Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of comprehensive breastfeeding support counseling on breastfeeding competence and self-efficacy of primiparous women referring to the women's clinic of Shariati Hospital in 1404-1405: A randomized controlled clinical trial

Protocol summary

Study aim

This study aimed to evaluate how effective a comprehensive breastfeeding support counseling program is at improving breastfeeding competence and self-efficacy in first-time mothers

Design

This study is a randomized controlled clinical trial conducted on 98 primiparous mothers at Shariati Hospital in Bandar Abbas.

Settings and conduct

The intervention group receives six breastfeeding support counseling sessions at Shariati Hospital's obstetrics clinic. Two sessions (45–60 min) are given during pregnancy at weeks 34 and 37 to prepare mothers psychologically and practically for breastfeeding. Four sessions (30–45 min) are given postpartum on day 1, week 1, week 2, and week 6 to support breastfeeding initiation and manage postpartum challenges.

Participants/Inclusion and exclusion criteria

Inclusion: Iranian primiparous mother, ≥18 yrs, term singleton, healthy baby >2500g, literate, delivery at Shariati Hospital, willing/able to attend sessions, no breast disease, chronic illness, or addiction. Exclusion: Unwillingness, infant breastfeeding problems, pregnancy/delivery complications, assisted reproduction, preterm labor risk, multiples, BMI>40, premature or low birth weight (<2500g), ICU admission, HIV/contraindicated drugs, fetal anomalies, high-risk pregnancy, illness preventing breastfeeding, communication or psychiatric issues

Intervention groups

The study population includes all primiparous women referred to the Obstetrics and Gynecology Clinic of Shariati Hospital in Bandar Abbas in 2026

Main outcome variables

Self-efficacy score؛Competency score؛Age؛Education؛Employment status؛Residence؛Economic status؛Number of pregnancies؛Neonatal hyperbilirubinemia (jaundice)؛Postpartum hemorrhage؛Breastfeeding success؛Postpartum depressionPain؛Wound infection؛Neonatal hypothermia؛Continuation of breastfeeding؛Breastfeeding support counseling

General information

Reason for update

Acronym

TCBS

IRCT registration information

IRCT registration number: **IRCT20231202060247N2**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **prospective**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date

2026-07-04, 1405/04/13

Registrant information

Name

nasibeh roozbeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15
Expected recruitment end date
2027-01-05, 1405/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of comprehensive breastfeeding support counseling on breastfeeding competence and self-efficacy of primiparous women referring to the women's clinic of Shariati Hospital in 1404-1405: A randomized controlled clinical trial

Public title
The effect of comprehensive breastfeeding support counseling
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian nationality Primary birth Age over 18 years Singleton pregnancy and full term Healthy newborn weighing over 2500 grams Ability to read and write Birth at Shariati Hospital, Bandar Abbas Willingness to participate in the study Ability to attend counseling sessions regularly No breast disease No history of chronic diseases No addiction to medication, smoking, drugs, or alcohol
Exclusion criteria:
Unwillingness to participate in the study Infant contracting diseases incompatible with breastfeeding Having any medical complications during pregnancy or childbirth Women who have conceived using fertility treatments Those at high risk of preterm birth multiple Morbid obesity (BMI > 40) Premature baby (less than 37 weeks) Admission of the baby or mother to the intensive care unit Taking medications that are contraindicated in pregnancy or HIV-positive Fetal abnormalities Low birth weight infants >2500 grams Having a high-risk pregnancy Having medical conditions that prevent breastfeeding Having communication problems Having psychiatric illnesses
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be assigned to two intervention and control groups using a block randomization method. The randomization tool will include randomization software to ensure a balanced distribution of confounding variables. To reduce initial differences between groups, a one-to-one matching strategy will also be used. Each participant in the intervention group will be matched with one participant in the comparison group. In addition to the matching strategy, participants will be divided into blocks of 4 or 6 based on common characteristics between individuals. Then, random assignment to groups will be performed in each block. Blocking will be performed by a person not involved in sampling and data analysis.
Blinding (investigator's opinion)
Double blinded
Blinding description
To conceal allocation, participants will select one from a pre-prepared set of sealed envelopes. The inside of each envelope is marked with a label "1" or "2" in a 1:1 ratio. Label "1" will be assigned to the intervention group, while label "2" will indicate the control group. After allocation and matching, participants will be randomly assigned 1:1 to one of the two intervention groups and the control group. In this study, to comply with blinding, patients and outcome assessors will be unaware of the group allocation of participants, and this study will be a double-blind clinical trial.
Placebo
Not used
Assignment
Other
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
بلوار امام حسین
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Postal code
7919693116
Approval date
2025-10-29, 1404/08/07
Ethics committee reference number
IR.HUMS.REC.1404.257

Health conditions studied

1

Description of health condition studied
breastfeeding
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Breastfeeding self-efficacy and breastfeeding competence
Timepoint
34th week of pregnancy and 6th week postpartum
Method of measurement
Breastfeeding Self-Efficacy Questionnaire - Breastfeeding Competence Questionnaire

Secondary outcomes

1

Description
Neonatal hyperbilirubin - postpartum hemorrhage - breastfeeding success - postpartum depression - neonatal anthropometric indices (weight, height, head circumference) - pain - wound infection - neonatal hypothermia - breastfeeding continuation - breastfeeding support counseling
Timepoint
Bilirubin level of the newborn on day 3 - Rate of early postpartum hemorrhage (first 24 hours) and rate of late postpartum hemorrhage (first week) - Breastfeeding success score in the first week after delivery - Postpartum depression score in the 6th week after delivery - Anthropometric indices of the newborn (height, weight, head circumference) in the first 24 hours and 6th week after delivery - Pain level in the first 24 hours and the first week after delivery - Rate of wound infection in the first week after delivery - Rate of hypothermia after birth and 24 hours after that - Rate of breastfeeding continuity in the first, second and sixth weeks after delivery
Method of measurement
Maternal and Infant Clinical Assessment Checklist - Maternal and Infant Clinical Assessment Checklist - Edinburgh Postpartum Depression Questionnaire - Anthropometric Index Checklist - Visual Pain Scale Questionnaire - Maternal and Infant Clinical Assessment Checklist - Maternal and Infant Clinical Assessment Checklist - Daily Breastfeeding Success Monitoring Checklist - Breastfeeding Supportive Counseling Sessions

Intervention groups

1

Description
Intervention group: Intervention group: For the intervention group, breastfeeding support counseling will be provided in the breastfeeding counseling room located in the obstetrics and gynecology clinic of Shariati Hospital. Accordingly, 6 breastfeeding support counseling sessions will be provided in the two phases of pregnancy and postpartum. The goal of breastfeeding support counseling in the pregnancy phase will be to prepare the mother psychologically and practically for successful breastfeeding, and in the postpartum phase, to successfully start breastfeeding and manage postpartum breastfeeding challenges. Breastfeeding support counseling sessions during pregnancy will be two 45- to 60-minute sessions at 34 and 37 weeks of pregnancy, and in the postpartum period, there will be 4 30- to 45-minute sessions on the first day, first week, second week, and sixth week. In the intervention group In addition to supportive breastfeeding counseling, skin-to-skin contact after delivery will be provided by the researcher in the delivery room or operating room for one hour. In the intervention group, booklets containing the content and timing of supportive breastfeeding counseling will be provided to pregnant mothers in the first session.
Category
Behavior

2

Description
Control group: In the control group, breastfeeding counseling will be routinely provided by a lactation consultant at Shariati Hospital.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hormozgan University of Medical Sciences
Full name of responsible person
Nasibeh Roozbeh
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Sponsors / Funding sources

1

Sponsor
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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
Bandar Abbas 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
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Nasibeh Roozbeh
Position
Associate professor
Latest degree
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not 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