

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effectiveness of an Interventional-Supportive Program on Children's Anxiety and Pain Hospitalized in Surgery Department

Protocol summary

Study aim

Determining the Effect of an Interventional-Supportive Program on Hospitalized children's Anxiety and Pain

Design

Two-group clinical trial of non-random assignment

Settings and conduct

This research is a clinical trial that aims to investigate the impact of an interventional-supportive program on severity of pain and anxiety after pediatric surgery. Sampling is an easy-continuous type and 64 hospitalized and operated children, aged 3-6 years, are selected and placed in two groups of control and intervention. In the first stage, sampling is done in the control group. One day after the surgery, the severity of anxiety _using Piyeri tool_ and pain scale _using Toddler-Preschool-Post operative Scale(TPPPS)_ are measured by the researcher. This group is routinely cared and 1-2 hours later, the child's anxiety and pain are re-measured. Sampling continues till the number of samples in the control group is completed. In the intervention group, one day after the operation, the severity of child's anxiety and pain score are evaluated using the mentioned tools, and 1-2 hours after the implementation of the interventional-supportive program, the intensity of child's anxiety and pain score is re-evaluated using the above tools. .

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age of 3 to 6 years, Having mental health and alertness, Having gastrointestinal Surgery, Non-entry criteria: Taking pain and anxiety-reducing medication, Having growth and mental retardation, Having previous surgical experience, Having a chronic illness (epilepsy, seizures, diabetes, known heart disease, kidney disease, Asthma).

Intervention groups

For the intervention group, the interventional-supportive program will be done based on the prepared booklet derived from educational concepts of kindergartens programs, and no intervention for the control group.

Main outcome variables

Pain and Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191004044976N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **retrospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Sima Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 7821

Email address

simaaskari@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of an Interventional-Supportive Program on Children's Anxiety and Pain Hospitalized in Surgery Department

Public title

The Effectiveness of an Interventional-Supportive Program on Children's Anxiety and Pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

3 to 6 year old children Having mental health and consciousness Surgery on the gastrointestinal Children whose hospitalization is longer than two days after surgery

Exclusion criteria:

Taking anti anxiety drugs Having growth and mental retardation Having a history of chronic illness (epilepsy, seizures, diabetes, diagnosed heart disease, kidney disease) Previous surgical experience Taking anti pain drugs

AgeFrom **3 years** old to **6 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Building No.4, Isfahan University of Medical Science, Hezarjirib Ave, Isfahan

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8174673461

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.401

Health conditions studied**1****Description of health condition studied**

Pediatric surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

Before intervention, One hour After intervention.

Method of measurement

Toddler-Preschool-Post operative scale(TPPPS)

2**Description**

Anxiety

Timepoint

Before intervention, One hour After intervention.

Method of measurement

Piyeri's Self-report tool for severity of anxiety.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: One day after the surgery, first the child's pain is assessed by Toddler-Preschool-Post operative scale and the child's anxiety is assessed using self-report Piyeri tool by the researcher. Then, while creating peace in an intimate atmosphere and maintaining proper communication from person to person based on the child's mood, age, gender, developmental, emotional, psychological and social needs, using the designed booklet, the counseling-supportive intervention will be done for about 45 minutes. This intervention uses distraction methods, such as expressing emotions, storytelling, playing game, and the joy of doing handiwork. This booklet has been

developed according to the needs of children and educational goals for kindergartens and preschool ages and has benefits such as transferring experience and teaching life skills to children, developing self-confidence and increasing problem-solving skills, creativity and familiarity with mathematical concept. 1-2 hours after the intervention, using the mentioned tools, the child's pain and anxiety is re-measured.

Category

Treatment - Other

2**Description**

Control group: One day after the surgery, first the child's pain is assessed by Toddler-Preschool-Post operative scale and then the child's anxiety is assessed using self-report Piyeri tool by the researcher. For this group, only routine care is provided. 1-2 hours later, the child's anxiety and pain are re-measured. This process continues till the samples are completed in the control group.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hussein Pediatric Hospital

Full name of responsible person

Mehrdad Memarzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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

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

Sima Askari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Person responsible for updating data**Contact****Name of organization / entity**

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