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.sealedenvelpe.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
Karaj
Province
Alborz
Postal code
3154646695
Phone
+98 26 3254 6372
Email
emamali@abzums.ac.ir
Web page address
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
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3419 7000
Email
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, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3146883811

Phone
+98 26 3433 6007

Email
fatemeh.abdi87@yahoo.com

Person responsible for scientific 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
Gynecology and Obstetrics

Street address
Taleghani Boulevard,Taleghani square, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3146883811

Phone
+98 26 3419 7000

Fax

Email
fatemeh.abdi87@yahoo.com

Person responsible for updating data

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
Gynecology and Obstetrics

Street address
School of nursing, Eshteraki street, Baghestan BLVD, Karaj, Iran

City
Karaj

Province
Alborz

Postal code
3146883811

Phone
+98 26 3433 6007

Email
fatemeh.abdi87@yahoo.com

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