Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of breastfeeding education and infant health care with the participation of peers on the self-efficacy and self-esteem of mothers with premature neonates

Protocol summary

Study aim

To determine and compare the mean scores of self-efficacy and self-esteem of mothers in both the intervention and control groups before and after the study.

Design

Type of Trial: Clinical trial with a control group Groups: Two parallel groups (intervention and control) Blinding: Double-blind Phase: Phase 2 Sample Size: 92 participants (46 in each group, accounting for a 10% dropout rate) Randomization: Utilized Excel and the rand function for random allocation to groups

Settings and conduct

This double-blind clinical trial at Shahid Sadoughi Hospital in Yazd aims to assess the effects of breastfeeding and healthcare education on the self-esteem and self-efficacy of mothers with premature infants in the NICU. Participants: 92 mothers Groups: Intervention (education) and control (no intervention) Assessment: After the intervention Blinding: Double-blind for accuracy

Participants/Inclusion and exclusion criteria

Mothers who are willing to participate in the studyAbsence of mothers from educational classes

Intervention groups

Educational Group: Mothers who participate in the educational program receive training on caring for premature infants, managing stress, and utilizing available support resources. Control Group: Mothers who do not receive any educational intervention and care for their premature infants in a typical manner. This group serves as a baseline for comparing the outcomes of the educational group

Main outcome variables

Maternal Self-Esteem: Assessing changes in the self-esteem levels of mothers with premature infants. Maternal Self-Efficacy: Evaluating the impact of education on mothers' self-efficacy in breastfeeding. Breastfeeding Awareness: Increasing knowledge and awareness of mothers regarding breastfeeding and care for premature infants. Psychological Experience: Improving the psychological experience of mothers in facing the challenges of caring for premature infants.

General information

Reason for update

Acronym

BEPPS

IRCT registration information

IRCT registration number: **IRCT20250518065786N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name

Sarah Pashaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-16, 1404/05/25

Expected recruitment end date
2025-12-16, 1404/09/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of breastfeeding education and infant health care with the participation of peers on the self-efficacy and self-esteem of mothers with premature neonates

Public title
Examining the effect of education and support from other mothers on the confidence and self-efficacy of mothers with premature infants
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers who are willing to participate in the study and agree to its conditions
Exclusion criteria:
mothers who are unable to participate due to physical or mental conditions
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Description of Randomization Process In this study, the process of random allocation to the two groups (intervention and control) was performed using the Random Allocation software. This software automatically assigns each participant to one of the two groups, ensuring that all study units are randomly allocated to the groups without any bias. Randomization Method The randomization was done on an individual basis. Each mother with a preterm infant was randomly assigned to either the intervention group (receiving breastfeeding education and peer support) or the control group (receiving standard hospital care). Time Block Randomization To prevent information exchange between the groups and ensure proper implementation of interventions, time block randomization was utilized. In this method, sampling in the control group did not occur until the intervention group had been discharged. This approach ensures that no crossover or exchange of information takes place between the groups, allowing each group to independently receive their respective interventions. Allocation Concealment To ensure allocation concealment and prevent any bias, the allocation process was carried out using sealed envelopes. These envelopes contained the group allocation information for each participant, and the envelopes were opened only after the participant met the inclusion criteria. This process ensures that neither the researchers nor the participants were aware of the group allocation before the study commenced. Randomization Tools The randomization sequence was generated using Random Allocation software, which produces a completely random sequence without any human intervention. This method ensures unbiased group assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, a double-blinding method will be employed to maintain neutrality and reduce bias. Below are the details regarding the individuals who will be kept blinded in this study: Participants: All mothers of premature infants participating in this study will be unaware of the type of intervention (breastfeeding education or peer support) they are receiving. This is to prevent any influence of their expectations and biases on the study outcomes. Principal Investigator: The principal investigator, who is responsible for designing and overseeing the study, will also remain unaware of the details of the interventions assigned to each group. This helps to minimize bias in data interpretation and results. Healthcare Personnel: Physicians, nurses, and other healthcare staff responsible for patient care will not be informed about the intervention groups assigned to the mothers. This measure is taken to prevent any influence on the treatment and care process. Data Collectors: Individuals responsible for collecting data related to the study will remain blinded to the intervention groups. This helps to maintain the accuracy and integrity of the collected data. Outcome Assessors: Those evaluating the outcomes and results will also be kept unaware of the type of intervention the mothers have received. This aids in reducing bias in the assessment of results. Data Safety and Monitoring Committee: This committee will review the safety and validity of the data but will not be informed of the intervention details to maintain its impartiality. Draft Authors: Individuals responsible for preparing and writing the final manuscript will also be kept blinded to the intervention groups to prevent bias in data analysis and reporting.
Placebo
Not used
Assignment
Parallel
Other design features
Pre-test and Post-test Design: this study includes evaluations before and after the intervention, which helps assess changes in self-efficacy and self-esteem among mothers after receiving the educational

programs.Control and Experimental Groups:The presence of a control group receiving standard hospital services allows for a more precise evaluation of the impact of the educational interventions.Random Assignment:Random assignment of mothers to the experimental and control groups using random allocation software reduces bias and enhances the validity of the results.Use of Time Blocks:Utilizing time blocks prevents information exchange between the experimental and control groups, contributing to the credibility of the findings.Educational Sessions:The educational program consists of five 45-minute sessions conducted face-to-face and online. This format can enhance accessibility and engagement among mothers.Online Follow-up:Establishing a virtual group for the mothers in the experimental group provides an opportunity for sharing experiences and information, helping them quickly access expert responses to any questions.Use of Validated Tools:Employing reliable and validated questionnaires, such as the Rosenberg Self-Esteem Scale, increases the credibility and accuracy of the collected data.Continuous Monitoring:The researcher continuously monitors messages and interactions in the virtual group to prevent confusion among mothers and provide necessary guidance.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address
No. 3, Alley 20, Shahid Fatemi Street, Qom

City
yazd

Province
Yazd

Postal code
3715666595

Approval date
2025-05-13, 1404/02/23

Ethics committee reference number
IR.SSU.REC.1404.020

Health conditions studied

1

Description of health condition studied
Self-efficacy and Self-esteem

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-esteem score of mothers with premature babies in the Rosenberg Self-Esteem Questionnaire

Timepoint
Before the intervention - immediately after the intervention and one month after the intervention

Method of measurement
Rosenberg Self-Esteem Questionnaire

Secondary outcomes

1

Description
The self-efficacy score of mothers with premature infants in the mothers' self-efficacy questionnaire

Timepoint
Before the intervention - immediately after the intervention and one month after the intervention

Method of measurement
Mothers' self-efficacy questionnaire

Intervention groups

1

Description
Intervention group:Educational topics for the intervention group included: information about breastfeeding, health care for premature infants, and peer participation. Duration of intervention: five 45-minute sessions. Time of sessions: between 10:00 and 12:00 each day. Method of holding: Face-to-face sessions in the training room of the neonatal intensive care unit of Shahid Sadoughi Hospital in Yazd and also via virtual space. Number of sessions: including 5 educational sessions. Program development: based on the protocol presented in this study and in collaboration with a team consisting of a supervisor, counselor, and a psychologist.

Category
Other

2

Description
Control group:Control group: The control group will not receive any intervention. Mothers in this group will receive routine hospital care services in the field of breastfeeding and health care. After the evaluation is completed, an educational pamphlet on the implemented interventions in the field of breastfeeding and health care will be provided to them.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital Yazd

Full name of responsible person
Zahra Pourmovahed

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Avicenna Boulevard, Shahid Ghandi Boulevard, Yazd Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Amirhooshang Mehrparvar

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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
yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Zahra Pourmovahed

Position
Assistant 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
Title and Details of Documents: Individual Data of Mothers with Preterm Infants in an Interventional Study Details of Documents: This document pertains to the sharing of individual data from mothers participating in the interventional study related to breastfeeding and healthcare for preterm infants admitted to Shahid Sadoughi Hospital in Yazd. The information includes the following: Type of Data: The collected data includes demographic information of mothers, results from self-efficacy and self-esteem questionnaires, and information related to the outcomes of the educational intervention. Anonymization Method: All data will be processed prior to sharing to ensure that the identities of participants are not identifiable. This includes the removal or coding of identifiable information such as names, addresses, and contact numbers. Shareable Content: Complete Data: After processing and anonymization, the complete data set will be available for sharing as a collection of statistical data and information related to primary outcomes. Partial Data: There is also the possibility of sharing only a portion of the data, such as demographic information and results from self-efficacy and self-esteem questionnaires. This data can assist researchers and interested parties in conducting further analyses and reviewing the results. Access to Data: Access to the data will be provided free of charge to researchers and scholars, with the conditions for using the data outlined in the accompanying documentation. Ethical Considerations: All stages of data sharing will be conducted in compliance with ethical principles and the confidentiality of participants' information will be maintained. The researcher will ensure that there is no interference with the treatment of infants and that participation in the study is voluntary.
When the data will become available and for how long
Start Date of Access: Six Months After Publication of Results: Access to the data and documents will begin six months after the final results of the study are published. This timeframe allows researchers and interested parties to review the findings before submitting requests for access to the data and documents.
To whom data/document is available
Academic and Research Scientists: Researchers affiliated with academic institutions and research centers can submit requests for access to the data and documents. This includes faculty members, graduate students, and independent researchers. Industry Researchers: Individuals working in the industry may also submit requests for access to the data, provided they offer valid reasons and explanations regarding the intended use of the data. However, priority will be given to those directly involved in research projects related to health and care for infants. Request Conditions: All requests must be submitted in writing and should include detailed explanations of the intended use of the data and how it will be utilized. Requesters must also commit to adhering to ethical principles and maintaining the confidentiality of the information. Decision-Making: A committee composed of principal researchers and ethics officials will review the received requests and make decisions. This committee will be responsible for evaluating the reasons and objectives of the requests, as well as assessing their compliance with ethical standards and relevant regulations.
Under which criteria data/document could be used
Types of Permitted Analyses: Statistical and analytical analyses aimed at exploring patterns and trends within the data are permitted. For example, descriptive analyses, regression, and predictive modeling are allowed. Analyses that could identify or disclose the identity of participants are prohibited. Permitted Uses of Documents: Documents may be used for research, educational purposes, and publication of scientific articles. Commercial use of data and documents without written permission from the relevant committee is prohibited. Governance Mechanisms for Use: Users are required to adhere to ethical and legal principles when using the data and documents. All results and analyses must be presented in a de-identified manner, ensuring that any personal identification is removed. Conditions for Submitting Access Requests: Requests must be submitted in writing and should include the following information: Name and details of the requester Explanation of the intended use of the data or documents Type of analysis or intended use Commitment to adhere to ethical principles and maintain confidentiality of information
From where data/document is obtainable
Applicants should first contact the relevant research

ethics committee to obtain initial information and necessary approvals After receiving approval from the ethics committee, applicants can contact the project manager to submit their request Applicants can visit the official study website for more information on how to request and receive data.

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

Completing the Request Form: Applicants must complete the request form, which includes personal information, purpose of use, and the type of data requested. Duration: 1-2 days Submitting the Request to the Ethics Committee: Applicants need to submit their request to the relevant research ethics committee. This request should include the completed form and any necessary supporting documents. Duration: 1 day for submission Reviewing the Request by the Ethics Committee: The ethics committee will review the request and may ask the applicant for additional information if needed. Duration: 1-3 weeks (depending on the volume of requests and the committee's policies) Approval or Rejection of the Request: After the review, the ethics committee will inform the applicant of their decision. If approved, the applicant moves to the next step. If rejected, reasons for the rejection will be provided. Duration: 1 day Contacting the Project Manager: Upon approval, the applicant should contact the project manager to submit their request for the data or documents. Duration: 1 day Final Review and Approval by the Project Manager: The project manager will review the request and, if approved, will inform the applicant that the documents or data are ready. Duration: 1-2 weeks Receiving the Data or Documents: The applicant can receive the data or documents, which may be provided digitally or physically. Duration: Depending on the delivery method, 1-5 days Total Duration: Considering the above steps, the total time for receiving documents or data files typically ranges from 4 to 8 weeks. This duration may vary based on the complexity of the request and the responsiveness of the committee and project manager

Comments