Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of training based on Bandura's self efficacy theory on the sense of parental competence of mothers with premature infants hospitalized in the neonatal intensive care unit

Protocol summary

Study aim

Determining the effect of educational intervention based on Bandura's self efficacy theory on the sense of parental competence of mothers with premature infants hospitalized in the Neonatal Intensive Care Unit(NICU)

Design

Clinical trial with a control group, single-blind, using time blocks to prevent information transfer, randomized with Random Allocation software, on 72 participants (36 test and 36 control).

Settings and conduct

The location of the study was the neonatal intensive care unit of Shahid Sadoughi Hospital in Yazd. Individual and group training was provided using lecture, role-playing, question and answer, interactive images and dialogue methods. One-way blinding was used. The data analyst received the data in coded form, and the outcome evaluator was not involved in the implementation of the intervention and was unaware of the allocation order.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, being literate, gestational age of the infant 26 to 37 weeks, no confirmed physical or mental problems, no history of having a premature infant. Inclusion criteria: Participation in another intervention program, mother being a member of the treatment team, experiencing an unfortunate accident and divorce in the past six months, physical manifestation of a congenital disease in the infant.

Intervention groups

The control group receives only routine ward care, and the experimental group, in addition to routine care, receives an educational program based on the four components of Bandura's self efficacy theory in four consecutive sessions.

Main outcome variables

Mothers' level of parental competence

General information

Reason for update

Acronym

Neonatal Intensive Care Unit(NICU)

IRCT registration information

IRCT registration number: **IRCT20251106067894N1**
Registration date: **2025-11-25, 1404/09/04**
Registration timing: **prospective**

Last update: **2025-11-25, 1404/09/04**
Update count: **0**

Registration date

2025-11-25, 1404/09/04

Registrant information

Name

Shakiba Rashidi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of training based on Bandura's self efficacy theory on the sense of parental competence of mothers with premature infants hospitalized in the neonatal intensive care unit

Public title
Investigating the effect of training based on Bandura's self efficacy theory on the sense of parental competence of mothers with premature infants hospitalized in the neonatal intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People who are willing to participate in the study. Be literate in reading and writing. Their baby's gestational age is 26 to 37 weeks. Mothers should not have any confirmed physical or mental problems. Have no history of having a premature baby.

Exclusion criteria:
Parental participation in another intervention program during the study The mother is a member of the medical staff. A tragic accident or divorce has happened to them in the past six months. Physical manifestation of congenital disease in their baby

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Considering the conditions of admission and obtaining informed consent from mothers whose infants are hospitalized in the neonatal intensive care unit, the researcher divides 72 mothers (36 in the intervention group and 36 in the control group) into test and control groups according to the entry and exit criteria by random allocation using random allocation software. First, the test group is sampled and then the control group is sampled. To prevent the transfer of information between the two groups, a time block is used; in this way, after sampling the test group and performing the intervention, we wait until the test group is discharged, then we perform the control group sampling.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the educational intervention, complete blinding of participants is not possible. Participants are practically not blinded because they receive the educational intervention and know the difference. The researcher cannot be blinded because he or she provides the education. The clinical caregiver cannot be blinded because he or she is usually involved in routine infant care and, although he or she does not play a role in providing the education, is usually relatively aware of the mothers' condition. However, blinding of the outcome assessor and data analyst will be done. Mothers in the intervention and control groups will not be aware of the main hypothesis of the study and the allocation method. The person responsible for the statistical analysis will receive the data coded and labeled as Group A and Group B and will not be aware of the group allocation. The outcome assessor will also not be involved in the implementation of the intervention and will be unaware of the order of allocation. The person generating the randomization sequence will not be involved in the recruitment, data collection, or analysis. This method reduces performance and assessment bias as much as possible.

Placebo
Not used

Assignment
Single

Other design features

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. 116, Etrat Ave., East Masrour Blvd.

City
Shahin Shahr

Province
Isfehan

Postal code
8316839630

Approval date
2025-11-03, 1404/08/12

Ethics committee reference number
IR.SSU.REC.1404.117

Health conditions studied

1

Description of health condition studied
Mothers' sense of parental competence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The level of mothers' sense of parental competence, measured by the Gibaud Wallston Parental Competence Questionnaire.
Timepoint
At the beginning of the study (before the intervention), immediately after the intervention, and four weeks after the intervention
Method of measurement
Gibaud Wallston & Wandersman Parental Competence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In addition to routine care in the Neonatal Intensive Care Unit(NICU), the intervention group will be provided with a training program based on the four parts of Bandura's self efficacy theory in four consecutive sessions (maximum two hours each session). The sessions will be held individually or in groups in the NICU training room and will include four parts: functional experience (familiarization with the unit, infant behavior, and cuddling), substitution experience (showing pictures, modeling, and role-playing), verbal encouragement (feedback and encouragement while performing skills), and attention to emotional state (anxiety management and response to concerns).
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi hospital, Yazd
Full name of responsible person
Shakiba Rashidi
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No. 116, Etrat Ave., East Masrour Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
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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
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
Shakiba Rashidi
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available