

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of educational program on postpartum depression in Primiparous Women

#### Protocol summary

##### Summary

This study aims to compare the effect of educational programs on prevention of postpartum depression. This is a quasi- experimental study using a two-team field trial . To prevent contamination of the control group with the intervention , The location of study will include two health care centers in Sanandaj , a center for educational intervention and the other as a control center, selected randomly . In this study 100 primiparous women with Edinburgh score 12 or less, a singleton healthy term baby and without having known history of mental illness, 10-14 days after delivery will be recruited. The women who will experience adverse events during the study or wish to withdraw from the study will be excluded . In the intervention group 100 primiparous women will be participated. An educational programs on postpartum depression in three sessions: 10-14 days, 6 and 8 weeks after delivery that will be lasted 20 minutes per session will be provided by the researcher for mothers individually and then booklets will be delivered to the mother to recall. The researcher will follow the mothers and remind them the educational materials every 15 days by the phone. Control group include 100 primiparous mothers who will receive the routine postpartum care in (10-14 days, 6 and 8 weeks) after delivery . The Edinburgh questionnaire will be completed by both of groups in 8 weeks and 3 months after delivery. The educational program's effect will be measured by comparing the Edinburgh scores .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110163034N7**

Registration date: **2011-12-07, 1390/09/16**

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

Last update:

Update count: **0**

##### Registration date

2011-12-07, 1390/09/16

##### Registrant information

###### Name

Mansoureh Jamshidimanesh

###### Name of organization / entity

Iran University Faculty of Nursing & Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4365 1811

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, faculty of Nursing and Midwifery Tehran University of Medical Sciences

##### Expected recruitment start date

2011-10-22, 1390/07/30

##### Expected recruitment end date

2012-01-20, 1390/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of educational program on postpartum depression in Primiparous Women

##### Public title

The effect of education on the prevention of postpartum depression

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: Primiparous women who are able to read and write ; live with their husband; were pregnant naturally ; have singleton healthy term baby( infant) ; have Edinburgh score equal or less than 12 ; are without complications after delivery ; have no known history of psychiatric disorders in current and previous pregnancy.

Exclusion criteria: Primiparous women who suffered during the study ; mothers who withdraw during the study

### **Age**

No age limit

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **200**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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 School of Nursing and Midwifery,  
Tehran University of Medical Sciences

##### **Street address**

Tohid SQ, East Nosrat Ave

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2011-08-13, 1390/05/22

#### **Ethics committee reference number**

130-791-90-3

## **Health conditions studied**

### 1

#### **Description of health condition studied**

postpartum depression

### **ICD-10 code**

F53

### **ICD-10 code description**

Mental and behavioural disorders associated with the puerperium, not elsewhere classified

## **Primary outcomes**

### 1

#### **Description**

The Edinburgh postnatal depression scores

#### **Timepoint**

10-14 days after delivery (before intervention) - 8 weeks and 3 months after delivery

#### **Method of measurement**

The Edinburgh Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Individual educational program will be implemented by the researcher in 3 sessions of 20 minutes including: 10-14 days, 6 and 8 weeks after delivery. In the first session the mothers will be educated about post partum depression (definition, prevalence, symptoms, causes and practical solutions to deal with it, including :getting help from his wife and family - enough rest and sleep - good nutrition - exercise techniques, relaxation, and Infant massage ) then, a booklet, including discussed topics, delivered to recall the mothers and finally the mothers' questions will be answered by the researcher. In the second (6 weeks) and third sessions (8 weeks), the educational program will include more complete explanation of postpartum depression and practical strategies to deal with it . The Edinburgh questionnaire will be completed at baseline, 10-14 days, 8 weeks and 3 months after delivery.

#### **Category**

Prevention

### 2

#### **Description**

In the intervention group, the researcher will remind the mothers about training tips by the phone every 15 days after starting the educational program, and then will answer to the mother's questions. The researcher's phone number will be given to the mothers in order to answer their questions.

#### **Category**

Prevention

### 3

#### **Description**

In control group:the mothers will receive routine post partum care in health care centers in 10-14 days, 6 and 8 weeks after delivery, the Edinburgh questionnaire will be completed at baseline, 14-10 days , then in 8 weeks and 3 months after delivery.

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ghods urban Health care center

**Full name of responsible person**

Hoda Ghadimi

**Street address**

Ghods urban Health care center , Taleghani St., Sanandaj ,Kordestan ,Iran

**City**

Sanandaj

2

**Recruitment center**

**Name of recruitment center**

Nebovat Urban Health care center

**Full name of responsible person**

Soheila Daneshvar

**Street address**

Nebovat Urban Health care center , Ekbatan St.,Sanandaj , Kordestan , Iran

**City**

Sanandaj

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research,Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Ali Cheraghi

**Street address**

School of Nursing and Midwifery, Tehran University of Medical Sciences Tohid SQ East Nosrat Ave Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research,Tehran 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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

School of Nursing and Midwifery, Tehran University of Medical Sciences

**Full name of responsible person**

Mansoureh Jamshidimanesh

**Position**

MSc Midwifery, Master of Science

**Other areas of specialty/work**

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**Position**

Midwifery, Master of Science

**Other areas of specialty/work**

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## **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*