Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Miandrood. 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. chemiotherapy) 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 alchohol 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) Pregnancy Depressian 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 guality

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 zirnani
Street address
Jamkhaneh health center, Shafa st., Jamkhaneh Village, Miandorod, Mazandaran
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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
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Email
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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 Haghighi
Position
Associate professor
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Position
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Latest degree
Bachelor
Other areas of specialty/work
Midwifery

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Person responsible for updating data

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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