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: empty
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 device 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

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

Health conditions studied

1
Description of health condition studied
breast feeding education
ICD-10 code
P92.5
ICD-10 code description
Neonatal difficulty in feeding at breast

Primary outcomes

1
Description
breastfeeding self efficacy
Timepoint
3 month after
Method of measurement
Questionnaire

2
Description
breastfeeding knowledge

Secondary outcomes
empty

Intervention groups

1
Description
Control group: usual care after delivery
Category
Behavior

2
Description
The instruction package includes a video CD and a Pamphlets that will be designed and constructed by the researcher. The instruction will be given to study examples face to face for twenty minutes by researcher. The package Content is: benefits for mother and baby, the correct method of breastfeeding, duration of breastfeeding, common problems and ways to deal with it during lactation.
Category
Behavior

Recruitment centers

1
Recruitment center
Name of recruitment center
17 Shahrivar Hospital
Full name of responsible person
1

Recruitment center

<table>
<thead>
<tr>
<th>Name of recruitment center</th>
<th>Shahid Chamran Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name of responsible person</td>
<td>Zahra Sohrabi</td>
</tr>
</tbody>
</table>

Street address

Madar square, Save

City

Save

Sponsors / Funding sources

1

Sponsor

<table>
<thead>
<tr>
<th>Name of organization/entity</th>
<th>Tehran University of Medical Sciences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name of responsible person</td>
<td>Dr Unesian</td>
</tr>
</tbody>
</table>

Street address

Sixth Floor, Central University, Qods Street, Keshavarz Blvd, Tehran

City

Tehran

Grant name

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Country of origin

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

Person responsible for general inquiries

<table>
<thead>
<tr>
<th>Name of organization/entity</th>
<th>School of Nursing and Midwifery, Tehran University of Medical Sciences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full name of responsible person</td>
<td>Zahra Sohrabi</td>
</tr>
</tbody>
</table>

Position

Master Student of Midwifery

Other areas of specialty/work

School of Nursing and Midwifery, Tohid square.

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1419733171

Phone

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Fax

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Email

zsohrabi@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

<table>
<thead>
<tr>
<th>Name of organization/entity</th>
<th>Tehran University of Medical Sciences</th>
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<td>Mandana Mir Mohammad Ali Ei</td>
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Position

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Person responsible for updating data

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+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