Clinical Trial Protocol
Iranian Registry of Clinical Trials
22 Aug 2019

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

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** | None |
| **Sample size** | Target sample size: 200 |
| **Randomization (investigator's opinion)** | Randomized |
| **Blinding (investigator's opinion)** | Not blinded |
| **Blinding description** | Placebo Not used |
| **Assignment** | Parallel |

**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**

---

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 |

---

**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**
1390/05/22

**Approval date**
2011-08-13

**Ethics committee reference number**
130-791-90-

**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**
1
Recruitment center
Name of recruitment center
Ghods urban Health care center
Full name of responsible person
Hoda Ghdadimi
Street address
Ghods urban Health care center , Taleghani 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
empty
Type of organization providing the funding
empty

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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact

Person responsible for scientific inquiries
Contact

Person responsible for updating data
Contact

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty