

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

delshad2@iums.ac.ir

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

Street address

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

City

Tehran

Postal code

Phone

+98 2166927171222

Fax

Email

jamshidimanesh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Mansoureh Jamshidimanesh

Position

Midwifery, Master of Science

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 2166927171222

Fax

Email

jamshidimanesh@yahoo.com

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