

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

###### Name

Nasrin Abedinia

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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###### Email address

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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 no history of postpartum psychosis and before they have not tried 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 properly with 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**

Research Center of Maternal-Fetal and Neonatal

**Full name of responsible person**

Nasrin Abedinia

**Position**

MSc/ Researcher

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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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*