

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating and comparison the effect of play therapy and storytelling on reducing anxiety in children admitted to the Hospital: a randomized clinical trial

Protocol summary

Study aim

Determining the comparative effect of play therapy and storytelling on the level of anxiety of hospitalized children

Design

A clinical trial with a control group, with parallel groups, single-blind, randomized, on 75 patients and in general, with three groups; randomization with the table of random numbers

Settings and conduct

This research is a single-blind clinical trial study on children hospitalized in Imam Ali Hospital in Karaj. Blinding will be done on the researcher filling the questionnaires. hospitalized children will be randomly divided into three groups: control, play therapy, and storytelling.

Participants/Inclusion and exclusion criteria

Inclusion: children aged 3 to 10, admitted to the ward for at least 48 hours, staying in the hospital for at least 5 days, diagnosed disease, obtaining informed consent from the child's parents; Exclusion: the presence of cognitive, nervous and learning problems, the child's lack of consciousness, inability to participate in interventions and cancer.

Intervention groups

The intervention in the play therapy group will be in the form of playing with medical toys to show the doctor - patient games for children. In this regard, some of the equipment available in the hospital, such as cotton, microset, abaisse-langue and needleless syringe, will be used so that the child can make crafts with them. Also, storytelling through two children's story books titled "Should I Go to the Hospital?" Written by Pat Thomas, translated by Dr. Geeta Mullally, will be read to the child on the first day. And on the second day, the book "Franklin Goes to the Hospital" written by Paulette Bourgeois and translated by Shahreh Hashemi will be

read by the child's parents. The control group will also receive the usual hospital treatments.

Main outcome variables

Reduction of anxiety symptoms; greater adherence to treatment in child patients

General information

Reason for update

Acronym

PTS (Play therapy and storytelling)

IRCT registration information

IRCT registration number: **IRCT20220704055367N1**

Registration date: **2022-07-13, 1401/04/22**

Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**

Update count: **0**

Registration date

2022-07-13, 1401/04/22

Registrant information

Name

Fatemeh Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

fatemeh.abdi87@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating and comparison the effect of play therapy and storytelling on reducing anxiety in children admitted to the Hospital: a randomized clinical trial

Public title
comparison the effect of play therapy and storytelling

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Aged between 3 to 10 Hospitalization for at least 48 hours Staying in the hospital for at least 5 days
 Diagnosed disease Obtaining informed consent from the child's parents
Exclusion criteria:
 The presence of cognitive, neurological or learning problems Having cancer Inability to participate in the desired intervention Child's lack of consciousness

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
In this intervention, the members of the play therapy, storytelling and control intervention groups will have the same size. Hence, for this purpose, the block randomization method, which is a limited randomization method and related to studies with groups containing the same sample size, will be used. Also, in this study, according to the sample size of each group, 25 blocks will be considered. In order to implement this method, the <https://www.sealedenvelope.com> will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a blinded clinical trial. Therefore, blinding will be implemented in the evaluators who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all three groups, in the form of a contract between the researchers. Also, it will be specified with one of the English letters above it, which questionnaire was completed by the participants of which of the study groups; However, the evaluators of the data analysis will not be aware of the

English letter of agreement between the researchers assigned to each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Research Ethics Committee of Alborz University of Medical Sciences
Street address
 Ethics committee office, Second floor, Safarian alley, 45 meters to Golshahr
City
 Karaj
Province
 Alborz
Postal code
 3149779453

Approval date
2022-06-25, 1401/04/04

Ethics committee reference number
IR.ABZUMS.REC.1401.084

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety score in Spence's questionnaire

Timepoint
Measuring the anxiety score at the beginning of the study (before the start of the intervention), the first day of the intervention and the second day of the intervention

Method of measurement
Spence Children's Anxiety Scale and Visual Facial Anxiety Scale

2

Description

Patient's treatment compliance

Timepoint

Measuring the treatment compliance score at the beginning of the study (before the intervention), the first day of the intervention and the second day of the intervention

Method of measurement

Morisky Medication Adherence Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Storytelling: Storytelling will be performed through two children's story books titled "Should I go to the hospital?" Written by Pat Thomas with translation by Dr. Gita Mullally on the first day. Besides, on the second day, the book "Franklin goes to the hospital" written by Paulette Bourgeois and translated by Shahreh Hashemi will be read by the child's parents.

Category

Treatment - Other

2

Description

Intervention group 2: Play therapy: It will be in the form of playing with medical objects such as cotton, brutte set, tongue depressor, needless syringe and similar staff. Then, the child can even make crafts with these things.

Category

Treatment - Other

3

Description

Control group: Receiving routine intervention of the ward

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Educational-Medical Center

Full name of responsible person

Fatemeh Abdi

Street address

Resalat crossroad

City

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Province

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<https://emamali.abzums.ac.ir/fa-IR/emamali.abzums.ac/5418/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Alborz Univeirsity of Medical Sciences (ABZUMS),
Northern Taleghani boulevard, Taleghani square

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3149779453

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info@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of nursing, Eshteraki street, Baghestan BLVD,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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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

Gynecology and Obstetrics

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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

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome and general demographic information can be shared.

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

Doctors, nurses, midwives, researchers working in universities and medical centers and hospitals, clinical psychologists

Under which criteria data/document could be used

Under no circumstances due to commitment to the patient and his companion

From where data/document is obtainable

Communication through e-mail (if possible to share information from a legal and ethical point of view, such as sharing the primary outcome of the study) To receive information, contact the following email address: fatemeh.abdi87@yahoo.com In the case of sending letter with regard to the current study, the following postal address of the corresponding author is available: School of nursing, Eshteraki street, Takhti Park, Baghestan BLVD

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

Finding the responsible author's email, stating the reason, complying with ethical and legal issues; In this case, a quick response will be given to the requester.

Comments