Effect of educational package on breastfeeding self-efficacy in postpartum period.

Protocol summary

Summary
This is a single blind intervention study that will be done on 300 nulliparous women admitted to Saveh hospitals after delivery. Tools using in this study will be two questionnaires and a checklist that will be given to the individuals who wishing to participate in the study. To prevent the relationship between intervention and control group, the hospitals will be divided in intervention and control groups randomly. To prevent the relationship between intervention groups, at the begin of each day, the rooms will be randomly divided in two groups: first group 20 minutes face to face training The instruction will be given to the second group, without training. Control group will receive routine hospital program. The instruction package includes a video CD and a Pamphlet that will be designed and constructed by the researcher. After three months, the breast feeding self efficacy score, mother’s knowledge and practice will be measured using checklist and questionnaires by home visiting the subjects. Then the self efficacy score, knowledge and practice in two intervention groups will be compared with control group. For data analysis, SPSS software, version 16 will be used.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201102275912N4
Registration date: 2012-09-24, 1391/07/03
Registration timing: registered while recruiting

Last update:
Update count: 0
Registration date
2012-09-24, 1391/07/03

Registrant information
Name
Mandana Mir Mohammad Ali Ei
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)

Phone
+98 21 6692 7171
Email address
mirmohammad@tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2012-07-22, 1391/05/01
Expected recruitment end date
2012-12-21, 1391/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of educational package on breastfeeding self-efficacy in postpartum period.

Public title
Effect of educational package on breastfeeding self-efficacy in postpartum period.

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: Having a healthy newborn; Singleton pregnancy; primiparity; Having at least basic literacy; Pregnancy without High Risk Conditions; No smoking mothers; Living in Save; Having a phone number; Having the CD divece at home.exclusion criteria: mother or infant conditions, illness during the study that breastfeeding is contraindicated.

Age
From 18 years old to 35 years old

Gender
Female

Phase
N/A

Groups that have been masked
No information
### Sample size
Target sample size: **300**

### Randomization (investigator's opinion)
Randomized

### Randomization description

### Blinding (investigator's opinion)
Single blinded

### Blinding description

### Placebo
Not used

### Assignment
Parallel

### Other design features

### Secondary ids
empty

### Ethics committees

<table>
<thead>
<tr>
<th>Ethics committee</th>
<th>Name of ethics committee</th>
<th>Street address</th>
<th>City</th>
<th>Postal code</th>
<th>Approval date</th>
<th>Ethics committee reference number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tehran University of Medical Sciences</td>
<td>Sixth Floor, Central University, , Qods Street, Keshavarz Blvd, Tehran</td>
<td>Tehran</td>
<td>332/130/91/</td>
<td>2012-06-16, 1391/03/27</td>
<td></td>
</tr>
</tbody>
</table>

### Health conditions studied

<table>
<thead>
<tr>
<th>Description of health condition studied</th>
<th>ICD-10 code</th>
<th>ICD-10 code description</th>
</tr>
</thead>
<tbody>
<tr>
<td>breast feeding education</td>
<td>P92.5</td>
<td>Neonatal difficulty in feeding at breast</td>
</tr>
</tbody>
</table>

### Primary outcomes

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>breastfeeding self efficacy</td>
<td>3 month after</td>
<td>Questionnaire</td>
</tr>
</tbody>
</table>

### Secondary outcomes
empty

### Intervention groups

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>control group: usual care after delivery</td>
<td>3 month after</td>
<td>Questionnaire</td>
</tr>
</tbody>
</table>

### Recruitment centers

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>17 Shahrivar Hospital</td>
<td></td>
</tr>
</tbody>
</table>
Zahra Sohrabi  
Street address  
Madar square, Save  
City  
Save  

2  
Recruitment center  
Name of recruitment center  
Shahid Chamran Hospital  
Full name of responsible person  
Zahra Sohrabi  
Street address  
Madar square  
City  
Save  

Sponsors / Funding sources  

1  
Sponsor  
Name of organization / entity  
Tehran University of Medical Sciences  
Full name of responsible person  
Dr Unesian  
Street address  
Sixth Floor, Central University, Qods Street, Keshavarz Blvd, Tehran  
City  
Tehran  
Grant name  
Grant code / Reference number  
Is the source of funding the same sponsor organization/entity?  
Yes  
Title of funding source  
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  
Name of organization / entity  
School of Nursing and Midwifery, Tehran University of Medical Sciences  
Full name of responsible person  
Zahra Sohrabi  
Position  
Master Student of Midwifery  
Other areas of specialty/work  
Street address  
School of Nursing and Midwifery, Tohid square.  
City  
Tehran  
Postal code  
1419733171  
Phone  
+98 21 6692 7171  
Fax  
+98 66904252  
Email  
zsohrabi@razi.tums.ac.ir  
Web page address  

Person responsible for scientific inquiries  

Contact  
Name of organization / entity  
Tehran University of Medical Sciences  
Full name of responsible person  
Mandana Mir Mohammad Ali Ei  
Position  
Master of Midwifery  
Other areas of specialty/work  
Street address  
School of Nursing and Midwifery, Tohid square.  
City  
Tehran  
Postal code  
1419733171  
Phone  
+98 21 6692 7171  
Fax  
+98 66904252  
Email  
mirmohamad1@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  
Zahra Sohrabi  
Position  
Master Student of Midwifery  
Other areas of specialty/work  
Street address  
School of Nursing and Midwifery, Tohid square.  
City  
Tehran  
Postal code  
1419733171  
Phone  
+98 21 6692 7171  
Fax  
+98 66904252  
Email  
zsohrabi@razi.tums.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