

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of mandala coloring meditation technique on PTSD of mothers of premature infants

Protocol summary

Study aim

Determination and comparison of post-traumatic stress disorder before and after the intervention in two control and intervention groups

Design

A clinical trial type study with two control and intervention groups, with parallel groups, randomized on 41 mothers with premature babies.

Settings and conduct

Children's Medical Center Hospital, Shariati, Waliasr Imam Khomeini

Participants/Inclusion and exclusion criteria

Having a baby hospitalized in a special care unit, not having a history of premature baby hospitalization, not being abnormal, suffering from depression and anxiety during the study, and the mother's unwillingness to continue participating in the study.

Intervention groups

Mothers of premature babies do mandala coloring

Main outcome variables

Post-traumatic stress disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221025056293N1**

Registration date: **2022-11-18, 1401/08/27**

Registration timing: **prospective**

Last update: **2022-11-18, 1401/08/27**

Update count: **0**

Registration date

2022-11-18, 1401/08/27

Registrant information

Name

Fatemeh Alimohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5583 3896

Email address

fatemehalimohammadi340@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mandala coloring meditation technique on PTSD of mothers of premature infants

Public title

The effect of mandala coloring on PTSD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a baby hospitalized in a special care unit Not having a history of hospitalization of a premature baby The baby is not abnormal

Exclusion criteria:

Suffering from depression and anxiety during the study Mother's unwillingness to continue participating in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 41

Randomization (investigator's opinion)

Randomized

Randomization description

Selection is done by a simple random method. In this method of sampling, two groups (mandala and control) are written on a card and placed in closed envelopes, and the mothers select the envelopes from the box to determine which group they will fall under..

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

Ethics Committee of Tehran School of Nursing and Midwifery

Street address

Tawheed Square, Dr. Mirkhani St. (East Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-10-24, 1401/08/02

Ethics committee reference number

IR.TUMS.FNM.REC.1401.085

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Post-traumatic stress disorder in mothers of premature babies

Timepoint

Investigating post-traumatic stress disorder before the beginning of the stages and one month after mandala coloring

Method of measurement

Perinatal Post Traumatic Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mothers of premature babies first completed the post-natal stress disorder questionnaire and then colored mandala designs from simple to complex for 11 sessions, each session lasting 20 minutes, and one month after the intervention, the stress disorder questionnaire was completed again. After the accident, they answer perinatal.

Category

Lifestyle

2

Description

Control group: mothers with premature babies hospitalized in the neonatal intensive care unit are selected, who only complete the post-traumatic stress disorder questionnaire one month later.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Fatemeh Ali Mohammadi

Street address

Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., end of Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1419733151

Phone
+98 21 6147 2353
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2

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Fatemeh Ali Mohammadi
Street address
Tehran, North Kargar St., Jalal Al Ahmad Street,
Shariati Hospital's Educational Research and
Treatment Center
City
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Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
shariatihosp@tums.ac.ir

3

Recruitment center

Name of recruitment center
Imam Khomeini's Waliasr complex
Full name of responsible person
Fatemeh Ali Mohammadi
Street address
Tehran, at the end of Keshavarz Boulevard, Dr. Gharib
Street; Imam Khomeini Hospital Complex
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۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mehrnaz Granmayeh
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
City
Tehran
Province

Tehran
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1419733171
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+98 21 6692 7171
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fnm@tums.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran School of Nursing and Midwifery
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
Tehran University of Medical Sciences
Full name of responsible person
Batol Purabuli
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Alimohammadi
Position
Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Fax**Email**

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Increasing information

From where data/document is obtainable

Tehran University School of Nursing and Midwifery
Library

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

Submit your application to Tehran University School of Nursing and Midwifery

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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Alimohammadi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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