

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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

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##### **Postal code**

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### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Taleghani Therapeutic Educational Hospital

##### **Full name of responsible person**

Vahideh Hadavi

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Railway square, 22 Bahman street, Tabriz

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### **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

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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**Full name of responsible person**  
Dr Parviz Shahabi

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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

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Position**  
Lecturer

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Master

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## Person responsible for updating data

#### Contact

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**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