

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effectiveness of the educational program based on the theory of planned behavior on donating breast milk to the milk bank in breastfeeding mothers

Protocol summary

Study aim

Determining the effectiveness of the educational program based on the theory of planned behavior on donating breast milk to the milk bank in nursing mothers

Design

A quasi-experimental study with an intervention group and a control group, not being randomized and not being blinded, on 66 breastfeeding mothers

Settings and conduct

Among all health centers affiliated to Tehran university of medical sciences Two centers that nursing mothers visit the most and have the equipment to hold in-person classes will be selected. Then we randomly chose one center for collecting intervention (33 people) and one center for control group (33 people). Nursing mothers who meet the study entry criteria and have expressed their consent will be selected by convenience sampling.

Participants/Inclusion and exclusion criteria

Mother's willingness to participate in the study; Being a resident of Tehran; Breastfeeding now; Having an infant under one year old; mother has sufficient breast milk for her own baby with the approval of a doctor or midwife; Not taking drugs or, smoking and not being addicted; Mother has no psychological or medical problem; Infant has no psychological or medical problem

Intervention groups

Intervention group will start receiving 60-minute weekly educational program based on TPB components preferably face-to-face for 4 weeks at the health center. Control group will receive only routine care and they will not receive any intervention.

Main outcome variables

knowledge, attitude, subjective norms, perceived behavioral control, behavioral intention and milk donation behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230124057203N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Fatemeh Shateranni

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of the educational program based on the theory of planned behavior on donating breast milk to the milk bank in breastfeeding mothers

Public title

Assessing the effectiveness of the educational program based on the theory of planned behavior on donating breast milk to the milk bank in breastfeeding mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mother's willingness to participate in the study
Being a resident of Tehran
Being breastfeeding mother
Having an infant under one year old
Mother's breastmilk is sufficient for her own baby with the approval of a doctor or midwife

Exclusion criteria:

taking drugs or being smoker or being addict
Mother has any kind of serious medical or psychological conditions
Infant has any kind of serious medical or psychological conditions

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not 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

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.TUMS.FNM.REC.1401.150

Health conditions studied

1

Description of health condition studied

Breast milk donation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The number of mothers who has donated their breast milk

Timepoint

Before, immediately and 3 months after intervention

Method of measurement

The researcher made questionnaire that includes 7 sections. The first part is to check the demographic information including age, education, number of pregnancies, delivery method, gender of the current child, etc. The second part includes questions related to knowledge with a four-option scale. The third part includes questions related to attitude with a five-point Likert scale, the fourth part includes questions related to subjective norms with a five-point Likert scale, the fifth part includes questions related to perceived behavioral control with a five-point Likert scale, the sixth part includes questions related to Behavioral intention with a five-point Likert scale and the seventh part of the questions related to the behavior of breast milk donation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will consist of 33 nursing mothers referring to the intervention health center, who will be selected by convenience sampling method. For the mothers of the intervention group, 4 weekly 60-minute training sessions will be held based on components of theory of planned behavior in person at the health center and if it is not possible, it would be held virtually. In order to prevent the loss of samples and increase the flexibility of the face-to-face training

program for mothers, the number of training courses will be planned as 3 courses of 11 people, and the duration of each course will be 4 weeks considering the weekly sessions.

Category

N/A

2

Description

Control group: The control group will include 33 nursing mothers referring to the control health center, who will be selected by convenience sampling method. Mothers in this group will only receive routine training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayat health center

Full name of responsible person

Dr Jamal Karimi

Street address

Behind Ghale Marghi Barracks, Mahan Street, Tehran

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2

Recruitment center

Name of recruitment center

Emam Mohammad Bagher Health Center

Full name of responsible person

Dr Ahadpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahzad Pashaeipour

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School of Nursing & Midwifery of Tehran University of Medical Sciences, Tohid sq, Nosrat st, Tehran

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http://fnm.tums.ac.ir/102053/sec_18/p_1/lang/Fa

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 Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Shateranni

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

because of confidentiality the participant's characteristics wont be shared.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available