

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison Of The Effect Of Face To Face Training And Training Package On The Attitude And Willingness Of Mothers With Premature Babies To Feed With Milk Donated From The Milk Bank

#### Protocol summary

##### Study aim

Determining the effect of face-to-face training and educational package on the attitude and willingness of mothers with premature babies to feed with donated milk

##### Design

A semi-experimental trial will be conducted in two test groups on 66 eligible mothers of premature babies hospitalized in one of the selected medical sciences hospitals of Tehran province. Sampling is done according to the available method according to the entry criteria. The samples were randomly divided into two equal experimental groups 1 and 2.

##### Settings and conduct

After obtaining permission from the ethics committee and obtaining informed consent from the parents, educational intervention on two groups will be done. Before the intervention, the demographic information questionnaire and attitude and willingness questionnaires towards milk bank are completed by the samples. For the first group, direct training will be done face to face, and for the second one, it will be done through a training package. After the training, the study questionnaires will be completed again. The data is entered in spss v20 and statistical analysis is performed.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: willingness to participate in the study; premature babies who are unable to feed with breast milk; being literated; not to have a physical or mental problem, have the cooperation in participating in training sessions The exclusion criteria: the history of using donated milk in the mother's previous babies or first and second degree relatives; religious obstacles; Any medical problem of the baby, digestive disorders, abnormal appearance

##### Intervention groups

The two experimental groups including: the face-to-face

training and educational package

##### Main outcome variables

The attitude and willingness of mothers

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230124057204N1**

Registration date: **2023-06-25, 1402/04/04**

Registration timing: **prospective**

Last update: **2023-06-25, 1402/04/04**

Update count: **0**

##### Registration date

2023-06-25, 1402/04/04

##### Registrant information

##### Name

Sahar Shahidi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3660 2208

##### Email address

s.shahidi@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-06, 1402/04/15

##### Expected recruitment end date

2023-09-06, 1402/06/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison Of The Effect Of Face To Face Training And Training Package On The Attitude And Willingness Of Mothers With Premature Babies To Feed With Milk Donated From The Milk Bank

**Public title**

Comparison Of The Effect Of Face To Face Training And Training Package On The Attitude And Willingness Of Mothers With Premature Babies To Feed With Milk Donated From The Milk Bank

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study Mothers with premature babies hospitalized in the neonatal intensive care unit who are unable to feed with breast milk Having the ability to take care of a baby and be literate Not to have a confirmed physical and mental problem and have the necessary training and cooperation in participating in training sessions

**Exclusion criteria:**

History of using donated milk in the previous babies of the mother or first and second degree relatives Any reason that prevents you from receiving donated milk, such as religious barriers Any medical problem, including the baby's digestive problems or other problems and diseases that prevent milk intake. Abnormal appearance and other problems of premature babies that affect the mother.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 66

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples were randomly assigned to two groups of face-to-face training and training package in such a way that during the first 4 to 6 sessions, all samples were sampled by the available method and face-to-face training, and the next 4 to 6 sessions were sampled by The available method and training is the use of a training package.

**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 Yazd University of Medical Sciences

**Street address**

Bahonar Square, The Central Building Of Yazd University of Medical Sciences

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2022-11-16, 1401/08/25

**Ethics committee reference number**

IR.SSU.REC.1401.079

**Health conditions studied****1****Description of health condition studied**

Attitude and willingness of mothers with premature babies to donate milk

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The attitude of mothers with premature babies towards feeding from the milk bank

**Timepoint**

Before the beginning of the educational intervention and after its completion

**Method of measurement**

A three-part researcher-made questionnaire

**2****Description**

The willingness of mothers with premature babies towards feeding from the milk bank

**Timepoint**

Before the beginning of the educational intervention and after its completion

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Direct face-to-face training will take place in the first group. Before the intervention, demographic information is obtained by completing a demographic questionnaire. The interventions include an educational program that is implemented to educate mothers with premature babies in the hospital who are unable to breastfeed. A 2-hour training session is arranged with the agreement of the mothers and in coordination with the departments, and it is implemented by the researcher after completing the milk bank workshop in the milk room located in the department. The training is face-to-face, which includes: the existence of milk banks, the benefits of using donated milk, the comparison of donated milk and formula in terms of ingredients, the disadvantages of powdered milk, prevention of infections and diseases, helping to improve physical and mental development and Encouraging mothers to use donated milk from the milk bank. After completing the training, the mother will be asked to raise any questions or doubts about feeding with donated milk, and the researcher will answer her questions.

#### Category

Other

### 2

#### Description

Intervention group: In the second group, the training content will be the same as the face-to-face group, with the difference that the training content includes video files that can be used on tablets, smart phones, and televisions, and educational booklets approved by professors will be presented to mothers. If the mothers wish, the educational video file will be sent to the authorized messenger, and to ensure that they have read the educational package before completing the questionnaires after the educational interventions, the mothers will be asked about this.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mahdieh Educational Hospital

##### Full name of responsible person

Sahar Shahidi

##### Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh

Sq, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

11858- 17311

##### Phone

+98 21 5506 2628

##### Email

mahdiyeh\_hospital@sbm.ac.ir

##### Web page address

https://mmc.sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Mr. Alireza Moradi

##### Street address

Bahonar Boulevard, the central building of Shahid Sadoughi University of Medical Sciences, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Email

yazd.ircme@ssu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yazd 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

Yazd University of Medical Sciences

##### Full name of responsible person

Sahar Shahidi

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Bouali St., Shahid Sadoughi School of Nursing and Midwifery, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3824 1751

**Email**

s.shahidi@stu.ssu.ac.ir

Sahar Shahidi

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Postal code**

8916978477

**Phone**

+98 35 3824 1751

**Email**

s.shahidi@stu.ssu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Javadi

**Position**

Vice-Chancellor of the Faculty of Nursing and Midwifery, Shahid Sadoughi University of Medical Scien

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Bouali St., Shahid Sadoughi School of Nursing and Midwifery, Yazd

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**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3824 1751

**Email**

javadinurse@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All participant data can be shared after being unidentified

**When the data will become available and for how long**

Start the access period after 6 months printing the results

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

For use in studies allowed.

**From where data/document is obtainable**

s.shahidi@stu.ssu.ac.ir

**What processes are involved for a request to access data/document**

The application will be sent to the project implementer by email and within one week will receive the necessary items.

**Comments**