Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Feb 2020

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
Registreant 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 MidwiferyTehran 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-

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
<table>
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<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Ghods urban Health care center</th>
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<tbody>
<tr>
<td></td>
<td>Full name of responsible person</td>
<td>Hoda Ghadimi</td>
</tr>
<tr>
<td></td>
<td>Street address</td>
<td>Ghods urban Health care center , Taleghani St., Sanandaj ,Kordestan ,Iran</td>
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<tr>
<td></td>
<td>Full name of responsible person</td>
<td>Soheila Daneshvar</td>
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<td></td>
<td>Street address</td>
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**Sponsors / Funding sources**

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<th>Name of organization / entity</th>
<th>Vice chancellor for research, Tehran University of Medical Sciences</th>
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<tr>
<td></td>
<td>Full name of responsible person</td>
<td>Dr Mohammad Ali Cheraghi</td>
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<td></td>
<td>Street address</td>
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**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

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<tr>
<td>Email</td>
<td><a href="mailto:jamshidimanesh@yahoo.com">jamshidimanesh@yahoo.com</a></td>
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**Person responsible for updating data**

**Contact**

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**Sharing plan**

- Deidentified Individual Participant Data Set (IPD) empty
- Study Protocol empty