

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Assessment the effect of Orem's self-care counselling on the postpartum self- evaluation of primiparous women

#### Protocol summary

##### Study aim

Evaluation the the effect of Orem's self-care counselling on the post partum self- evaluation of primiparous women

##### Design

A randomized controlled clinical trial with a parallel group design of 58 participants

##### Settings and conduct

Research population comprise postpartum women of Mohammadshahr in the Alborz province. A sample of 58 eligible mothers will be selected by simple random. In intervention group, participants will attend weekly in group counselling session for 3 sessions (90 minutes) in groups of six people, according the Orem's model. The participants will be evaluated before and 6 weeks after the intervention by postpartum self-evaluation questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: being Iranian, being literated, primipara, low risk pregnancy, absence of physical and mental illness, absence of postpartum Depression, absence of postpartum complications, being interested to contribute in the study. Exclusion criteria: Neonatal illness, Neonatal Hospitalisation.

##### Intervention groups

"Intervention group" will receive group counselling in 3 sessions (90 minutes)weekly. "Control group" will not receive any counselling.

##### Main outcome variables

Postpartum self-evaluation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160424027557N8**

Registration date: **2018-10-13, 1397/07/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-13, 1397/07/21**

Update count: **0**

##### Registration date

2018-10-13, 1397/07/21

##### Registrant information

###### Name

Mahnaz Akbari Kamrani

###### Name of organization / entity

Alborz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3433 6007

###### Email address

dr.akbarikamrani@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the effect of Orem's self-care counselling on the postpartum self- evaluation of primiparous women

##### Public title

Effect of counselling on the postpartum self- evaluation

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Being Iranian Being literated Being married Being primiparous Having single pregnancy Having low risk pregnancy Having term newborn Absence of physical and mental illness Absence of postpartum Depression Absence of postpartum complications Being interested to contribute in the study

**Exclusion criteria:**

Neonatal illness Neonatal Hospitalisation

**Age**

From **18 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The block sampling was used for random allocation using Excel software to form the groups. Samples were divided into intervention and control groups by quadruple random blocks. There were six possibilities for blocking (BAAB, ABAB, AABB, ABBA, BBAA, BABA). First, one of the blocks was selected and four of the participants in that block were selected. As a result, the number A belongs to the intervention group and the number B belongs to the control group.

**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 Alborz University of Medical Sciences

**Street address**

Vice-Chancellor for Research and Technology, Alborz University of Medical Sciences, above Taleghani Square, Taleghani Square

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2018-02-24, 1396/12/05

**Ethics committee reference number**

IR.ABZUMS.REC.1396.203

**Health conditions studied**

**1**

**Description of health condition studied**

Routine postpartum follow-up

**ICD-10 code**

Z39.2

**ICD-10 code description**

Routine postpartum follow-up

**Primary outcomes**

**1**

**Description**

Postpartum self-evaluation

**Timepoint**

Before and after intervention

**Method of measurement**

Postpartum self-evaluation questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Participants will attend in group counselling (90 minutes) for 3 sessions in groups of six people weekly, according the Orem's model. Counselling content includes: the purpose of the study, general health, developmental health and illness.

**Category**

Lifestyle

**2**

**Description**

Control group: Participants will not receive any intervention. After the study, a booklet containing the content of the consultation will be given to them.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alborz University of Medical Sciences

**Full name of responsible person**

Maryam Chamangasht

**Street address**

Bakhtiari Ave., Tabatabaie Comprehensive Health Services Center

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Mohammadshahr

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3198764653

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khcalborz@abzums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Noorisepehr

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Research@abzums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Alborz 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Maryam Chamangasht

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

counseling in midwifery

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chamangasht2015@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Dr. Mahnaz Akbari Kamrani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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**Email**  
Dr.akbarikamrani@abzums.ac.ir

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

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

All collected variables

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

From 2019

### **To whom data/document is available**

It will be available only for people working in academic institutions.

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

No Criterion

### **From where data/document is obtainable**

By Email: Dr.akbarikamrani@abzums.ac.ir and Dr. Mahnaz Akbari Kamrani would be responsive

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

By Email

### **Comments**