

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

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

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

City

Yazd

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