

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

#### Protocol summary

##### Study aim

To determine The effect of counseling with skill training approach on postpartum maternal functioning

##### Design

Randomized controlled trial with two parallel arms

##### Settings and conduct

This study will be conducted on women who are referred to Tabriz health centers, so that the researcher will attend in the health centers and will select women with first and second birth, based on their records and invite them to participate in the study through phone contact. In the face to face meeting, the Barkin Maternity Functioning Questionnaire will be completed, and women who receive a score of under 80 will be included in the study and will receive written consent. Participants will be assigned to two groups of counseling and control. Four counseling sessions will be held for intervention group. Two weeks after the last session, post-test questionnaires including maternal functioning, infant care behavior and maternal self-efficacy will be completed by the participants in both counseling and control groups.

##### Participants/Inclusion and exclusion criteria

Participants with first and second birth and with maternal functioning score below 80 and postpartum depression score above 12

##### Intervention groups

For the intervention group, four counseling sessions will be provided from the fourth week after delivery at intervals of one week. The duration of each session will be 60 to 90 minutes. The control group will receive routine care.

##### Main outcome variables

Maternal functioning at 10 weeks after childbirth

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120718010324N49**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

#### Registration date

2019-01-18, 1397/10/28

#### Registrant information

##### Name

Mojgan Mirghafourvand

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6969

##### Email address

mirghafourvandm@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-01-20, 1397/10/30

#### Expected recruitment end date

2019-06-19, 1398/03/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

**Public title**

The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Woman with First and second birth Maternal functioning score below 80 Mother's ability to take care of the baby Healthy term baby The desire to attend in counseling sessions Not having neonatal anomalies (including diagnosed physical and mental abnormalities) Having at least a secondary or higher education The normal postpartum period until time to enter the study Age between 15 to 49 years

**Exclusion criteria:**

Uncertainty about being able to attend all consultation sessions Change location to another city Having cardiovascular diseases, high blood pressure, liver disease and other chronic diseases, according to the participant's statement Hospitalization of the child Unsolvable lactation problem Obtaining postpartum depression score higher than 12 Neuropsychiatric diseases and recent disasters according to mother expression

**Age**

From **14 years** old to **49 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be conducted using the website [www.random.org](http://www.random.org) and through blocking with block sizes of four and six and an allocation ratio of 1: 1 to the two groups of counseling and control.

**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**

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

513894797

**Approval date**

2019-01-08, 1397/10/18

**Ethics committee reference number**

IR.TBZMED.REC.1397.789

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

Postpartum maternal functioning

**ICD-10 code**

Z39.0

**ICD-10 code description**

Encounter for care and examination of mother immediately after delivery

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

Maternal functioning

**Timepoint**

Before the intervention and 2 weeks after the end of intervention (four weeks after childbirth)

**Method of measurement**

Maternal Functioning Barkin Index (MFBI)

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

Infant care behavior

**Timepoint**

Before the intervention and 2 weeks after the end of the intervention (four weeks after childbirth)

**Method of measurement**

Infant Care Behavior Questionnaire

**2****Description**

maternal self-efficacy

**Timepoint**

Before the intervention and 2 weeks after the end of the intervention (four weeks after childbirth)

**Method of measurement**

## Intervention groups

### 1

#### Description

Intervention group: For intervention group, four 60-90 minutes counseling sessions with a skill-based approach will be provided.

#### Category

Behavior

### 2

#### Description

Control group: The control group will received routine care.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health centers of Tabriz city

##### Full name of responsible person

Fatemeh Karami

##### Street address

South Shariati

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

##### Phone

+98 41 3479 6969

##### Email

fatemeh.karami1995@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Abolghasem Jouyban

##### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

#### Phone

+98 41 3479 6969

#### Email

iro@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

Fatemeh Karami

##### Position

MSc student of conseling in Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

Faculty of Nursing Midwifery, South Shariati Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947977

##### Phone

+98 31 5224 1540

##### Email

fatemeh.karami1995@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Mojgan Mirghafourvand

##### Position

PhD of Reproductive Health

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery  
**Street address**  
Faculty of Nursing Midwifery, South Shariati Street  
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**Email**  
mirghafourvandm@tbzmed.ac.ir  
**Web page address**  
<http://nursing.tbzmed.ac.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mojgan Mirghafourvand  
**Position**  
PhD of Reproductive Health  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Nursing & midwifery faculty, South Shariati Street  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5138947977  
**Phone**

+98 41 3479 6770

### Fax

+98 41 3479 6969

### Email

Mirghafourvandm@tbzmed.ac.ir

### Web page address

<http://nursing.tbzmed.ac.i>

## 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

Data of participants are privacy.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

The results of clinical study will be published as article.

### When the data will become available and for how long

Immediately after publishing the results.

### To whom data/document is available

All researchers

### Under which criteria data/document could be used

Scientific using with citation to article

### From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

### What processes are involved for a request to access data/document

Maximum one week after the communication by email.

### Comments