Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of education based on the theory of planned behavior and video based education on the knowledge, attitude, and breastfeeding performance of mothers of premature infants hospitalized in the neonatal intensive care unit

Protocol summary

Study aim

Comparison the effect of education based on the theory of planned behavior and video based education on the knowledge, attitude, and breastfeeding performance of mothers of premature infants hospitalized in the neonatal intensive care unit

Design

A clinical trial with intervention and control groups, single-blinded, using convenience sampling, conducted on 58 patients. The sample size was determined using G*Power software.

Settings and conduct

This clinical trial was conducted in the NICU of Shahid Sadoughi Hospital, Yazd. Fifty-eight eligible mothers of preterm infants were non-randomly selected and allocated into two groups (29 each) using a single-blind method. Both groups completed the baseline questionnaires. The intervention group then received TPB-based breastfeeding education, whereas the control group received standard video education. Post-test data were collected by having all participants complete the same questionnaires two weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers of premature infants hospitalized in the NICU, Iranian nationality, basic literacy, no substance abuse, medically stable; premature infants hospitalized in NICU with sucking ability and no need for gavage feeding. Exclusion criteria: Mothers with breastfeeding contraindications, concurrent participation in other studies; infants unable to receive breast milk, infants with cardiac anomalies and various syndromes.

Intervention groups

Intervention group: Mothers of preterm infants hospitalized in the NICU who received breastfeeding education based on the Theory of Planned Behavior.

Control group: Mothers of preterm infants hospitalized in the NICU who received routine breastfeeding video education.

Main outcome variables

Breastfeeding knowledge, attitude, and practice scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251117068027N1**

Registration date: **2026-02-26, 1404/12/07**

Registration timing: **prospective**

Last update: **2026-02-26, 1404/12/07**

Update count: **0**

Registration date

2026-02-26, 1404/12/07

Registrant information

Name

maryam babaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4434 0516

Email address

m.babaee@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-14, 1404/12/23

Expected recruitment end date
2026-07-14, 1405/04/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of education based on the theory of planned behavior and video based education on the knowledge, attitude, and breastfeeding performance of mothers of premature infants hospitalized in the neonatal intensive care unit

Public title
Comparison the effect of theory-based education versus video-based education on breastfeeding
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers of premature infants hospitalized in the NICU. Iranian nationality. Having at least basic literacy (reading and writing). No maternal addiction to alcohol or cigarettes. Medically stable and able to attend the sessions. Premature infants hospitalized in the NICU, possessing the ability to suck and not requiring gavage feeding.
Exclusion criteria:
Mothers with contraindications for breastfeeding, such as having AIDS/HIV or active tuberculosis. Mothers who use medications that are prohibited during breastfeeding. Mothers who are simultaneously participating in another study related to breastfeeding while enrolled in our study Infants who are unable to receive breast milk due to medical conditions or anomalies such as cleft palate Infants with cardiac anomalies and various syndromes.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Assessor blinding: This is the most important form of blinding feasible in this design. The person who collects the questionnaires after the intervention and the person who enters and analyzes the data in SPSS software must not know which group (test or control) each participant was in. This prevents biased interpretation of the results.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Nursing and Midwifery School, Shahid Sadoughi University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, Bouali Street, Yazd, Iran.
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۹۷۸۴۷۷
Approval date
2025-11-11, 1404/08/20
Ethics committee reference number
IR.SSU.REC.1404.134

Health conditions studied

1

Description of health condition studied
Breastfeeding in premature neonates
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Breastfeeding knowledge score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Breastfeeding Knowledge scale

2

Description
Breastfeeding attitude score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Theory of Planned Behavior scale

3

Description
Breastfeeding Performance score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Breastfeeding Performance scale

Secondary outcomes

1

Description
Perceived Behavioral Control Score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Theory of Planned Behavior scale

2

Description
Subjective Norms Score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Theory of Planned Behavior scale

3

Description
Behavioral Intention Score
Timepoint
before the intervention and two weeks after the intervention.
Method of measurement
Theory of Planned Behavior scale

Intervention groups

1

Description
Intervention group: Mothers of preterm infants hospitalized in the NICU who received breastfeeding education based on the Theory of Planned Behavior. The educational intervention will consist of 4 training sessions, each lasting 60 to 90 minutes. These sessions will be conducted over 4 days during the week (Saturday to Tuesday). The sessions will be held in small groups, with 4 or 5 mothers participating together with the instructor.
Category
Other

2

Description
Control group: Video-based training on breastfeeding will be delivered to them.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Maryam Babaee
Street address
Ibn Sina Boulevard, Shahid Ghandi Boulevard, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mehran Karimi
Street address
Central Administration Building, Shahid Sadoughi University of Medical Sciences, Baharan Square
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sh.bolandian@yahoo.com
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

Shahnaz Bolandian Bafghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Bouali Street, Yazd.

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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

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

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

The raw data files of the demographic information, Theory of Planned Behavior, knowledge, and breastfeeding practice scale are shareable.

When the data will become available and for how long

Access period begins in 2025.

To whom data/document is available

Researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

The use of the scales in research projects is permitted.

From where data/document is obtainable

To receive the scales, please send a message to the email address: sh.bolandian@yahoo.com

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

To receive the scales, please send a message to the email address: sh.bolandian@yahoo.com

Comments