Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of an empowering educational intervention on the performance and adjustment to the maternal role in mothers with premature infants: A randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of an empowering educational intervention on maternal functioning and maternal role adaptation among mothers of preterm infants.

Design
Three-arm, parallel-group randomized controlled trial with 1:1:1 allocation; 96 mothers will be assigned to researcher-led education, self-learning, or control groups.

Settings and conduct
The study will be conducted at the High-Risk Infant Clinic of Dr. Ali Shariati Hospital, Bandar Abbas. Participants will be assigned by block randomization. Outcome assessors and data analysts will be blinded to intervention allocation.

Participants/Inclusion and exclusion criteria
Inclusion: Iranian married mothers residing in Hormozgan, with ≥lower secondary education, a healthy singleton preterm infant born at 28–33 weeks (+ 6 days) and aged <4 months, attending the high-risk clinic of Dr. Ali Shariati Hospital, Barkin maternal functioning score <80, primary caregiver status, and a valid telephone number. Exclusion: Maternal chronic, psychiatric, or neurological disease; substance misuse; major personal/family crisis within 6 months; major adverse event within 3 months; severe unresolved breastfeeding problem; or confirmed infant risk of intraventricular hemorrhage.

Intervention groups
Group 1 will receive the educational package in four weekly, researcher-led sessions of 60–90 minutes for five participants. Group 2 will receive and self-study the same printed content over 4 weeks. The control group will receive routine post-discharge care without the study educational intervention.

Main outcome variables
Maternal functioning, maternal role adaptation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260601069597N2**
Registration date: **2026-08-20, 1405/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-20, 1405/05/29**
Update count: **0**

Registration date
2026-08-20, 1405/05/29

Registrant information

Name
Mojdeh Banaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3128 5022

Email address
mojdeh.banaei@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-11, 1405/05/20

Expected recruitment end date
2026-09-21, 1405/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of an empowering educational intervention on the performance and adjustment to the maternal role in mothers with premature infants: A randomized controlled clinical trial

Public title
Effect of an empowering educational intervention on performance and adjustment to the maternal role

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality Resident of Hormozgan province Ability to read and write Married Mothers with premature babies born with a gestational age of 28 weeks to 33 weeks and 6 days Mothers whose babies were less than 4 months old at the time of study entry Mothers with babies discharged from the neonatal ward and neonatal intensive care unit of Shariati Hospital, Bandar Abbas city, referring to the hospital's high-risk clinic Having a contact number for follow-up Singleton baby Willingness to participate in the study Having a healthy premature baby Mother as the primary caregiver of the baby after discharge Barkin maternal functioning score <80

Exclusion criteria:
A history of cardiovascular disease, hypertension, liver disease, or other chronic medical conditions in the mother, based on self-report. A current psychiatric or neurological disorder in the mother, based on self-report. Current substance misuse in the mother, based on self-report. A major personal or family crisis experienced by the mother within the preceding 6 months, based on self-report. A major adverse life event, such as the death of a close relative or divorce, experienced by the mother within the preceding 3 months, based on self-report. A severe and unresolved breastfeeding problem at the time of enrollment. A confirmed high-risk status for intraventricular hemorrhage in the infant.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
A block randomization method will be used to allocate eligible participants to the three study groups, namely the researcher-led education group, the self-learning group, and the control group, with an allocation ratio of 1:1:1. The unit of randomization will be the individual mother. No stratified randomization will be used. The randomization sequence will be generated using the Random Allocation Software, with four blocks of 24 participants each. Each block will contain 8 participants allocated to each of the three study groups. After enrollment of each eligible participant, the corresponding allocation code will be assigned according to the pre-generated randomization sequence. To ensure allocation concealment, the randomization sequence will be generated by an individual independent of the researcher responsible for participant recruitment and outcome assessment. The allocation codes will be placed in sequentially numbered, opaque, sealed envelopes. The envelope corresponding to each participant will be opened only after the participant has been enrolled and completed the baseline assessment, thereby revealing the assigned study group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to double-blind the study, the data analyst and outcome assessors will be unaware of the group allocation. The data analyst will not be aware of the group allocation and will conduct the analysis under the names of groups A, B, C, and in order to blind the outcome assessors, a person outside the research team who has no knowledge of the grouping will measure the outcomes and only see the mothers' numbered code, not which group they are in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences

Street address
Hormozgan University of Medical Sciences and Health Services, Shahid Chamran Blvd., Bandar Abbas

City
Bandar Abbas

Province
Hormozgan

Postal code
791969311

Approval date
2025-12-06, 1404/09/15

Ethics committee reference number
IR.HUMS.REC.1404.276

Health conditions studied

1

Description of health condition studied
Maternal functioning/Maternal role Adaptation
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
Maternal Functioning
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Barkin Index of Maternal Functioning (BIMF)

2

Description
Maternal Role Adaptation
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Maternal role adaptation questionnaire

Secondary outcomes

1

Description
Postpartum maternal bonding
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Postpartum Bonding Questionnaire

2

Description
Infant Weight
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Infant Growth and Clinical Follow-up Checklist

3

Description
Infant Length
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Infant Growth and Clinical Follow-up Checklist

4

Description
Infant Head Circumference
Timepoint
Before the start of the intervention and at weeks 4 and 8 after initiation of the intervention
Method of measurement
Infant Growth and Clinical Follow-up Checklist

Intervention groups

1

Description
First Intervention Group (Researcher-Led Education Group): Participants assigned to this group will receive the structured educational package developed for the study through four weekly group-based sessions, each lasting 60–90 minutes. Each session will be conducted in groups of five participants and delivered directly by the researcher. In session 1, the characteristics of preterm infants, their specific needs following hospital discharge, and common health problems encountered by preterm infants will be discussed. In session 2, the content will focus on the importance and significance of the maternal role, the mother's role in caring for a preterm infant, and empowerment-oriented education on providing care for the preterm infant at home. In session 3, the educational content will address maternal psychological well-being, mothers' physical and psychological preparedness, self-care, and sources of maternal social support. In session 4, the previously presented content will be reviewed, followed by discussion of mother–infant interaction, parental communication skills with the infant, and maternal self-efficacy. The session will also provide a supportive environment in which mothers can express their feelings, concerns, and questions. Positive thinking and maternal strengths will be encouraged, and participants' questions and concerns will be addressed at the end of the session.
Category
Rehabilitation

2

Description
Second Intervention Group (Self-Learning Group):Participants assigned to this group will receive a printed version of the structured educational package developed for the study from the researcher on a weekly basis. The educational content will be provided in four consecutive sections over a 4-week period, such that the participants will receive the complete educational package by the end of the fourth week. The educational content provided to this group will be identical in terms of topics and educational materials to that delivered to the researcher-led education group. However, unlike the researcher-led education group, participants in the self-learning group will receive the educational materials in printed form and will study the content independently without attending face-to-face educational sessions. Participants will be instructed to study and review each

section during the corresponding week.

Category

Rehabilitation

3

Description

Control Group: Participants assigned to the control group will receive routine post-discharge care for their infants according to the usual practice of the hospital and high-risk infant clinic. This care will consist of the standard care routinely provided by nursing staff and the healthcare team in accordance with the usual institutional procedures and practices. No additional structured educational intervention from the study educational package will be provided to participants in the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

High-Risk Infant Clinic, Dr. Ali Shariati Hospital, Bandar Abbas

Full name of responsible person

Mojdeh Banaei

Street address

Next to the Revolutionary Court, Nasser Boulevard

City

Bandar Abbas

Province

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Fax

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Hormozgan University of Medical Sciences

Full name of responsible person

Shahram Zare

Street address

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Bandar Abbas

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Postal code

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Email

shzare@hums.ac.ir

Web page address

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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

The Hormozgan 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

HoHormozgan University of Medical Sciences

Full name of responsible person

Mojdeh Banaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Ph.D.
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Person responsible for updating data

Contact
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
Mojdeh Banaei
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Email
m.banaei@hums.ac.ir
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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
The anonymized raw data from the maternal functioning and motherhood adjustment questionnaires, along with the variable coding file and research protocol, will be made available to researchers after the publication of the main study results.
When the data will become available and for how long
All identifying information about participants is removed and the data is presented in aggregated or anonymized form. Data will be available for 5 years from the publication of the original article or the end of the study, upon reasonable request from researchers and after approval by the principal investigator.
To whom data/document is available
Researchers, faculty members, and research students who submit a justified scientific request and accept the commitment to maintain the confidentiality of participant information.
Under which criteria data/document could be used
The anonymized data will be used for research and educational purposes only. Use of the data is subject to formal request, approval from the principal investigator, and adherence to the principles of confidentiality and research ethics. Publication or commercial use of the data will not be permitted without written permission.
From where data/document is obtainable
Applicants can submit their application through the principal investigator of the project or the faculty/research center conducting the study.
What processes are involved for a request to access data/document
The applicant must submit a written request including the purpose of using the data and their research plan. After the request is reviewed by the principal investigator and the principles of confidentiality and research ethics are ensured, the anonymized data will be made available to the applicant. The response time to requests will be a maximum of two weeks.
m.banaei@hums.ac.ir
Comments
All shareable data will be anonymized before being released to applicants, and no identifying information about participants will be made available to third parties. Data sharing will be conducted in accordance with research ethics and university regulations.