

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of counseling based on Problem Solving on postpartum depression

#### Protocol summary

##### Summary

**Objectives:** This study aimed to determine the effect of exercise on quality of life for women after childbirth .  
**Design:** This study is an international study in two groups (intervention and control groups) .  
**Participants :**The study population will be 80 randomly selected women who had normal vaginal delivery and 3 to 5 days after delivery will refer to health care centers in Hamadan city for routine maternal and infant health cares.Using a tale of random numbers, random sampling will done . First, from all health care centers in Hamadan city 4 health care centers will select randomly ( 2 health care centers for control group and 2 health care centers for intervention group). Then, from eligible women in each health care center 20 women will select randomly. With this way, Eighty postpartum women randomly will be selected in two control and intervention groups (40 in each group).  
**Setting and conduct:** In the first postpartum care after delivery (3 to 5 days after delivery) using a structured questionnaire include quality of life condition, exercise behavior and demographic characteristics data of women in two groups will be completed.Questionnaires will be completed by interviews with both groups of the study .  
**Intervention:** for intervention group, in addition to routine care in 3 to 5 days after delivery by a movie on postpartum exercises, women will be trained and encouraged to exercise extend educational booklets and CDs. Women will be recommended to do postpartum exercise up to 6 weeks twice a day for 10 to 15 minutes each day at home. This exercise should be performed at least 5 days a week. **Control:** during this period, the control group received only routine care. Main outcome measures are exercise and quality of life. Comparison of two groups will done in 3 to 5 days after delivery (postpartum care I), 10 to 14 days after delivery (postpartum care II) and 60 days after delivery (postpartum care III) in terms of exercise behavior and quality of life.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016090310426N14**  
Registration date: **2016-10-26, 1395/08/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-26, 1395/08/05

##### Registrant information

##### Name

Parisa Parsa

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1822 4396

##### Email address

parsa@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor of Research in Hamadan University of Medical Sciences.

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of counseling based on Problem Solving on postpartum depression

**Public title**

The effect of counseling based on Problem Solving on postpartum depression among mothers attending to health centers of Hamadan city, 1395

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Having singleton birth ; Normal vaginal delivery ; Delivery of term and healthy newborn; living with spouse; literacy; 1st to 3 rd Gravidity; Age between 18 to 40 years; No history of infertility; lack of postpartum problem in labor; No known mental illness. Exclusion criteria: Taking of psychiatric drugs; Having stress or family problems; Having mental disorders; Underlying disease (including diabetes mellitus, autoimmune diseases and other chronic diseases; Drug addiction; immigration of mother; Scale score of 10 or higher of depression scale Edinburgh and confirmed by clinical psychologist ( lack of the blues after childbirth)

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**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 of Hamadan University of Medical Sciences

**Street address**

Hamadan University of Medical Sciences- Shahid Fahmideh Street- Counterpoint of Mardom Park- Hamadan

**City**

Hamadan

**Postal code**

65178

**Approval date**

2016-09-17, 1395/06/27

**Ethics committee reference number**

IR.UMSHA.REC.1395.291

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

Postpartum depression

**ICD-10 code**

F 53

**ICD-10 code description**

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

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

Postpartum depression

**Timepoint**

10 to 14 days after delivery, 60 days after delivery

**Method of measurement**

Standard questionnaire postpartum depression of Edinburgh

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The experimental group, in addition to routine care in 10 to 14 days after delivery will receive a face to face consultation based on problem solving in four counseling sessions per week for 45 to 60 minutes per session in the health centers classroom. Questionnaire will complete at 10 to 14 days after delivery (postpartum care II) an 60 days after delivery (postpartum care III).

**Category**

Prevention

**2****Description**

The control group will receive only routine care.

**Category**

N/A

**Recruitment centers**

1

#### Recruitment center

**Name of recruitment center**

Public Health Deputy of Hamadan Univrsity of Medical Sciences

**Full name of responsible person**

Parsatoo Ahangpour

**Street address**

Phalastin Square, Public Health Deputy of Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

#### Sponsors / Funding sources

1

#### Sponsor

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Shahid Fahmideh Street, Counterpoint of Mardom Park , Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamadan 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

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Shahid Fahmide street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3835 0150

**Fax**

**Email**

parsa@umsh.ac.ir

**Web page address**

#### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Shahid Famideh Street , Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3835 0150

**Fax**

**Email**

parsa@umsh.ac.ir

**Web page address**

#### Person responsible for updating data

#### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Parisa Parsa

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Shahid Fahmideh street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

**Postal code**

6517838698

**Phone**

+98 81 3835 0150

**Fax**

**Email**

parsa@umsha.ac.ir

**Web page address**

#### 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*