

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of therapeutic application of painting on hospitalization anxiety and coping strategies on hospitalized children

Protocol summary

Study aim

Determining the effect of painting therapy on anxiety and coping strategies of children hospitalized in Akbar children's hospital

Design

A randomized clinical trial with two groups of intervention and control group, Using the lottery the control group was sampled first and then the intervention group sampling was started

Settings and conduct

This study was conducted at the Akbar children's hospital. The intervention group participated in a group for 5 sessions of 1hour therapeutic use of painting in the game room. Sessions were conducted on the basis of theme-oriented method by the researcher and in relation to topics including: Free(session 1), Patient feelings about the hospital and its environment(Session 2), Illness and patient(Session 3), Care team including nurses and doctors(Session 4), Treatment services and procedures(Session 5). In each session, after brief explanation, the painting tools(crayons, watercolors, pastels, markers, and in the fourth session the gouache) was provided as a package to the child. The child painted on the theme assigned. At the end of each session, the researcher asked the child to design a story for his painting. At the 3rd session, children were asked to play a show of their story with cutting off the characters and gluing them on a craft stick. The 4th session was painting on the wall with a brush and syringe and 5th session was coloring.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 7 to 12 years Non-inclusion criterion: Isn't in the first 24 hours of admission; History of admission; Anxiety score of below 19; Mental retardation, Down syndrome and cognitive impairment; Inability to leave the bed

Intervention groups

Intervention group: painting, five sessions, with theme-oriented method, each session 1hour, two sessions a day

Control group: No intervention received

Main outcome variables

Anxiety; Coping Strategy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039799N1**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **retrospective**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Mehri Miri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 8513

Email address

mirim931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2018-11-22, 1397/09/01
Trial completion date
 2018-12-11, 1397/09/20

Scientific title
 Effect of therapeutic application of painting on hospitalization anxiety and coping strategies on hospitalized children

Public title
 Effect of painting therapy on hospitalization anxiety

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The child should be hospitalized The child's age should be between 7 and 12 years old
Exclusion criteria:
 The child should not leave the bed The child is not in the first 24 hours of admitting The child has a previous history of admission The child will be discharged from the hospital in less than 3 days The child has an anxiety score of less than 19 The child has mental retardation, Down syndrome and known cognitive impairment Parents and child are not willing to participate in the study

Age
 From **7 years** old to **12 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
 Not randomized

Randomization description

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
 Research Ethics Committee of Mashhad University of Medical Sciences
Street address

School of Nursing and Midwifery, Ebne Sina Street, Mashhad
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9137913199
Approval date
 2018-05-05, 1397/02/15
Ethics committee reference number
 IR.MUMS.REC.1397.037

Health conditions studied

1

Description of health condition studied

Hospitalized children's Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Children that scored more than 19 in Anxiety score in Revised Children Manifest Anxiety Scale (RCMAS)

Timepoint

Measure anxiety before and immediately after the intervention

Method of measurement

Revised Children Manifest Anxiety Scale

2

Description

Coping strategies in Coping Strategies Inventory-Short Form

Timepoint

Checking coping strategies before and immediately after the intervention

Method of measurement

Coping Strategies Inventory-Short Form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Art painting (painting), five sessions, with theme-oriented method, each session 1 hour, two sessions a day

Category

Rehabilitation

2

Description

Control group: Filling the Revised Children Manifest Anxiety Scale and Coping Strategies Inventory-Short Form on Day 1 and 3 and they receive only routine interventions in the duration of hospitalization

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar children's hospital

Full name of responsible person

Dr Ali Khakshour

Street address

In front of No. 14, Shahid Kaveh Blvd

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Razavi Khorasan

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9138813944

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Research Chancellor, In front of No.18, Daneshgah Ave

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mehri Miri

Position

MSc. Pediatric Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Latest degree

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Email

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

Only the article will be published

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available