

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluation of the effectiveness of Guided Imagery on anxiety and breast milk volume of mothers of preterm infants

#### Protocol summary

##### Study aim

Determining the effect of Guided Imagery on anxiety and breast milk volume of mothers of preterm infants

##### Design

Non-randomized clinical trial with control group, Parallel, Without blinding, On 60 mothers of premature infants

##### Settings and conduct

After obtaining the consent of the mothers of premature infants admitted to the neonatal intensive care unit of Imam Reza, Ghaem, Umm Al-Banin, Hasheminejad hospitals, the guided imagery technique is performed for the mothers of the intervention group. Mothers in the control group receive routine ward care. Anxiety is measured twice before and after the intervention. Milk volume is measured and recorded four times with a graduated milk glass.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Mother of the baby was born with a fetal age of 28 to 32 weeks 2. The mother has a baby without congenital heart, genetic, gastrointestinal and neurological abnormalities 3. Maternal non-use of psychiatric drugs including: diazepam, oxazepam, alprazolam, chlordiazepoxide 4. The mother has not experienced a traumatic event or stressful event such as the death of a loved one, accident, family quarrels, financial problems in the last 6 months 5. The mother has not previously attended similar relaxation classes or psychotherapy courses Exclusion criteria: 1. Start oral feeding for the baby 2. Lack of cooperation of the mother in doing the exercises

##### Intervention groups

In the intervention group, the guided imagery technique is performed for one week after training. The mothers in the control group receive routine ward care, including breastfeeding training and how to express milk and breast massage by the ward nurses.

##### Main outcome variables

Anxiety, Breast Milk Volume

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210324050763N1**

Registration date: **2021-06-17, 1400/03/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-17, 1400/03/27**

Update count: **0**

##### Registration date

2021-06-17, 1400/03/27

##### Registrant information

##### Name

Narges Rashid Nooghabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

rashidnn981@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-05, 1400/03/15

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of Guided Imagery on anxiety and breast milk volume of mothers of preterm infants

#### Public title

Evaluation of the effectiveness of Guided Imagery on anxiety and breast milk volume of mothers of preterm infants

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The mother of the baby was born with a fetal age of 28 to 32 weeks The mother has a baby without congenital heart, genetic, gastrointestinal and neurological abnormalities Age over 18 years old mother Maternal non-use of psychiatric drugs including: diazepam, oxazepam, alprazolam, chlordiazepoxide The mother has not experienced a traumatic event or stressful event such as the death of a loved one, accident, family quarrels, financial problems in the last 6 months. The mother has not previously attended similar relaxation classes or psychotherapy courses The mother is not addicted The mother does not take drugs that are contraindicated during breastfeeding, including doxepin tricyclic antidepressants, iodinated compounds, gold salts, salicylates, and anticonvulsants during the intervention. The mother has no history of breast surgery and breast problems (breast fissure, congestion, mastitis and breast abscess) The mother should not take milk-enhancing drugs, including Galactomade and metoclopramide The mother should not have contraindications to breastfeeding such as: galactosemia, mother with active tuberculosis, drug abuse, human immunodeficiency virus, users of certain drugs such as antimetabolites and chemotherapy drugs

##### Exclusion criteria:

Start oral feeding for the baby Transfer the baby to other centers Infant death Lack of cooperation of the mother in doing the exercises Mother withdraws from further study Use other relaxation methods such as: yoga, meditation, relaxation Illness of the baby (requires mechanical ventilation)

#### Age

From **18 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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 Mashhad University of Medical Sciences

###### Street address

School of Nursing and Midwifery, Ebne Sina St.

###### City

MASHHAD

###### Province

Razavi Khorasan

###### Postal code

9137913199

##### Approval date

2021-04-20, 1400/01/31

##### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.009

#### Health conditions studied

##### 1

##### Description of health condition studied

Anxiety

##### ICD-10 code

F41.9

##### ICD-10 code description

Anxiety disorder, unspecified

##### 2

##### Description of health condition studied

Breast Milk Volume

##### ICD-10 code

##### ICD-10 code description

#### Primary outcomes

##### 1

##### Description

Anxiety

##### Timepoint

Before intervention, Immediately after intervention

##### Method of measurement

Spielberger's State-Trait Anxiety Inventory

##### 2

##### Description

Breast MilkVolume

##### Timepoint

Before the intervention, The third day of the intervention 2 hours after the technique, The seventh day of the intervention 2 hours after the technique and one week after the intervention

**Method of measurement**

Milk volume registration form

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Mothers in the intervention group should do this technique twice a day (9 am and 9 pm) for 15 minutes each time for a week after training. In addition to performing the technique, the mothers of the intervention group benefit from the usual actions of the ward.

**Category**

N/A

**2**

**Description**

Control group: Mothers in the control group receive routine care, including breastfeeding training and how to express milk and breast massage by ward nurses.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Hamid Reza Behnam Vashani

**Street address**

Ebne Sina Street

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3854 3031

**Email**

behnamhr@mums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Hamid Reza Behnam Vashani

**Street address**

Ahmad Abad Street

**City**

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**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3840 0001

**Email**

behnamhr@mums.ac.ir

**3**

**Recruitment center**

**Name of recruitment center**

Ommolbanin Hospital

**Full name of responsible person**

Hamid Reza Behnam Vashani

**Street address**

Corner of Ayatollah Behjat 16, Zarrineh Crossroads

**City**

MASHHAD

**Province**

Razavi Khorasan

**Postal code**

91447347667

**Phone**

+98 51 3223 1061

**Email**

behnamhr@mums.ac.ir

**4**

**Recruitment center**

**Name of recruitment center**

Hasheminezhad Hospital

**Full name of responsible person**

Hamid Reza Behnam Vashani

**Street address**

Moftteh Street, at the end of Abu Reihan Blvd

**City**

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**Postal code**

9138813944

**Phone**

+98 51 3273 7011

**Email**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Robab Latifnejad Roodsari

**Street address**

Ebne Sina Street

**City**

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**Province**

Razavi Khorasan

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**Phone**

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**Email**

latifnejadr@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Narges Rashid Nooghabi

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Ebne Sina street

**City**

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**Province**

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**Postal code**

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**Phone**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Narges Rashid Nooghabi

**Position**

Master Student

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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Razavi Khorasan

**Postal code**

9137913199

**Phone**

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**Email**

rashidnn981@mums.ac.ir

## Sharing plan

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

Undecided - It is not yet known if there will be 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**

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