

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of breastfeeding mothers by trained volunteers mothers to the initiation and continuation of breastfeeding in district 19 of Tehran

Protocol summary

Summary

In this clinical trial, 150 nursing mothers will be trained by peers (in terms of age, education, and financial and social status) who have been previously trained. In this study, initiation and continuation of breastfeeding of mothers will be examined throughout infancy. Intervention method: Twenty-five volunteer health assistants and trainers in Mother and Infant Centers from district 19 of Tehran, Iran (who agreed to participate in training groups) will be trained in a two-day workshop by experienced instructors and specialists in breastfeeding. Textual and electronic training media will also be provided to them. Next, these trained health assistants will form training committees consisting of volunteer peer mothers. With the cooperation of instructors from the Center for Breastfeeding Research, these health assistants will begin training the volunteer mothers such that after a one-month course, the members will be able to undertake training and advising of their peers in the district. In all stages of training, if need be, health assistants can visit or contact by telephone during predetermined times the instructors and counselors of the Center for Breastfeeding Research and refer cases needing special treatment or intervention. During the work of this group of trained health assistants, the state of affairs of the district in terms of initiation of breastfeeding, continuation of breastfeeding, and effective factors in early discontinuation of breastfeeding will be examined in 150 eligible (according with the study criteria) mothers. After formation of the training groups, they will begin their intervention in the form of training and advice under the supervision of the health assistants and members of the research center. Six months into this intervention, the state of the district will be reevaluated by examination of the 150 eligible mothers who were training during their breastfeeding term. Mothers and trained persons shall participate in this study voluntarily and live in district 19 of Tehran. Demographic data, midwifery experience, history of

received training, and infant data will be gathered using questionnaires. Data on the level of awareness and performance of the mothers concerning continuation of breastfeeding will be gathered according to the guidelines and procedure of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Study population: Two groups of mothers that have infants from 4 to 20 months of age and live in district 19 of Tehran, Iran. The first group of 150 mothers will be examined under the previously mentioned conditions prior to intervention. After a period of six months from the initiation of intervention, the second group of 150 eligible mothers will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504049568N12**
Registration date: **2015-05-16, 1394/02/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2357

Email address

mfnhrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences, research department

Expected recruitment start date
2015-03-01, 1393/12/10

Expected recruitment end date
2017-01-01, 1395/10/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of breastfeeding mothers by trained volunteers mothers to the initiation and continuation of breastfeeding in district 19 of Tehran

Public title
Effect of breastfeeding mothers by trained volunteers mothers to the initiation and continuation of breastfeeding in district 19 of Tehran

Purpose
Supportive

Inclusion/Exclusion criteria
Breastfeeding mother (4 months-24 months) will included

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

TUMS
Street address
Research department of TUMS-Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2015-03-16, 1393/12/25
Ethics committee reference number
93-04-105-27808-143712

Health conditions studied

1

Description of health condition studied
Breastfeeding continuation in breastfeed mothers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Breastfeeding continuation
Timepoint
after intervention
Method of measurement
observation and interview

Secondary outcomes

1

Description
Onset of breastfeeding
Timepoint
after intervention
Method of measurement
observation and interview

Intervention groups

1

Description
education and consultation ,in breastfeeding period -for nursing mother An education plan as a workshop,continued by elongated and continuously face to face consultation,every time is needed
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Breastfeeding Research Center

Full name of responsible person

Dr. Fatemeh Nayeri

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Departement of TUMS

Full name of responsible person

Dr. Younessian

Street address

Blvd. Keshavarz

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Departement of TUMS

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**

Breastfeeding Research Center

Full name of responsible person

Fatemeh nayeri

Position

Chief

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Full name of responsible person

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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*