Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ctiteria: 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 Shahrbabaki
Name of organization / entity
Country
Iran (Islamic Republic of)
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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

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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

Street address
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

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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