Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of acknowledgement and self-awareness on breastfeeding

Protocol summary

Summary

A clinical trial aimed at psychosocial factors such as self-awareness and knowledge and effective communication with the medical staff and its impact on breast-feeding mothers. The inclusion criteria: nulliparous pregnant women and having at least 18 years of age who have decided to breastfeed. Not having Systemic disease during pregnancy and postpartum psychosis and not having training and experience of breastfeeding. On the first day postpartum mothers participating in the study will be discussed with the consent and demographic data will be completed by the investigator. If there is any disease in the mother's ability to breastfeed her baby, or that influenced excluded from the study. 104 mothers will be randomly divided into two groups (52 interventions and 52 controls). Random segmentation method using a permutation. Before intervention will be provided efficacy questionnaire, STAI Edinburgh and to mothers. How and number lactation, each time breastfeeding, duration of breastfeeding, use of food aid, food aid, and the use of artificial milk to those will asked to mothers at baseline and at 6, 12, 18 and 24 months by delivery telephone follow-up procedure . Interventions including education of health care personnel relation with pregnant women, providing training package for information on parenting and education of mothers in relation to maternal efficacy immediately after the delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013123010746N3**
Registration date: **2014-01-04, 1392/10/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-01-04, 1392/10/14

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source
Research Council of Tehran University of Medical Sciences

Expected recruitment start date
2014-03-20, 1392/12/29

Expected recruitment end date
2017-03-20, 1395/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of acknowledgement and self-awareness on breastfeeding

Public title
Effectiveness of acknowledgement and self-awareness on breastfeeding

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:nulliparous pregnant women at least 18 years of age who have decided to breastfeed. None of the samples was not affected by systemic diseases

during pregnancy.There is not history of postpartum psychosis and before they have not trianed breastfeeding. Not having any disease or defects in newborns and mothers having any disease that affects her ability to breastfeed. These cases will be excluded.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **104**

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 of Tehran University of Medical Sciences

Street address
Research Qods St., Keshavarz Blvd Tehran University of Medical Sciences

City
Tehran

Postal code
Iran

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
22127

Health conditions studied

1

Description of health condition studied
anxiety and depression

ICD-10 code
F32.9

ICD-10 code description
Depressive episode, unspecified

2

Description of health condition studied
Anxiety

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Increase breastfeeding

Timepoint
Baseline and at 6, 12, 18 and 24 months from delivery

Method of measurement
Breastfeeding self-efficacy questionnaire; Edinburgh Test; Test Spielberger Trait anxiety and trait STAI -

Secondary outcomes

1

Description
Increased efficacy

Timepoint
Baseline and at 6, 12, 18 and 24 months from delivery

Method of measurement
Efficacy Questionnaire

Intervention groups

1

Description
In the intervention group, including training of health care workers (nurses or midwife delivery) to communicate proper of mothers who have given birth to their baby recently. The psychologist will be made at least two group sessions. The training consisted of four 10 skills are life skills. Listed four skills associated with effective communication, stress management and anger is. With this training, it is expected that staff communicate better and more responsive with mothers. In addition they attend their mothers' demands to encourage breastfeeding. Also in relation to mothers' parenting awareness training package will be provided and it is necessary will be held individual psychological counseling sessions. In relationship self-Efficacy, mothers will reach with breastfeeding education and counseling psychology.

Category
Behavior

2

Description
In the control group, only if required to contact mothers with telephone when they have problems and we do not abandon ethically.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Prenatal clinic Imam Khomeini hospital and Milad Hospital
Full name of responsible person
Street address
Prenatal clinic Imam Khomeini hospital and Milad Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Tehran University of Medical Sciences
Full name of responsible person
Mamak Shariat
Street address
Qods St., Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Council of 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
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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