

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of volunteer's telephone-based support on the effect of volunteers' telephone-based support on decreasing the postnatal depression decreasing the postnatal depression

#### Protocol summary

##### Summary

**Abstract Objectives:** The aim of this research is to study the effect of volunteer's telephone-based support on decreasing postnatal depression. **Materials and Methods:** In a randomized controlled trial, the mothers fill the Edinburg Postnatal Depression Scale (EPDS) on 10-15 days after uncomplicated childbearing. After applying exclusion criteria, 54 eligible mothers with mild and moderate depression (scores= 11-14) will be allocated into intervention group 1 and group 2T randomly. the intervention group 1 receive routine postnatal health care beside telephone based support by health volunteers and will be asked and explained about their questions The intervention group 2 will use the routine postnatal health care,. A questionnaire will be used to collect demographic and contextual variables. After 6 weeks mothers will fill the EPDS and depression scores will be measured again. Data will be analyzed using chi-square test, Fisher's exact test, t-test and paired t-test. **key words:** women health, telephon based support, health volunteer, EPDS, postnatal depression

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202159027N1**  
Registration date: **2012-04-09, 1391/01/21**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-04-09, 1391/01/21

##### Registrant information

**Name**

Hourieh Shamshiri Milani

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2240 3893

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2012-04-21, 1391/02/02

##### Expected recruitment end date

2012-09-20, 1391/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of volunteer's telephone-based support on the effect of volunteers' telephone-based support on decreasing the postnatal depression decreasing the postnatal depression

##### Public title

The effect of volunteer's telephone-based support on the effect of telephone-based support on postnatal depression

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

The inclusion criterion were: term live childbirth.

Exclusion criteria were: history of mental disorder; episodes of mental disorders during pregnancy or last year that necessitate medicine use; dead fetus; history of postpartum depression; current use of psychiatric prescribed drugs and the EPDS score more than 14

#### **Age**

No age limit

#### **Gender**

Female

#### **Phase**

N/A

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

No information

#### **Sample size**

Target sample size: **54**

#### **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**

community medicine Department

##### **Street address**

Velenjak, Koodakyar street, Faculty of Medicine Shahid Beheshti University of Medical Sciences, Velenjak

##### **City**

Tehran

##### **Postal code**

1985734957

#### **Approval date**

2012-03-05, 1390/12/15

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

15862/308

## **Health conditions studied**

### **1**

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

Postnatal depression

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

F53

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

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

## **Primary outcomes**

### **1**

#### **Description**

Postnatal depression

#### **Timepoint**

Before intervention and six weeks after intervention

#### **Method of measurement**

Edinburg Postnatal Depression Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

The intervention group 1 will receive routine postpartum care plus volunteers' telephone-based supports till 6 weeks. Eight health volunteers will be trained and every of them will cover 3-4 mothers for 2-3 times per week, telephone-based supporting. During every call after greeting, they will ask their health status, mood and relationship with their newborns and whether there is any problem? They will solve the problem according to their training guidance. They will be in close contact with the main researcher and should not talk to the other volunteers in this regard. The control group do not receive this support and only receive routine postpartum care. At the end of 6 weeks, EPDS will be filled again in two groups and the depression scores were calculated.

#### **Category**

N/A

### **2**

#### **Description**

Interventeion group 2: The intervention group two will receive only routine postnatal care and have the same characteristic as intervention group one.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

the hospitals of Shahid Beheshti University of Medical Sciences

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

Hourieh Shamshiri Milani

##### **Street address**

Velenjak- Daneshjoo Blvd. Koodakyar Ave. Faculty of Medicine, 8th floor, Department of Community Medicine

##### **City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Deputy of Reaserch, Faculty of Medicnie, Shahid Beheshti University of Medica

**Full name of responsible person**

Dr. Houssein Ghoodarzi

**Street address**

Velenjak- Daneshjoo Blvd. Koodakyar Ave. Faculty of Medicine, 8th floor, Department of Community Medicine

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Reaserch, Faculty of Medicnie, Shahid Beheshti University of Medica

**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****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hourieh Shamshiri Milani

**Position**

Obstetrician & Gynecologist- MPH, Assistant Professor

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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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*