Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of supportive home care and counseling on maternal and breastfeeding performance after cesarean section in primiparous women: a randomized clinical trial

Protocol summary

Study aim

Determine the effect of supportive home care and counseling on maternal and breastfeeding performance after cesarean

Design

A concealed, RCT with a parallel group design of 60 women after cesarean, will be enrolled. The participants will be assigned into two groups by blocked randomization using RAS with block sizes of 4, 6 and the allocation ratio of 1:1 and will be followed for 4 months.

Settings and conduct

Sampling will be performed on women admitted to Alavi center who had a cesarean the day before; Participants will be randomly assigned to two groups. 10-15 days, two and four months after delivery, questionnaires of breastfeeding and maternal performance and self-efficacy will be completed by both groups. Birth weight, two and four months weights will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women, gave birth by cesarean Delivery of a single and term baby with more than 2500 grams Without breastfeeding barriers and contraindications

Intervention groups

For intervention group, three home care and supportive counseling sessions will be held during 3 and 7 days, and one month after birth including training maternal self care (breast care, nutrition principles in breastfeeding, care of sutures, sexual relationship resuming and contraception counseling), infant care, evaluating stress, and training coping skills. The control group will receive routine postnatal care.

Main outcome variables

Comparison of breastfeeding and maternal performance in two groups, will be measured by the breastfeeding performance checklist and Barkin Maternal Performance questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170506033834N6**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **prospective**

Last update: **2021-08-10, 1400/05/19**
Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Roghaiyeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3479 6770

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nourizadehr@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-16, 1400/05/25

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of supportive home care and counseling on maternal and breastfeeding performance after cesarean section in primiparous women: a randomized clinical trial

Public title
The effect of supportive home care and counseling on maternal and breastfeeding performance after cesarean section in primiparous women: a randomized clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women who gave birth by cesarean section Age18-35 years Delivery of a single baby with intrauterine age over 37 weeks Having a desire to breastfeed Living in Ardabil
Exclusion criteria:
Existence of systemic and chronic diseases or aggravating disorders during pregnancy and childbirth, including gestational or overt diabetes, blood pressure disorders, Heart disease and ... Breast anomaly or history of breast surgery Depressive disorders before pregnancy and childbirth Cases of infant anomaly and death Lack of rooming for mother and baby due to hospitalization of the baby Breastfeeding contraindications (Women undergoing chemotherapy, women with HIV infection, women with untreated active tuberculosis, and consumption Radioactive drugs, anti-metabolites and illicit drugs during lactation and ...)
Age
From **18 years** old to **35 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
Participants will be assigned to two groups of intervention (home care recipient) and control, using RAS software using random blocking method with 4 and 6 blocks with a ratio of 1: 1. For hiding, the allocation type will be written on paper and numbered in a series of opaque envelopes (Allocation Concealment). The envelopes will be opened sequentially by the person not involved in the sampling.
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 Commite of Tabriz University of Medical Sciences
Street address
Azadi Street, South Shariati, Faculty of Nursing and Midwifery
City
Tabriz
Province
East Azarbaijan
Postal code
0415138947
Approval date
2020-11-09, 1399/08/19
Ethics committee reference number
IR.TBZMED.REC.1399.781

Health conditions studied

1

Description of health condition studied
Postpartum
ICD-10 code
Z39
ICD-10 code description
Encounter for maternal postpartum care and examination

Primary outcomes

1

Description
Score of maternal functioning
Timepoint
10 days, 2 and 4 months after cesarean
Method of measurement
Barkin Index of Maternal Functioning

2

Description
Frequency of Breastfeeding and defecation
Timepoint
10 days, 2 and 4 months after cesarean
Method of measurement
Breastfeeding Practice Checklist

Secondary outcomes

1

Description
Score of breastfeeding Self-Efficacy
Timepoint
10 days, 2 and 4 months after cesarean
Method of measurement
Breastfeeding Self-Efficacy Scale

2

Description
Score of maternal Self-Efficacy
Timepoint
10 days, 2 and 4 months after cesarean
Method of measurement
Maternal Self-Efficacy Questionnaire

3

Description
Infant weight
Timepoint
After birth, 2 and 4 months after cesarean
Method of measurement
Health record

Intervention groups

1

Description
For intervention group, three home care and supportive counseling sessions will be held during 3 and 7 days, and one month after birth including training maternal self care (breast care, nutrition principles in breastfeeding, care of sutures, sexual relationship resuming and contraception counseling), infant care, evaluating stress, and training coping skills.
Category
Behavior

2

Description
Control group: The control group will receive only routine postpartum care
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Educational and Medical Center
Full name of responsible person
Mahsa Ferasati
Street address
Moallem Ave, Alavi Educational and Medical Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
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Golgasht St., University of Tabriz, Central Building
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahsa Ferasati
Position
Master student of counseling in midwifery
Latest degree
Bachelor

Other areas of specialty/work
Midwifery
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Azadi Street, South Shariati, Faculty of Nurcing and Midwifery, Tabriz
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Person responsible for scientific inquiries

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Name of organization / entity
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Ph.D in Reproductive Health
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Person responsible for updating data

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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
No more data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
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