

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the effect of consultation based on Bristol tool on self-efficacy and continuation of breast-feeding among primi-parous women undergoing cesarean section.

Protocol summary

Summary

Objectives: the aim of this study is to determine the effect of consultation based on Bristol tool on self-efficacy and continuation of breast-feeding among primiparous mothers undergoing Cesarean section in Fatemeh Hospital, Hamadan city, Iran, 2017. Design: This study is an experimental study with two intervention and control groups. Participants: the study participants are 80 mothers undergoing Cesarean section. They will be selected by convenience sampling (40 in each group). The samples will be allocated into the intervention and control groups using eight block method. Setting and conduct study: Before consultation, participants will complete a consent form. Then, data will be gathered using a questionnaire including demographic characteristics, self-efficacy and continuation of breast-feeding. Intervention: for intervention group, check list of Bristol assessment tool will be completed by the researcher. Based on this assessment tool, breast-feeding consultation will be done for 4 sessions. Individual breastfeeding counseling will be conducted at two hours, second day, one week and one month after delivery. Also at first session, mothers will receive educational booklet about breastfeeding. Then follow up via telephone will be done in the 1st, 2nd, 3rd and 4th months after delivery for evaluation of mothers' breastfeeding problems. During this period, mothers in control group will receive only routine care. Four months after delivery, questionnaires will be completed again by the participant of both groups and they will be compared on self-efficacy and continuation of breast-feeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041810426N16**

Registration date: **2017-06-13, 1396/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-13, 1396/03/23

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1822 4396

Email address

parsa@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of consultation based on Bristol

tool on self-efficacy and continuation of breast-feeding among primi-parous women undergoing cesarean section.

Public title

Effects of consultation based on Bristol tool on breast-feeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Cesarean section delivery; primiparous; literacy; Residency in Hamadan city; Having a mobile number for follow-ups; Singleton birth and term delivery. Exclusion criteria: Inability to do breastfeeding according to physician's approval; Problems after cesarean section such as bleeding and anesthesia related problems; Underlying disease in mother such as cardiac, pulmonary, chronic and infection diseases; Addiction; Neonatal abnormality and diseases.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, in front of Mardom Park, Shahid Fahmideh Street, Hamadan

City

Hamadan

Postal code

65178

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.UMSHA.REC.1396.66

Health conditions studied**1****Description of health condition studied**

Breast-feeding disorders among mothers undergoing Cesarean section

ICD-10 code

O92.2

ICD-10 code description

Other and unspecified disorders of breast associated with childbirth

Primary outcomes**1****Description**

Mother's self-efficacy in breastfeeding

Timepoint

2 hours after delivery, second day after delivery, 7 to 10 days after delivery, one month after delivery and four months after delivery

Method of measurement

Breastfeeding Self-Efficacy

Secondary outcomes**1****Description**

Maintaining of exclusive breastfeeding

Timepoint

2 hours after delivery, second day after delivery, 7 to 10 days after delivery, one month after delivery and four months after delivery

Method of measurement

Breast-feeding checklist

Intervention groups**1****Description**

Intervention: for intervention group, check list of Bristol assessment tool will be completed by the researcher. Based on this assessment tool, breast-feeding consultation will be done for 4 sessions. Individual breastfeeding counseling will be conducted at two hours, second day, one week and one month after delivery. Also at first session, mothers will receive educational booklet about breastfeeding. Then follow up via telephone will be done in the 1st, 2nd, 3rd and 4th months after delivery for evaluation of mothers' breastfeeding problems. Four months after delivery, questionnaires will be completed again by the participant of both groups and they will be compared on self-efficacy and continuation of breast-feeding.

Category

Early detection

2**Description**

Control group: only will receive routine care.

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Fatemih Hospital in Hamadan

Full name of responsible person

Raheleh Khodabandelou

Street address

Fatemieh Hospital, Pasdaran Street, Hamadan

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Hamadan

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Mardom Park, Shahid Fahmideh Street, Hamadan**City**

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Associate Professor

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty