Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Family-Centered Care Model on Mothers' parenting self-efficacy Parenting Self-Efficacy and Quality of Care for Premature Infants Hospitalized in Teaching Hospitals

Protocol summary

Study aim
To determine the effect of implementing a family-centered care model on mothers' parenting self-efficacy and the quality of care for preterm infants hospitalized in teaching hospitals in Sari in 2026.

Design
A randomized controlled trial (RCT) with pre-test, post-test, and one-month follow-up. Sample (n=72) allocated via block randomization (blocks of 4).

Settings and conduct
his study will be conducted in the NICUs of teaching hospitals in Sari

Participants/Inclusion and exclusion criteria
Mother of a preterm infant admitted to the neonatal intensive care unit Infant gestational age less than 37 weeks At least 48 hours and at most 7 days have passed since the infant's admission at the time of enrollment Mother aged 18 years or older Ability of the mother to read and write Willingness to participate in the study Written informed consent provided by the parents No diagnosed psychiatric disorder or acute family crisis Non-preterm infant with gestational age of 37 weeks or more Infant admission for less than 48 hours or more than 7 days at the time of enrollment Mother younger than 18 years Mother unable to read and write Unwillingness to participate in the study No written informed consent provided Presence of a diagnosed psychiatric disorder or an acute family crisis

Intervention groups
Intervention group: Mothers receive 4 daily individual sessions (60 min each) covering preterm infant care, participation, emotional support, and discharge readiness. Control group: Receives only routine ward care.

Main outcome variables
Mothers' parenting self-efficacy and quality of care for preterm infants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260721070284N1**
Registration date: **2026-08-11, 1405/05/20**
Registration timing: **prospective**

Last update: **2026-08-11, 1405/05/20**
Update count: **0**

Registration date
2026-08-11, 1405/05/20

Registrant information

Name
Fatemeh Khodadadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3320 7554

Email address
behinakhodadadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-16, 1405/05/25

Expected recruitment end date
2026-09-16, 1405/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Family-Centered Care Model on Mothers' parenting self-efficacy Parenting Self-Efficacy and Quality of Care for Premature Infants Hospitalized in Teaching Hospitals

Public title
The Effect of Family-Centered Care Model on Mothers' parenting self-efficacy Parenting Self-Efficacy and Quality of Care for Premature Infants Hospitalized in Teaching Hospitals

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Mother of a preterm infant admitted to the neonatal intensive care unit Infant gestational age less than 37 weeks At least 48 hours and at most 7 days have passed since the infant's admission at the time of enrollment Mother aged 18 years or older Ability of the mother to read and write Willingness to participate in the study Written informed consent provided by the parents No diagnosed psychiatric disorder or acute family crisis

Exclusion criteria:
Non-preterm infant with gestational age of 37 weeks or more Infant admission for less than 48 hours or more than 7 days at the time of enrollment Mother younger than 18 years Mother unable to read and write Unwillingness to participate in the study No written informed consent provided Presence of a diagnosed psychiatric disorder or an acute family crisis

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting participants using convenience sampling and meeting the inclusion criteria, individuals were assigned to the intervention and control groups using a block randomization method with blocks of four to maintain a balance of sample sizes in the two groups during the sampling process. For this purpose, a random allocation sequence was generated using the Randomization.com website. In this process, each participant's case number was considered as a unique sample code, and based on the generated random sequence, participants were assigned to the intervention and control groups with an allocation ratio of 1:1 (30 people in each group). In order to reduce allocation bias, the process of generating the random sequence and assigning participants to the study groups was performed by an individual outside the research team who had no role in sampling, implementing the intervention, collecting data, and analyzing the results. Also, to maintain allocation concealment, the random sequence was placed in Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). After each participant entered the study and completed the admission process, the envelope corresponding to the assigned number was opened in order and the allocated group was determined. In this way, the researcher and participants were unaware of the allocated group before entering the study, and the possibility of bias in sample allocation was minimized.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Aliabad Katoul Branch, Islamic Azad University

Street address
University Blvd, Islamic Azad University, Aliabad Katoul Branch

City
Aliabad Katoul

Province
Golestan

Postal code
4941793451

Approval date
2026-07-12, 1405/04/21

Ethics committee reference number
IR.IAU.AK.REC.1405.009

Health conditions studied

1

Description of health condition studied
Preterm Infant

ICD-10 code
P07.3

ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
Parenting self-efficacy score

Timepoint
Before the intervention (pre-test), immediately after the intervention (post-test), and one month after the intervention
Method of measurement
Parenting Self-Efficacy Questionnaire by Domka et al. (1996)

2

Description
Infant care quality score
Timepoint
Before the intervention (pre-test), immediately after the intervention (post-test), and one month after the intervention
Method of measurement
Winsley and Gettys Quality of Infant Care Questionnaire (2013)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to receiving routine ward care, the intervention group will receive an educational program based on the family-centered care model individually in 4 sessions, each session lasting 60 minutes. Educational content is based on the stages of the family-centered care model and using a variety of educational methods, including: face-to-face education, presentation of educational brochures, structured discussions and dialogues, practical demonstrations, skills practice with feedback, educational videos, situation simulations, problem solving, active participation of the mother in care, and questions and answers. In the first session, the condition of the premature baby, possible problems and complications, the importance of proper care, the consequences of lack of proper care, and the role of the family in care are taught, and the needs and concerns of the mothers are identified. In the second session, basic skills for caring for premature babies are taught and practiced, including: drug care, monitoring vital signs, identifying warning signs, and daily care. In the third session, additional training in feeding, soothing the baby, solving potential problems, shared decision-making, and determining the role of family members in care is provided, and problem-solving skills are practiced. In the fourth session, the materials and skills taught are reviewed, learning and skills of mothers are assessed, and the home care plan and post-discharge actions are explained.
Category
Behavior

2

Description
Control group: During the study period, the control group will only receive routine ward care according to the usual hospital schedule, and no intervention based on the family-centered care model will be implemented for them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Teaching hospitals in Sari
Full name of responsible person
Fatemeh Khodadadi
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University Blvd, Islamic Azad University, Aliabad Katoul Branch
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nafiseh Hekmatipour
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N_hekmati68@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Fatemeh Khodadadi
Position
Master of Science Student in Pediatric Nursing, Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Nursing Department Faculty (Assistant Professor)
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Person responsible for updating data

Contact
Name of organization / entity
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Fatemeh Khodadadi
Position
Master of Science Student in Pediatric Nursing, Nurse
Latest degree
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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not 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
he Impact of Implementing a Family-Centered Care Model on Mothers' Parenting Self-Efficacy and the Quality of Care for Preterm Infants Hospitalized in Teaching Hospitals of Sari, 2026
When the data will become available and for how long
Data access will be available 6 months after the publication of the final study results. The exact publication date will be determined after the completion of data analysis and article acceptance in scientific journals.”
To whom data/document is available
Access to the research data will be restricted to

members of the core research team (including the Principal Investigator, research collaborators, and data analysts), Research Ethics Oversight Committees, and other researchers who obtain permission for access to de-identified, coded data by submitting a formal research proposal and obtaining approval from the Ethics Committee of Faculty of Medical Sciences, Islamic Azad University, Aliabad-e Katul Branch. Raw data containing direct participant identifiers will not be shared

Under which criteria data/document could be used

"The data and documents from this research are to be used solely for non-commercial research and educational purposes. The use of de-identified, coded data is limited to analyses directly related to the objectives and research questions of the original study, including: Replication of Original Findings: Enabling the examination and reproduction of analyses reported in the primary publication. Secondary Analyses: Investigating novel relationships or supplementary hypotheses derived from the existing data that are directly relevant to the study topic (family-centered care, parenting self-efficacy, quality of preterm infant care). Use in Educational Projects: Sharing anonymized data samples with students and junior researchers for coursework or preliminary research projects, under the direct supervision of a faculty advisor. Requirements for Submitting a Data Access Request: Submission of a written research proposal clearly outlining the intended use of the data. Completion and signing of a Confidentiality Agreement provided by Islamic Azad University, Aliabad-e Katul Branch. Obtaining final approval from the Ethics Committee for Research at Faculty of Medical Sciences, Islamic Azad University, Aliabad-e Katul Branch. Commitment to not attempt re-identification of participants and to maintain complete data confidentiality. Agreement to properly cite the original study in all reports, publications, and presentations based on this data. Prohibition of re-publishing or selling the data to third parties."

From where data/document is obtainable

“To submit a request for access to the data and documents of this research, please contact the Research Office of Islamic Azad University, Aliabad-e Katul Branch. Additionally, for initial coordination and to obtain the necessary forms, you may contact the Principal Investigator of the study, Ms. Fatemah Khodadadi.”

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

The process for requesting access to the data and documents of this research is as follows: Initial Submission: The applicant must submit a written request along with their research proposal to the Research Office of Islamic Azad University, Aliabad-e Katul Branch. Preliminary Proposal Review: The Research Office will review the proposal for alignment with the overall research objectives and completeness of initial documentation. Provision of Confidentiality Agreement: Upon preliminary approval, the Confidentiality Agreement form will be provided to the applicant for completion and signature. Submission to Ethics Committee: The completed proposal, signed confidentiality agreement, and other required documents will be forwarded to the Ethics Committee for Research at Faculty of Medical Sciences, Islamic Azad University, Aliabad-e Katul Branch for final review and approval. Ethics Committee Review and Approval: The Ethics Committee will review the request from research and ethical perspectives and, if necessary, issue supplementary instructions. Issuance of Access Permit: After obtaining approval from the Ethics Committee, an access permit will be issued, and the de-identified dataset and/or required documents will be provided to the applicant via secure email or a designated portal. Monitoring and Reporting: The Principal Investigator (Ms. Fatemeh Khodadadi) will oversee the appropriate use of the data. The applicant is obligated to submit the results of their research in the form of reports or articles to the Research Office and the Ethics Committee."

Comments

“This research was funded by the Research Deputy of Islamic Azad University, Aliabad-e Katul Branch. All study procedures were conducted in strict accordance with the ethical principles of medical research and with the necessary approvals from the Ethics Committee for Research at the University. We kindly request all researchers intending to use the data from this study to fully adhere to the previously mentioned guidelines and to cooperate with the core research team to collectively advance knowledge in maternal and neonatal health. For any further guidance, please contact the Research Office of Islamic Azad University, Aliabad-e Katul Branch or Ms. Fatemeh Khodadadi (Principal Investigator).”