Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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Markazi

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3819693345

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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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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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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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Person responsible for updating data

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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