Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of mindfulness training with and without father participation on stress and parent-infant bonding in mothers of premature infants

Protocol summary

Study aim

To determine and compare the effect of mindfulness training with father participation and without father participation on stress levels and parent infant bonding among mothers of preterm infants hospitalized in the neonatal intensive care unit

Design

Randomized clinical trial phase two with two parallel groups on eighty mothers of preterm infants the sample size is forty per group for randomization variable block randomization with sizes of six and nine using Stata software version seventeen was used blinding will be done for the data analyst.

Settings and conduct

This study will be conducted in the neonatal intensive care unit of a teaching hospital. The study population includes mothers of hospitalized preterm infants. Sampling is continuous and after obtaining informed consent, participants are allocated into two groups, mindfulness training with father participation and mindfulness training without father participation. The intervention includes mindfulness training sessions for mothers, with father participation in one group. Data are collected before and after the intervention. Due to the nature of the intervention, blinding of participants is not possible.

Participants/Inclusion and exclusion criteria

Inclusion criteria Mothers of hospitalized preterm infants; informed consent; no previous mindfulness training; no severe psychiatric disorder; ability to attend sessions. Exclusion criteria Lack of willingness to participate; presence of severe psychiatric disorder; use of psychoactive medication; inability to attend sessions.

Intervention groups

Mindfulness training with father participation group; Mindfulness training without father participation group

Main outcome variables

Parental stress in the NICU; Parent–infant bonding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260419069104N1**
Registration date: **2026-06-14, 1405/03/24**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **0**

Registration date

2026-06-14, 1405/03/24

Registrant information

Name

mahsa Shabani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2027-01-06, 1405/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of mindfulness training with and without father participation on stress and parent-infant bonding in mothers of premature infants

Public title

Comparing the effect of mindfulness training with and without father participation on stress and parent-infant bonding in mothers of premature infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers with premature babies (delivered before 37 weeks) . A maximum of 3 days had passed since delivery at the time of the mother's entry into the study . The baby was hospitalized in the intensive care unit for at least 3 weeks The mother and father did not participate in mindfulness training courses The mother did not use sedatives and psychotropic drugs according to her self-report . Being literate to answer the questionnaires . Having Iranian nationality . Mothers had access to a smartphone.

Exclusion criteria:

Lack of parental cooperation at any stage of the study . Early discharge of the infant from the hospital, which results in the mother not being available to continue the intervention Failure of the mother or father to attend more than one session of the educational program Sudden life-threatening event, such as grade 3 or 4 cerebral hemorrhage in the infant during the study Death of the infant during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use Variable Block Size Blocked Randomization to balance the number of group assignments at regular intervals (blocks) while minimizing the possibility of the researcher guessing the next assignment.Groups (K=2): - o A: Mindfulness training with father participation - o B: Mindfulness training without father participation - • Block sizes used: 6 and 9 are both multiples of 3 to maintain balance. - • Objective: Final allocation of 40 mothers (with a 15% dropout probability) to each group (total of 80 mothers). - The final allocation table will be created using a reliable statistical software (Stata17) and by randomly combining blocks of 6 and 9. This table contains 80 consecutive numbers from 1 to 80, each number assigned to one of the groups A or B. - Block size Distribution of groups in the block - 6 2 cases A, 2 cases B - 9 3 cases A, 3 cases B Allocation Concealment - To ensure no bias in the allocation process, the blinding process will be carried out as follows: - 1. The randomly generated sequence will be printed on 80 separate sheets, each sheet containing only the name of the allocated group A or B. - 2. Each sheet will be placed in an opaque envelope and the envelopes will be sealed and numbered sequentially from 1 to 80. 3. The sealed envelopes are kept by someone outside the research team who was responsible for sample recruitment. - 4. Each mother's group allocation will only be revealed after final verification of the inclusion criteria and informed consent, by opening the sealed envelope corresponding to her serial number. - This process ensures that the person responsible for enrolling and assessing mothers does not know the group she is allocated to before deciding to accept her into the study, which is one of the main pillars of quality clinical trials.

Blinding (investigator's opinion)

Double blinded

Blinding description

Allocation Concealment - To ensure no bias in the allocation process, the blinding process will be carried out as follows: - 1. The randomly generated sequence will be printed on 80 separate sheets, each sheet containing only the name of the allocated group A or B. - 2. Each sheet will be placed in an opaque envelope and the envelopes will be sealed and numbered sequentially from 1 to 80. 3. The sealed envelopes are kept by someone outside the research team who was responsible for sample recruitment. - 4. Each mother's group allocation will only be revealed after final verification of the inclusion criteria and informed consent, by opening the sealed envelope corresponding to her serial number. - This process ensures that the person responsible for enrolling and assessing mothers does not know the group she is allocated to before deciding to accept her into the study, which is one of the main pillars of quality clinical trials.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Iranian School of Nursing and Midwifery

Street address

Tehran Province, Tehran, Rashid Yasemi St

City

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Province

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Postal code

۱۹۹۶۷۱۳۸۸۳

Approval date

2026-06-03, 1405/03/13

Ethics committee reference number

IR.IUMS.NURSE.REC.1405.010

Health conditions studied

1

Description of health condition studied

Comparison of stress levels and parent-infant bonding in mothers of premature infants hospitalized in the neonatal intensive care unit who underwent mindfulness training with and without father participation.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Stress in mothers of premature babies

Timepoint

The outcome variables are measured at three time points as follows: 1. Pre-test phase: before the start of the training sessions (intervention). 2. Mid-phase: during the implementation of the intervention, immediately after the end of the fourth session. 3. Post-test phase: immediately after completing the training course (end of the eighth session).

Method of measurement

Parental stress scale-PSS

Secondary outcomes

1

Description

Parent-infant-bound

Timepoint

This variable is measured at three time points: 1- Pre-test (before the start of the intervention) 2- During the intervention (after the end of the fourth session) 3- After the end of the intervention (end of the eighth session - post-test)

Method of measurement

Parental-Infant Bonding Questionnaire

Intervention groups

1

Description

Intervention group: Mindfulness training with father participation. In this group, mothers receive mindfulness training in 8 sessions of 45 to 60 minutes. Fathers in this group have a supportive role by being present with mothers in face-to-face sessions and supporting them in doing mindfulness exercises. Data on the level of stress and parent-infant bonding are measured at three time points. T1: Before the intervention begins. T2: During the intervention (after the end of session 4). T3: After the end of the intervention (after the end of session 8).

Category

N/A

2

Description

Control group: Mindfulness training without father involvement

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar (AS) Educational and Medical Center

Full name of responsible person

Mahsa Shabani

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Tehran, Vali Asr St., above Vanak Square, Rashid Yasemi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mitra Farajnejad Qadi

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mahsa Shabani

Position
Master's student in neonatal intensive care

Latest degree
Master

Other areas of specialty/work
Nursery

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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

Not applicable