Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

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 Scinces
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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 divice 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/ɔ

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

Timepoint
3 month after

Method of measurement
Questionnaire

3

Description
breastfeeding practice

Timepoint
3 month after

Method of measurement
Questionnaire

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

3

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 without training. 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

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 Scienes

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 Scienes

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

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Person responsible for updating data

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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