

# 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  
**Email**  
cmcpr@tums.ac.ir

## 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**  
Tehran  
**Province**  
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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
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  
**Postal code**  
1419733171  
**Phone**  
+98 21 6692 7171  
**Email**  
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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**Province**  
Tehran  
**Postal code**  
1419733171  
**Phone**  
+98 21 6692 7171  
**Email**  
fnm@tums.ac.ir

## 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

**Street address**

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

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**Province**

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**Postal code**

1419733171

**Phone**

+98 21 6692 7171

**Fax****Email**

fatemehalimohammadi340@gmail.com

**Email**

fatemehalimohammadi340@gmail.com

**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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