

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluating the Effect of Mandala Art Therapy on Stress and Anxiety Among Mothers of Children Admitted to the Pediatric Intensive Care Unit (PICU)

Protocol summary

Study aim

The Effect of Mandala Therapy on Stress and Anxiety Among Mothers of Children Admitted to the Pediatric Intensive Care Unit

Design

A clinical trial with a control group, with parallel groups, without blinding, was conducted on 100 mothers with children hospitalized in the special care department of Afzalipur Hospital in Kerman. A table of random numbers was used for randomization

Settings and conduct

In two groups, Anxiety and stress of mothers are measured with Spielberger's State-Trait Anxiety Questionnaire and Cohen's Perceived Stress. If the score of anxiety and stress was moderate to severe, the samples will be placed in two groups of intervention and control in a simple random manner. In the mandala group, a mandala design is colored for 6 days and every day for 30 minutes. Then, the mother's anxiety and stress are checked on the sixth day after the end of the intervention, and in the control group, the mother's anxiety and stress are checked at the same time intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Mothers of hospitalized children aged 1 to 12 years, Moderate to severe anxiety and stress before the intervention; Exclusion criteria: Mother's mental illness

Intervention groups

In the mandala group, several different designs of mandala painting and a pack of 6 colored pencils are provided to the mother. And she is asked to choose one of the designs every day for 6 days and paint it in 30 minutes. The control group will not receive any intervention and only the anxiety and stress of the mothers will be assessed at the same time interval as the intervention group.

Main outcome variables

Anxiety, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053920N2**

Registration date: **2023-05-17, 1402/02/27**

Registration timing: **prospective**

Last update: **2023-05-17, 1402/02/27**

Update count: **0**

Registration date

2023-05-17, 1402/02/27

Registrant information

Name

Reihane Moghimian Shahrabaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 9438

Email address

moghimianreihane1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Mandala Art Therapy on Stress and Anxiety Among Mothers of Children Admitted to the Pediatric Intensive Care Unit (PICU)

Public title
The Effect of Mandala on Stress and Anxiety of Mothers

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and written consent Mothers of hospitalized children aged 1 to 12 years The age range of the mother is 50-18 Mother's anxiety and stress before the study based on Spielberger scale and perceived stress scale should be moderate to high
Exclusion criteria:
History of mental illness in the mother

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples to intervention and control groups is done by a simple random method and through a random number table. In this way, the researcher touches one of the numbers from left to right and records the numbers and assigns them to different groups. Even numbers will be considered for the intervention group and odd numbers for the control group, and sampling will continue until the required sample size is completed in the research.

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 Kerman University of Medical Sciences
Street address
Jahad Blvd, Ebn Sina Avenue, Somayeh Crossroads, Kerman
City
Kerman
Province
Kerman
Postal code
7613859610
Approval date
2023-04-10, 1402/01/21
Ethics committee reference number
IR.KMU.REC.1402.013

Health conditions studied

1

Description of health condition studied
Stress and Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety score based on Spielberger scale
Timepoint
Before and after the intervention
Method of measurement
Spielberger State-Trait Anxiety Inventory

2

Description
Stress score on Cohen's perceived stress scale
Timepoint
Before and after the intervention
Method of measurement
Cohen Perceived Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the mandala coloring group, after measuring the mother's stress and anxiety, several

different designs of mandala painting are provided to the mother separately on A4 paper and a pack of 6 colored pencils. And mothers are asked to paint the mandala for 30 minutes every day for up to six consecutive days. Determining the time of coloring will be done according to the required of mothers. Before the intervention and on the sixth day after the intervention, the anxiety and stress questionnaire will be completed again.

Category

Treatment - Other

2**Description**

Control group: In the control group, there is no intervention and the mother's anxiety and stress is checked only at the same time intervals in the group of mandala coloring.

Category

Treatment - Other

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

Afzalipour Hospital in Kerman

Full name of responsible person

Monirsadat Nematollahi

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Afzalipur Hospital, Afzalipur Imam Pardiseh Highway, Kerman

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

Kerman University of Medical Sciences

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

Reihane Moghimian Shahrbabaki

Position

Master of pediatric nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

No more information

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