

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Impact of pictorial and movable story book on preoperative anxiety and postoperative behavioral disturbances among hospitalized 4 - 8 year-old Children with tonsillectomy.

Protocol summary

Summary

The present study will evaluate the impact of pictorial and movable story book on preoperative anxiety and postoperative behavioral disturbances. The aim of this study will be to reduce anxiety and behavioral disorders on the children who experienced the tonsils surgery. Sixty children will be taken a part in this study. Inclusion criteria: age between 4 -8 years; Lack of chronic diseases (cancer, liver disease and kidney); Have good speaking and hearing abilities; The presence of a parent or guardian at the time of admission; No surgery and hospitalization in the past; The lack of central nervous system diseases and mental illness; Exclusion criteria: Children and parents not wanting to continue studying; Stopping the surgery under any conditions; lack of cooperation in listening to the story. Subjects will be selected through the random numbers chart (30 numbers from 0 to 9 would be randomly selected. We would write AB statement (intervention-control) for each selected number from 0-4 and we would write BA statement (control-intervention) if the number is among 5-9. Then we would put them in one of the groups under study: first group listening to pictorial and movable story book about Tonsils surgery and hospitalization at night before surgery and another group no story book would be read routinely. The level of anxiety of the children before and after surgery will be evaluated using RCMAS questionnaire and the level of behavioral disturbances after surgery will be evaluated using a created researcher's questionnaire by the phone in 10 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082223704N1**

Registration date: **2015-12-13, 1394/09/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-13, 1394/09/22

Registrant information

Name

Zohreh Sekhavatpour

Name of organization / entity

Dezful University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 4222 0627

Email address

sekhavat.z@dums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Dezful University of Medical Sciences

Expected recruitment start date

2015-07-19, 1394/04/28

Expected recruitment end date

2015-12-19, 1394/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of pictorial and movable story book on

preoperative anxiety and postoperative behavioral disturbances among hospitalized 4 - 8 year-old Children with tonsillectomy.

Public title

Impact of pictorial and movable story book on preoperative anxiety and postoperative behavioral disturbances.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 4 -8 years; Lack of chronic diseases (cancer, liver disease and kidney); Have good speaking and hearing abilities; The presence of a parent or guardian at the time of admission; No surgery and hospitalization in the past; The lack of central nervous system diseases and mental illness; Exclusion criteria: Children and parents not wanting to continue studying; Stopping the surgery under any conditions; lack of cooperation in listening to the story.

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Dezful University of Medical Science

Street address

Azadegan Blvd

City

dezful

Postal code

Approval date

2015-07-29, 1394/05/07

Ethics committee reference number

IR.Dums.REC.1394.4

Health conditions studied

1

Description of health condition studied

Situational anxiety and behavioral disturbances

ICD-10 code

F40.2

ICD-10 code description

specific (isolated) phobias

2

Description of health condition studied

Situational anxiety and behavioral disturbances

ICD-10 code

R46.6

ICD-10 code description

Undue concern and preoccupation with stressful events

Primary outcomes

1

Description

Manifest and hidden Anxiety children

Timepoint

Immediately after the intervention and before surgery and after 10 days

Method of measurement

RCMAS scale

Secondary outcomes

1

Description

Behavioral disturbances

Timepoint

Before and 10 days after operation

Method of measurement

Created researcher questionnaire

Intervention groups

1

Description

Intervention group: the story book will be read For 30 minutes on the night before surgery. The researcher would fill the anxiety and the behavioral disorders

questionnaire before and after surgery and 10 days after through a phone call with the child's mother. This story will be designed in four parts. Part I: Presentation of information. In this section, two types of information would be given to children. Information regarding procedures includes basic information about the surgery and everything from the entry to exit from the hospital and sensory information includes feelings such as pain, itching, burning, pain in the region of the cut, and nausea and numbness that can be experienced during the treatment would be told to the child. Part II: Behavioral guidelines. In this section, effective behaviors such as breathing before the start of anesthesia would be told to the child and they would be playing the roles. And the child would be asked to repeat them. Part III: Cognitive interventions. In this part of the story book, the researcher would show images of the operating room along with all the equipment used in operating rooms to the child and this will change the child's recognition of the fact that these instruments will be painful. After telling the story for the child, he will be asked to do the works and tell his parents about them in order to review them in his mind. Part IV: Emotional interventions. In the entire process in this story book, the child would be asked to express his feelings and emotions such as anxiety or fear clearly. The child may tell us which part or parts make him frightened more or what he is anxious about.

Category
Behavior

2

Description

Control group: Only routine will be performed. In order to avoid any bias, the anxiety questionnaire would be filled before and after surgery and ten days after intervention of the assessment group including child's clinical psychologist, a nurse and the researcher in this section. Then the researcher would review the child's behavioral disorder through a self-made questionnaire before surgery and ten days after surgery by a phone calling talking to the child's mother

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Big Hospital Dezfoul
Full name of responsible person
Zohreh Sekhavatpour
Street address
Beginning of the road Andimeshk
City
Dezfoul

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Dezfoul University of Medical Sciences
Full name of responsible person
Dr Fereydon Nirozad
Street address
Azadegan Blvd, Dezfoul University of Medical Science, Research Center
City
Dezfoul
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, Dezfoul 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
Dezfoul University of Medical Science
Full name of responsible person
Seyedeh Maryam Molayi
Position
Research Manager
Other areas of specialty/work
Street address
Azadegan Blvd, Dezfoul University of Medical Science, Research Center
City
Dezfoul
Postal code
64611-58119
Phone
+98 61 4242 9731
Fax
+98 42429532
Email
Reaserch@dums.ac.ir
Web page address
Http://Research.dums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dezfoul University of Medical Science

Full name of responsible person

Zohreh sekhavatpour

Position

Master of Nursing

Other areas of specialty/work**Street address**

Dezfoul University of Medical Science, Paramedicine

City

Dezfoul

Postal code

64611-58119

Phone

+98 61 4222 0627

Fax

+98 42429532

Email

Sekhavat.z@dums.ac.ir

Web page address

Http://Research.dums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Dezfoul University of Medical Science

Full name of responsible person

Zohreh Sekhavatpour

Position

Faculty Dezfoul University of Medical Science

Other areas of specialty/work**Street address**

Dezfoul University of Medical Science, Paramedicine

City

Dezfoul

Postal code

64611-58119

Phone

+98 61 4222 0627

Fax

+98 42429532

Email

Sekhavat.z@dums.ac.ir

Web page address

Http://Research.dums.ac.ir/

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