

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of family-centered play therapy on anxiety in school-age children admitted to pediatric wards

Protocol summary

Study aim

To determine the effect of family-centered play therapy (FCPT) on anxiety in school-age children admitted to pediatric wards.

Design

This research is a Quasi-experimental study. The patients were randomly assigned to intervention and control groups (40 people in each group) based on random allocation.

Settings and conduct

The study location was in pediatric departments 1 and 2 of Afzalipur Hospital, Kerman University of Medical Sciences. Hospitalized children were included in the study if eligible and randomly assigned to the intervention and control groups by simple random method. Blinding was not done in this study. Parents in the intervention group played Dominos games with their children. The control group received routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized children aged 6-11 years. At least 24 hours have passed since their hospitalization. Their parents should be with the child as the main caregivers. The child has age-appropriate cognitive (mental) development. The child does not have mental disorders. The child does not have an acute physical disorder. The child has not been abused.

Intervention groups

In the intervention group, the parents were taught to play dominoes with their child twice a day (30 minutes each time) for three days. Parents were asked to play with the child when the child wished to play at least twice a day for half an hour. The control group received routine care.

Main outcome variables

The anxiety caused by hospitalization in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160914029817N11**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Esmat Nuhi

Name of organization / entity

Kerman University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-30, 1398/08/08

Expected recruitment end date

2021-02-26, 1399/12/08

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2020-04-27, 1399/02/08

Trial completion date

2021-02-26, 1399/12/08

Scientific title

The effect of family-centered play therapy on anxiety in school-age children admitted to pediatric wards

Public title

The effect of family-centered play therapy on anxiety in admitted children

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized children should be 6-11 years old. At least 24 hours have passed since their hospitalization. Their parents should be with the child as the main caregivers. The child should have age-appropriate cognitive (mental) growth and development. The child does not have mental disorders. The child does not have an acute physical disorder. The child has not been subjected to child abuse.

Exclusion criteria:**Age**

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected by a simple random sampling method based on random allocations using coin-tossing lottery. The intervention group was considered the head and the control group was considered to be the tail. Based on the sample size (40 people in each group), a coin was thrown to the number of people and people were randomly assigned to two groups. In order to prevent the interference between the groups, sampling was done from pediatric departments 1 and 2 during two weeks. The conditions of nursing care were completely similar in the two departments.

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 Kerman University of Medical Sciences

Street address

Deputy of Research and Technology, At the beginning of Ebnsina Street, Somayeh Crossroad (Tahmasb Abad)

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.KMU.REC.1398.360

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

The anxiety of hospitalized children

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

anxiety

Timepoint

Before the intervention and the end of the third day after the intervention.

Method of measurement

The Spielberger State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

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

Intervention group: First, the objectives of the study were explained to the children and parents in very simple language. Then, oral consent was obtained from the children and written consent was obtained from their parents. The questionnaire including demographic information and the Spiel Berger anxiety questionnaire was completed by the researcher in the second 24 hours of the child's hospitalization. The reason for completing the questionnaire on the second day of hospitalization was the stability of the parents' mental state and the assignment of the child in terms of diagnosing the disease and starting the treatment process. The researcher gave the parents in the intervention group a Dominoes game package (Dominoes is a game played with rectangular pieces) and taught them to play with their child at least twice a day for three days and 30 minutes each time. The playing time was determined

based on the child's request. At the end of the third day of the intervention, the researcher again completed the Spiel Berger Anxiety Inventory for each child.

Category

Other

2**Description**

Control group: The control group did not receive any intervention in the hospital except for routine care including medication interventions and teaching the necessary care to parents and children. There was no well-organized program for family-centered play therapy. The Spiel Berger Anxiety Inventory was also completed by the members of the control group on the second day of hospitalization and three days after the intervention. At the end of the study, the control group was given a toy package.

Category

Treatment - Other

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

Afzalipour Hospital

Full name of responsible person

Zahra Akhondzadeh

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Afzalipour Medical Education Center, Next to Shahid Bahonar University, Imam Khomeini Highway.

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

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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

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Esmat Nouhi

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

In order to build trust and maintain ethics in the research, the demographic characteristics of the participants were completely unrecognizable and confidential in the release of information. There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available