

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

۹۱۳۷۹۱۳۳۱۶

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

MASHHAD

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

MASHHAD

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3273 7011

Email

behnamhr@mums.ac.ir

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

MASHHAD

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

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

MASHHAD

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

rashidnn981@mums.ac.ir

Person responsible for scientific 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

MASHHAD

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

rashidnn981@mums.ac.ir

Person responsible for updating data

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

MASHHAD

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

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