusion and exclusion criteria

Consent of the child's mother for the child's participation in the research ,Child's cooperation to study , The presence of the mother next to the child at the time of sampling, Child Age between 4 and 6 years, Absence of mental and cognitive developmental disorders , Not having hyperactivity or autism, No record of entering the operating room for any reason, No history of previous surgery, Closed fracture in any of the lower limbs or non-dominant upper limbs of the child , Non-elective type of surgery

Intervention groups

The intervention includes the use of gloves which filled by water and a magic marker that is given to the child to draw simple shapes such as eyes or eyebrows on each finger of the glove at certain times of the scenario, following the narration of the scenario designed by the research team. The control group will not receive any intervention.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N11**

Registration date: **2023-01-18, 1401/10/28**

Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**

Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of interactive playing on the intensity of anxiety before orthopedic surgery in children 4 - 6 year

Public title

Effect of interactive playing on the anxiety before orthopedic surgery in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of the mother next to the child at the time of sampling
No history of entering the operating room for any reason
Closed fracture in any of the lower limbs or non-dominant upper limbs of the child
Absence of mental and cognitive developmental disorders
Not suffering from hyperactivity disorder or autism
Pain score less than 6 according to the Wong Baker scale

Exclusion criteria:

Lack of cooperation
Inability to continue intervention for any reason

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We use convenience sampling, but the samples will be allocated to intervention and control groups in the form of random blocks of four using the sealed envelope site. To ensure matching between the two groups as well as to achieve a completely random and balanced assignment, we will use a randomized classification using Stratified permuted block randomization. Individuals are then divided into two stratum of male and female, and for each class a separate random assignment is continued until the sample size is reached. For random assignment in each class based on different sequences of two methods A (intervention) and B (control), 4 blocks are defined and numbered from left to right from 1 to 4. Then using 1 to 4 random blocks of blocks are randomly selected. Thus, the assignment type is determined from left to right, respectively. Since we need 30 subject in each group, we have to randomly select the block 8 times for that class).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this research, for the interactive playing, we will use

the scenario designed by the research team, which uses a glove filled with water, the story is told by the researcher, and the child paints the items on each finger of the glove with a magic marker.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Semnan University of Medical sciences

Street address

Basij Blvd. Central Office of Semnan university of Medical sciences. Semnan. Iran

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Province

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Postal code

3513138111

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.SEMUMS.REC.1401.246

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F09

ICD-10 code description

Unspecified mental disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

1-The Yale Preoperative Anxiety Scale and 2-Visual analog scale of children's anxiety

Secondary outcomes

1

Description

Systolic and Diastolic Blood Pressure

Timepoint

Before and after intervention

Method of measurement

Digital Sphygmomanometer

2

Description

Pulse beat

Timepoint

Before and after intervention

Method of measurement

Wellex portable pulse oximeter model A310 made in Germany

3

Description

Oxygen saturation percentage

Timepoint

Before and after intervention

Method of measurement

Wellex portable pulse oximeter model A310 made in Germany

Intervention groups

1

Description

Intervention group: On the day of surgery, pulse, blood pressure, and blood oxygen saturation percentage of children in the intervention group with the same equipment in the presence of the child's mother and their anxiety with the preoperative anxiety scale of Yale University and visual analog scale (VAS) by a trained colleague of the project, it is measured and recorded. Then, using gloves filled with water and a magic marker that he gives to the child, the main researcher narrates the scenario designed by the research team and in several stages asks the child to identify parts of the face. Draw on each finger of the glove. At the end, for the second time, the aforementioned indicators are measured and recorded by the colleague of the project from the same arm as before and with the same instrument, and the child's anxiety is measured and recorded with the preoperative anxiety scale of Yale University and the visual analog scale (VAS).

Category

Prevention

2

Description

Control group: On the day of surgery, pulse, blood pressure, and blood oxygen saturation percentage of children in the intervention group with the same equipment in the presence of the child's mother and their anxiety with the preoperative anxiety scale of Yale University and visual analog scale (VAS) measured and recorded by a trained colleague of the project. No intervention was done for the control group and they were placed in a comfortable position on the bed for ten

minutes, which is equivalent to the intervention time for the intervention group. At the end, for the second time, the aforementioned indicators are measured and recorded by the colleague of the project from the same arm as before and with the same instrument, and the child's anxiety is measured and recorded with the preoperative anxiety scale of Yale University and the visual analog scale (VAS).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Farid Najd Mazhar

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Sponsors / Funding sources

1

Sponsor

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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
Semnan University of Medical Sciences
Proportion provided by this source
10
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable