

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the Efficacy of Maternal and Couple-Based Lactating Mindfulness Counseling on Breastfeeding Success and Sleep Quality of First Mother Women.

#### Protocol summary

##### Study aim

Determining the effectiveness of breastfeeding counseling with mindfulness approach in mother and couple on breastfeeding success and sleep quality of first pregnant mothers

##### Design

A clinical trial with a mother-centered and couple-centered control group, with parallel groups, one-way blind, randomized and six-block blocking was used for randomization.

##### Settings and conduct

This study compares the effectiveness of breastfeeding counseling with mindfulness approach in mothers and couples on the success of breastfeeding and sleep quality of first pregnant mothers (37 to 40 weeks) with the aim of reviewing patients referred to health centers in Miandrod. Is taken and after completing the GHQ (General health Questionnaire) (general health) and obtaining a score of 0 to 22 from the questionnaire and ensuring the inclusion criteria, the sample is allocated by the project manager in a randomized block method with six blocks (ABBABA). People under study and statistical advice are unaware of the allocations.

##### Participants/Inclusion and exclusion criteria

First pregnant Single twin Gestational age 37 to 40 weeks Not having a disease whose treatment interferes with breastfeeding Has at least basic literacy and reading and writing Persian No history of psychosocial diseases or interference with sleep quality Do not take sleeping pills during the last three months No smoking, alcohol Lack of chronic diseases Wanted pregnancy Written consent to participate in the study Score zero to 22 from the General Health Questionnaire

##### Intervention groups

Mothers Couples

##### Main outcome variables

Breastfeeding success; sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220128053847N1**

Registration date: **2022-02-12, 1400/11/23**

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

Last update: **2022-02-12, 1400/11/23**

Update count: **0**

##### Registration date

2022-02-12, 1400/11/23

##### Registrant information

##### Name

Masoumeh Taghavi zirvani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3373 3555

##### Email address

m.taghavi@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-30, 1400/11/10

##### Expected recruitment end date

2022-03-11, 1400/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing the Efficacy of Maternal and Couple-Based Lactating Mindfulness Counseling on Breastfeeding Success and Sleep Quality of First Mother Women.

## Public title

Maternal and Couple-Based Lactating Mindfulness Counseling on Breastfeeding Success and Sleep Quality of First Mother Women.

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

nullipara single pregnancy gestational age 37 to 40 weeks no diseases that interfere with breastfeeding (eg. chemotherapy) having basic literacy of reading and writing Persian no psycho-cognitive diseases or interference with sleep quality (anxiety, depression, severe stress, and etc.). not take sleep drugs in the last three months no smoking and alcohol no chronic diseases (cardio-vascular diseases, asthma, diabetes, and etc.). wanted pregnancy written consent to participate in the study earn point zero to 22 of GHQ (General health questionnaire)

### Exclusion criteria:

Cesarean section Any cases that cause grief in the mother (death of husband, parents, IUFD) Pregnant with Depressive disorder intestinal colic in children Start artificial feeding (for any reason) People who are absent more than 2 sessions of training.

## Age

From **18 years** old to **35 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **127**

More than 1 sample in each individual

Number of samples in each individual: **2**

In the couple counseling group, parents receive counseling at the same time

## Randomization (investigator's opinion)

Randomized

## Randomization description

Assignment of samples by the project manager in a randomized block method with six blocks (ABBABA) participants will be divided into 3 groups: 37 participants for each mothers and couples counseling, and 53 control participants.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

participants and statistical advice (people who analyze the results) are unaware of the allocations.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of shahroud university of medical sciences

##### Street address

No. 284, 28 th st , Ashab Ave , West Ring Road

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816918375

#### Approval date

2022-01-28, 1400/11/08

#### Ethics committee reference number

IR.SHMU.REC.1400.221

## Health conditions studied

### 1

#### Description of health condition studied

Brest feeding and sleep quality

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sleep quality score

#### Timepoint

Before the start of the intervention and the end of the last session of the intervention (5)

#### Method of measurement

Pittsburgh Questionnaire

### 2

#### Description

Success of exclusive breastfeeding

#### Timepoint

The beginning of the first session after delivery and the end of the 1st, 2nd, 3rd and 4th months after delivery

#### Method of measurement

Exclusive breastfeeding nutrition questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Mothers who are taught breastfeeding counseling with a mindfulness approach in 5 sessions.

#### Category

N/A

### 2

#### Description

Intervention group: Couples who are jointly trained in 4 sessions of breastfeeding counseling with a mindfulness approach.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Miandorod Health Centers

##### Full name of responsible person

Masoumeh Taghavi zirvani

##### Street address

Jamkhaneh health center, Shafa st., Jamkhaneh Village, Miandorod, Mazandaran

##### City

Miandorood

##### Province

Mazandaran

##### Postal code

4816918375

##### Phone

+98 11 3373 3555

##### Email

m.taghavi1496@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Masoumeh Taghavi Zirvani

##### Street address

No. 284, 28th St., Ashab Ave., west ring road, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816918375

##### Phone

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#### Email

m.taghavi1496@yahoo.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Miandorod Health Network

#### Proportion provided by this source

10

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Nahid Bolbol Haghghi

##### Position

Associate professor

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

Shahroud University of Medical Sciences, 7th Tir Sq., Shahroud.

##### City

Shahroud

##### Province

Semnan

##### Postal code

3614773943

##### Phone

+98 23 3239 5054

##### Email

nbhaghghi349@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Masoumeh Taghavi Zirvani

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

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student

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The information recorded from the participants is confidential and cannot be published.

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

No data of individual information will be published. Only, general data of the population and conclusion of statistics will be published.

**When the data will become available and for how long**

With publishing the final article.

**To whom data/document is available**

All of scientific researchers

**Under which criteria data/document could be used**

After publishing final article, all of the permissible information is accessible.

**From where data/document is obtainable**

m.taghavi1496@yahoo.com

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

By receiving the application message, it will be presented after checking the identity of the applicant.

**Comments**