

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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)

Phone

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Email address

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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 Age 18-35 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 of 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 Committee 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

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Roghaiyeh Nourizadeh

Position

Ph.D in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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