Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Parisa Parsa
Name of organization / entity
Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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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 Gravity; 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
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Full name of responsible person
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Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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