Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of the doula support on childbirth experience and breastfeeding function after cesarean section: A randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of the doula support on childbirth experience and breastfeeding function after cesarean section

Design

A controlled, parallel groups, randomized clinical trial on 84 women candidates for cesarean section (42 people in each group). The Randomizer software will be used for randomization

Settings and conduct

This study will be conducted in the operating room and labor of Al-Zahra and Taleghani hospitals in Tabriz. In addition to routine care, the intervention group will receive the support of a doula. To conceal the allocation, the type of intervention will be written on a sheet of paper and placed inside numbered opaque envelopes. The envelopes will be opened in the order in which the participants enter the study and the type of intervention will be determined. The follow-up will be between four and six weeks in the nearest hospital or health centers where the participants live.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age of 37 weeks or more Nulliparous women with first non-emergency caesarean section and no history of normal delivery and no onset of labor symptoms Absence of disease or abnormality of the baby at birth Having the ability to breastfeed. Exclusion criteria: mental illnesses such as depression, breastfeeding contraindications

Intervention groups

In addition to the usual care of the operating room, the intervention group will receive the doula support in the form of emotional-psychological, physical and educational support from one hour before the cesarean section to two hours after the operation in order to reduce her anxiety and stress and increase her self-confidence, encouragement, companionship and etc. The control group will receive only routine care in the operating room.

Main outcome variables

Childbirth experience; breastfeeding function; depression and Anxiety after cesarean delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240128060831N1**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Reyhaneh Ivanbagha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

Email address

ivanbagha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-02, 1403/01/14

Expected recruitment end date

2024-12-04, 1403/09/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the doula support on childbirth experience and breastfeeding function after cesarean section: A randomized controlled clinical trial

Public title
The effect of the doula support on childbirth experience and breastfeeding performance after cesarean section
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with a gestational age of 37 weeks or more nulliparous women with the first non-emergency cesarean section (cesarean section in cases such as breech presentation, cephalopelvic disproportion (CPD), fetal macrosomia, fetal distress, placental abruption) and without the onset of labor symptoms Women with a history of one caesarean section and no history of natural childbirth and no onset of labor symptoms Absence of disease or abnormality of the baby at birth Having the ability to breastfeed Having literacy in reading and writing to answer questions A resident of Tabriz
Exclusion criteria:
Mother's unwillingness to have a doula Mothers with mental illnesses such as depression, etc. according to the mother's statement or medical record Mothers with physical diseases that prevent breastfeeding, such as mastectomy The need to perform another surgery (hysterectomy) for the mother during cesarean section Contraindications and precautions in breastfeeding (untreated tuberculosis, chicken pox, measles, hepatitis, Malt fever, AIDS, chemotherapy, infant galactosomia, herpes lesions on the breast, use of certain drugs, breast abscess, mastitis, drug use, etc.) Mother's speech and hearing disorders
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible people will be assigned to intervention and control groups by random block method with block sizes of 6 and 4 and with an allocation ratio of 1:1 and classification based on nulliparousness or history of one cesarean section. The Randomizer software will be used to create the allocation sequence. Allocation sequence concealment will be done by someone other than the person involved in sampling and data collection. For Allocation Concealment, the type of intervention will be written on a sheet of paper and placed inside opaque envelopes numbered from 1 to 84. The envelopes will be opened in the order in which the participants entered the study and the type of intervention received will be determined.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
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
Research department, third floor, central construction number2, Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2024-01-01, 1402/10/11
Ethics committee reference number
IR.TBZMED.REC.1402.761

Health conditions studied

1

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

Primary outcomes

1

Description
Childbirth experience score
Timepoint
Between four and six weeks after cesarean delivery

Method of measurement
questionnaire for assessing the childbirth experience (QACE)

2

Description
Breastfeeding performance score
Timepoint
Between four and six weeks after cesarean section
Method of measurement
Breastfeeding performance questionnaire

Secondary outcomes

1

Description
Depression score
Timepoint
Once between four and six weeks after cesarean section
Method of measurement
Edinburgh postpartum depression questionnaire

2

Description
Anxiety score
Timepoint
Once between four and six weeks after cesarean section
Method of measurement
Specific postpartum anxiety questionnaire

Intervention groups

1

Description
Intervention group: The intervention group, in addition to the usual care in the operating room, from one hour before the cesarean section to two hours after the operation, the doula support in the form of emotional-psychological, physical and educational support in order to reduce anxiety and stress and increase her self-confidence, encouragement, companionship, reassurance, respect for the mother in decision-making, helping to communicate with other caregivers, empathetic relationship with mother and his family, constant presence and sympathetic behavior, giving hope and encouragement, creating a positive attitude about the birth of the baby, establishing skin-to-skin contact to the skin of the mother and the baby by placing the baby on the mother's chest immediately after the operation, helping the mother to start breastfeeding successfully one hour after birth, providing information such as answering her questions about the cesarean procedure with understandable answers, teaching how They will have baby care, proper breastfeeding and training on how to milk milk and store it when needed, baby vaccination, nutrition and personal hygiene, and additional training on self-care during the postpartum period. All actions taken by the researcher will be recorded by the prepared checklist. This checklist includes supportive actions of the doula consisting of 34 questions in three parts, one hour before cesarean section, during cesarean section, and up to two hours after cesarean section. Also, at the end of this checklist, there are four open-ended questions that evaluate the mother's expectations from the doula and their experiences of having a doula.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Therapeutic Educational Hospital
Full name of responsible person
Vahideh Hadavi
Street address
Baghshomal intersection, South army street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
hrahospital@tbzmed.ac.ir

2

Recruitment center
Name of recruitment center
Taleghani Therapeutic Educational Hospital
Full name of responsible person
Vahideh Hadavi
Street address
Railway square, 22 Bahman street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3442 8990
Email
ani.hos@tbzmed.ac.ir

3

Recruitment center
Name of recruitment center
Community health centers of Tabriz
Full name of responsible person
Vahideh Hadavi
Street address
Community health centers of Tabriz

City
Tabriz
Province
East Azarbaijan
Postal code
5143814998
Phone
+98 41 3444 0057
Email
iro@tbzmed.ac.ir
Web page address
http://tabriz-phc.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Parviz Shahabi
Street address
Research Department, third floor, central construction number2, Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3335 5921
Fax
Email
dabirkhanecent@tbzmed.ac.ir
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
Vahideh Hadavi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5135963777
Phone
+98 41 3479 6770
Email
vhhadavi70@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh Ivanbagha
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
ivanbagha@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhane Ivanbagha
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Midwifery

Street address
Faculty of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
ivanbahga@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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