

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Mandala staining on the anxiety of mothers with hospitalized neonatal care unite

Protocol summary

Study aim

The effect of Mandala staining on the anxiety of mothers with hospitalized neonatal care unite

Design

Clinical trial with a control group, with parallel groups, a blind strain, randomized on 90 patients. Sealed Envelope software will be used for randomization.

Settings and conduct

This study will be conducted in the educational center of Imam Khomeini hospital in Arak. After coloring by the intervention group, their anxiety level is measured and recorded. Only the analyzers do not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Having the ability to paint, Having a baby in the neonatal intensive care unit, Age over 20 years to 45 years:
Exclusion criteria: Suffering from anxiety and obsessive disorders, Having twins or multiples

Intervention groups

Intervention group: Demographic information and Spielberger anxiety questionnaires are completed by this group before and after the intervention. Coloring will be done only for the intervention group. How to paint and participate in the study is fully explained to the mothers by the researcher, and the mothers in the intervention group are asked to start painting in a private and quiet place. Coloring three times a week and each time for at least 15 minutes. Control group: They do not receive this intervention during this period. Spiel Berger's anxiety questionnaire is completed again by mothers in both groups after the intervention.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N5**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **prospective**

Last update: **2022-11-07, 1401/08/16**

Update count: **0**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mandala staining on the anxiety of mothers with hospitalized neonatal care unite

Public title

The effect of Mandala staining on the anxiety

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to participate in the study Having the ability to paint Having a baby in the neonatal intensive care unit
 Age over 20 years to 45 years
Exclusion criteria:
 Suffering from anxiety and obsessive disorders Having twins or multiples

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
 Mothers are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and does not have a specific pattern, and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created, and a block is randomly selected by placing it between the blocks, and from the arrangement pattern in that block for Child allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Single blinded

Blinding description
 The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medical sciences

Street address

Arak university of medical sciences, Basij Sq., Sardasht region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.ARAKMU.REC.1401.056

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Average anxiety score

Timepoint

Three times a week and each time for at least 15 minutes

Method of measurement

At the beginning and end of the study, the demographic questionnaire and the Spiel Berger questionnaire were completed by the mothers of both groups and based on this, the anxiety level of nurses is determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Demographic information and

Spielberger anxiety questionnaires are completed by this group before and after the intervention. Coloring will be done only for the intervention group. How to paint and participate in the study is fully explained to the mothers by the researcher, (The coloring should be the same as the mandala patterns that have been determined in advance, and each part of the pattern should be colored with different colors, and the coloring should be orderly.) then the mothers in the intervention group are asked to start painting in a private and quiet place. Coloring three times a week and each time for at least 15 minutes.

Category

Other

2

Description

Control group: They do not receive this intervention during this period. Spiel Berger's anxiety questionnaire is completed again by mothers in both groups after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Mahbobeh Sajadi

Street address

Gerdoo St., Tandorosti Blvd., Arak city Town

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3819693345

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Email

golmehrsherafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

Street address

University complex of the Great prophet, Basij square, Sardasht

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3819693345

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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

Arak University of Medical Sciences

Proportion provided by this source

80

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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

University complex of the Great prophet, Basij square, Sardasht.

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Postal code

3819693345

Phone

009886341735057

Email

golmehrsherafati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

Since the winter of 2023

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to reduce the level of anxiety of the families of hospitalized patients

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences

What processes are involved for a request to access data/document

These documents will be available on the website of Arak university of medical sciences.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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