Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of a Mindfulness Intervention on Breastfeeding Self-Efficacy in Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit: A randomized trial study

Protocol summary

Study aim
Determining the Effectiveness of Mindfulness on Breastfeeding Self-Efficacy in Mothers of Preterm Infants Hospitalized in the NICU

Design
This study is a randomized, single-blind, controlled, Phase 3 clinical trial involving 64 mothers of preterm infants. Mothers will be assigned to either the intervention group or the control group in a 1:1 ratio using a block randomization method with blocks of eight (generated by Random Allocation Software).

Settings and conduct
This clinical trial will be conducted at Besat Hospital in Sanandaj. Given the nature of the study, participating mothers will be aware of the intervention; therefore, blinding will be implemented only for the data analyst.

Participants/Inclusion and exclusion criteria
1- Mothers of hospitalized preterm infants with a gestational age of 32 to 37 weeks 2- Ability to attend educational sessions in the event of discharge 3- No history of mindfulness training 4- No history of using sedatives or psychotropic medications prior to or during pregnancy 5- No history of depression or anxiety disorders 6- Maternal age range (18 to 45 years) 7- Low breastfeeding self-efficacy score on the pre-test

Intervention groups
In addition to routine care, mothers in the intervention group will receive eight mindfulness training sessions delivered in person on an individual basis. After obtaining the relevant training certification, the researcher will conduct these sessions—each lasting 90 minutes and held weekly at the hospital—face-to-face with each mother in the intervention group. Additionally, at the end of each session, the mothers will be provided with audio files containing the mindfulness exercises covered in that session. Mothers in the control group will receive the ward's routine care.

Main outcome variables
Mothers' breastfeeding self-efficacy

General information

Reason for update

Acronym
MW-BSE

IRCT registration information
IRCT registration number: **IRCT20200913048704N6**
Registration date: **2026-10-25, 1405/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-25, 1405/08/03**
Update count: **0**

Registration date
2026-10-25, 1405/08/03

Registrant information

Name
Ali Zabihi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-05-22, 1406/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of a Mindfulness Intervention on Breastfeeding Self-Efficacy in Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit: A randomized trial study

Public title
The Effect of Mindfulness Exercises on Breastfeeding Self-Efficacy in Mothers of Premature Infants Hospitalized in the Neonatal Intensive Care Unit
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The mother's willingness to participate in the study and provide informed consent A mother with a preterm infant—born at a gestational age of 32 to 37 weeks—admitted to the Neonatal Intensive Care Unit (NICU) Mothers of premature infants who are able to breastfeed directly from the breast Ability to read and write in Persian Availability of the mother Ability to participate in the educational sessions in case of discharge from the hospital No previous history of mindfulness training No chronic underlying disease or congenital anomaly in the infant No history of maternal use of sedative or psychotropic medications before or during pregnancy No history of depression or anxiety Maternal age between 18 and 45 years Low breastfeeding self-efficacy score at pre-test
Exclusion criteria:
Death of the infant The infant requires treatment in such a way that continuation of breastfeeding directly from the breast is not possible The simultaneous presence of mothers from both the control and intervention groups in the ward, in a scenario where the time to infant discharge is longer for mothers in the control group than for those in the intervention group.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Mothers of infants hospitalized in the NICU at Besat Hospital in Sanandaj will be selected via a convenience sampling method and subsequently randomly assigned to either an intervention group or a control group. Given that study participants do not enter the study simultaneously and group assignment for each incoming participant is unpredictable, block randomization (using blocks of eight) will be employed to allocate the target mothers to one of the two study groups (Group A or Group B). Mothers will be assigned to one of two groups at a 1:1 ratio using a block randomization protocol (generated by Random Allocation Software), ensuring that the researcher cannot predict the group assignment of the next participant. Participant allocation to the intervention and control groups will be based on the output of randomization software (Random Sequence Generator). The randomization list will be prepared prior to the start of recruitment and kept in sealed, opaque envelopes. Upon the enrollment of each participant and the verification of eligibility criteria, the researcher will open the corresponding envelope in sequence, and the individual will be assigned to one of the two groups based on the number inside. To ensure allocation concealment, the personnel responsible for recruitment will remain unaware of the randomization list's contents.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the study design, participating mothers will be aware of the intervention group assignments; therefore, blinding will not be feasible during the initial phase. However, the data will be provided to the statistician for analysis in a blinded manner, using group randomization codes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganj-Afrouz Street, Kargar Square, Babol, Iran.
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date
2026-08-31, 1405/06/09
Ethics committee reference number
IR.MUBABOL.HRI.REC.1405.210

Health conditions studied

1

Description of health condition studied
-
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Maternal Breastfeeding Self-Efficacy
Timepoint
Before the intervention, after the intervention, concurrently with the final mindfulness practice session, and one month after the last mindfulness practice session
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Maternal stress, Exclusive Breastfeeding
Timepoint
Before the intervention, after the intervention, concurrently with the final mindfulness practice session, and one month after the last mindfulness practice session
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: In addition to routine care, mothers in the intervention group receive eight mindfulness practice sessions delivered in person on an individual basis. The researcher will conduct these mindfulness sessions at the hospital, holding one 90-minute session per week. Alongside the in-person instruction, audio files corresponding to each session will be provided to the mothers at the end of the session.
Category
Other

2

Description
Control group: Mothers in the control group will receive only routine ward care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital, Sanandaj
Full name of responsible person
Avat Karimi
Street address
Besat Hospital, Keshavarz Street, Sanandaj, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Ali Zabihi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
Data on primary and secondary outcomes

When the data will become available and for how long
6 months after the publication of the results

To whom data/document is available
All interested people

Under which criteria data/document could be used
The use of the results of this study is allowed in compliance with ethical principles.

From where data/document is obtainable
Via the corresponding author's email (Ali Zabihi) zabihi_alii@yahoo.com

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

Applicants will receive the results via email after one week.

Comments