

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the effectiveness of play therapy, storytelling and routine protocol on preoperative anxiety in preschool age children(3-6 years)

Protocol summary

Study aim

Comparison of the effectiveness of storytelling, play therapy and common hospital protocol on the severity of preoperative anxiety in children 3 to 6 years before and after the intervention

Design

A randomized clinical trial including a control group and non-blinded parallel groups was performed on 102 pre-school children (3 to 6 years) who were admitted to the hospital for a surgery. A simple random selection was employed using a table of random numbers to assign the children to one of the intervention group 1, group 2 and the control group. This process continued to the extent that the required sample size was attained in each group.

Settings and conduct

The current study was carried out at Golestan Hospital in Ahvaz. Children who were admitted for surgery selected according to the study criteria using a random allocation procedure. It should be noted that blinding was not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: preschool children, parental consent, mental wellbeing, prior 12 months non-admission to hospital or surgery, no concomitant treatment with medications. Exclusion Criteria: lack of proper communication.

Intervention groups

Intervention group one: Play therapy was used in this group. According to the age and gender of the child, suitable toys were given to her/him to choose one or some of the toys based on their interests. This intervention lasted for about 20 minutes. Intervention group two: Storytelling was used in this group. According to the child's age and gender, some books were read to him/her by the researcher or child's parents for about 20 minutes. Control group: In this group the common hospital's protocol included the presence of child's parents and/or hospital personnel, and medication under

the supervision of the anesthesiologist was used.

Main outcome variables

level of anxiety before surgery of children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041915N3**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **retrospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Kourosh Zarea

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8071

Email address

zarea_k@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

2020-01-05, 1398/10/15

Actual recruitment end date

2020-05-09, 1399/02/20
Trial completion date
 2020-05-09, 1399/02/20

Scientific title
 Comparing the effectiveness of play therapy, storytelling and routine protocol on preoperative anxiety in preschool age children(3-6 years)

Public title
 Comparing the effectiveness of play therapy and storytelling on preoperative anxiety in preschool age children

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children of pre-school age Parental informed consent
 Mentally health No admitted to hospital or surgery in pervious 12 months No concomitant drug treatment
Exclusion criteria:
 Inability to communicate properly

Age
 From **6 years** old to **12 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **102**
 Actual sample size reached: **97**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In the current study, the children who were admitted to the hospital for a surgery and were representative of the inclusion criteria were selected using a simple random allocation strategy based on a table of random numbers. The procedure was as follows: a number was called from the table when a child patient was brought to the operating room. If the last digit of the randomly selected number was one of 1, 2 or 3, the candidate was assigned to the first intervention group (the storytelling group) and if the last digit of the number was one of 4, 5 or 6, the candidate had to enter the second intervention group (the play therapy group). Finally, if the last digit of the selected number was one of 7, 8 or 9, the nominated child was considered a control group participant (receiving routine treatments) and if the last digit was zero, another number had to be selected from the table.

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

ethical Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Research Ethics Committee, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.AJUMS.REC.1399.104

Health conditions studied

1

Description of health condition studied

Pre-surgery anxiety in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

preoperative anxiety in pre-school age children

Timepoint

Anxiety measurement was performed before the intervention and immediately after the intervention.

Method of measurement

Observational Scale of Behavioral Distress-Revised (OSBD-R)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: The intervention in this group was Play Therapy. After random selection the child is assigned to this group and by entering the operation room, the child is assessed by the researcher. While the

child is brought to the operation room on a stretcher or in a wheelchair, he/she is given the chance to pick toys based on his/her gender. For example, toys such as dolls and kitchen utensils or household objects were options for female participants, and a car, a cannon, a rifle, or a set of building blocks were available for the male participants to choose from and start playing. This intervention lasted for about 20 minutes under the supervision of the researcher.

Category

Behavior

2

Description

Intervention group two: The method of the intervention in group two was storytelling. After random selection the child is assigned to this group, then he/she is assessed by the researcher. While the child is brought to the operation room on a stretcher or in a wheelchair, some story books such as "Hassani" are chosen based on the gender of the child from a series of short stories. These stories were visually appealing to the children because of varied and colorful images. The content was also relevantly chosen to include areas like, education, health, nutrition, discipline, and social regulation training. These books were read by the researcher, but in the presence of the parents. If the child did not like it, though, the parents were given the books to read them to the child, under the researcher's supervision; this intervention also lasted for 20 minutes.

Category

Behavior

3

Description

Control Group: The Common Hospital Protocol was followed for the participants in this group. Midazolam was prescribed by the anesthesiologist, for the purpose of child's sedation, and if the child's anxiety was not relieved, thiopental sodium was used at sufficient doses to cause drowsiness and/or loss of consciousness. However, for the children who did not require sedation, only their parents or often a health care professional such as an anesthesiologist or an operating room specialist were permitted to accompany the child and stay.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

kourosh zarea

Street address

NO. 201, atlati street, Ostadan district, Chamran

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zarea_k@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi moghadam

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Grant name

Grant code / Reference number

NCRCCD-9904

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Kourosh Zarea

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data files can be provided if necessary

When the data will become available and for how long

Not yet published

To whom data/document is available

Academic institutions and universities

Under which criteria data/document could be used

Researchers working in this field, if they obey full
confidentiality and just use for scientific proposes purely.

From where data/document is obtainable

By phone, fax or email and provide an official letter of
introduction from the scientific institute

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

First, he/she sends an official letter of introduction and a
letter of request to access the data via email. When the
letters were reviewed after a maximum of 20 days,
he/she is given the access.

Comments