Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of educating nulliparous mothers based on Precede model on mothers self-efficacy in complementary nutrition and growth index infants

Protocol summary

Study aim

Determining the effect of education of primiparous mothers based on the PRESID model on the self-efficacy of mothers in the field of complementary feeding and infant growth index.

Design

In this clinical trial with a control group, with parallel groups, a blind strain, randomized, will be conducted on 80 primiparous mothers. This study will use the block method to allocate the sample in two groups. and to generate a random sequence from http://www.graphpad.com/quickcalcs/index. cfm is used.

Settings and conduct

In the health center, the researcher will randomly divide the mothers into intervention and control groups. In the intervention group, educational intervention will be provided in 4 sessions of 60 minutes. The educational content will be taught in the form of group training of 5-7 people. The control group will receive routine health center training.

Participants/Inclusion and exclusion criteria

Mothers with four-month-old infants

Intervention groups

Intervention group: educational intervention based on the structures of the Persed model, especially predisposing structures, enabling factors and strengthening factors, will be provided in 4 sessions of 60 minutes (one session per week). Control group: they will receive only the routine training provided in health centers. The routine training in health centers is in this way that when the mother visits at the end of the fourth month, the necessary training on individual nutrition is provided to the mother.

Main outcome variables

Self-efficacy in the field of complementary nutrition, Child growth indicators

General information

Reason for update

Acronym

no

IRCT registration information

IRCT registration number: **IRCT20211211053351N3**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

sadeghi tahereh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 7313

Email address

sadeghit@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-03-12, 1402/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of educating nulliparous mothers based on Precede model on mothers self-efficacy in complementary nutrition and growth index infants

Public title
The effect of educating nulliparous mothers based on Precede model on mothers self-efficacy in complementary nutrition and growth index infants

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Complete the informed consent of parents to participate in the research Be Iranian and a resident of Mashhad Mother's age should be between 18 and 45 years. be the first delivery The age of pregnancy was between 38 and 40 The age of the infant should be between 4 and 5 months The infant does not have a history of hospitalization during infancy. Not IUGR Do not have medical and metabolic problems and FTT.

Exclusion criteria:
Not wanting to continue participating in the study. Failure to participate in more than two training sessions Medical problems occurred during the study for infants Carry out actions such as travel and change of location during the study period, which lead to non-follow-up of counseling sessions and messing up the infant's meal plan.. The infant has a history of hospitalization during the study period.

Age
From **4 months** old to **10 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block method will be used to allocate the sample in two groups.Randomization will be by block method. In this study, four blocks (AABB(1)- ABAB(2)- ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) will be the sampling guide. Then the list of blocks will be written and numbers will be assigned to them, then choosing random numbers between 1 to 6 (for example 1 4 5 and ...) using the site http://www.graphpad.com/quickcalcs/index. cfm numbers will be selected, finally specifying the treatment allocation list will be based on the previous random numbers (...AABB-BBAA-BABA-) and to generate a random sequence from http://www.graphpad.com/quickcalcs/index. cfm is used.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding (evaluator, analysts, allocation of sample data to groups) in the study child evaluator of weight, height and outcome and the health care workers who allocation of sample data to groups and also tantalizer are blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square , Mashhad, Razavi Khorasan, Iran.

City
Mashhad

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Postal code
9137913199

Approval date
2023-05-30, 1402/03/09

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.050

Health conditions studied

1

Description of health condition studied
The subject of study is not a disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mother's self-efficacy in the field of complementary feeding

Timepoint
Measuring the self-efficacy of the mother at the beginning of the study (before the start of the intervention) and at the end of the intervention three months later

Method of measurement

In this study, the meaning of self-efficacy is the feeling of competence, sufficiency, self-control and belief in abilities in the field of complementary feeding behaviors of breast-fed infants and will be investigated by a self-efficacy questionnaire.

2

Description

Infant growth index: according to head circumference, height and weight

Timepoint

Measuring the self-efficacy of the mother at the beginning of the study (before the start of the intervention) and at the end of the intervention three months later

Method of measurement

The growth indices of the normal range of height, weight and head circumference are based on the growth index of breast-fed infants under 24 months of the Ministry of Health and Medicine of Iran.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational intervention based on PERESED model structures, especially predisposing structures, enabling factors and strengthening factors will be provided during 4 sessions of 60 minutes (one session per week). The educational content will be taught in the form of group training of 5-7 people. In order to educate and gain the support of the family, an educational booklet will be prepared for the training of fathers and will be presented to the intervention group. Educational content will be provided using the teaching methods of lectures, group discussions, questions and answers, role playing, and individual counseling. Three months after the intervention, the mother will be met in health centers to evaluate and complete the questionnaire again.

Category

Lifestyle

2

Description

Control group: The control group will receive only the routine training provided in health centers. The routine training in health centers is in this way that when the mother visits at the end of the fourth month, the necessary training on individual nutrition is provided to the mother.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Street address

Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate ofFerdowsi University of Mashhad, Azadi Square , Mashhad, Razavi Khorasan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Street address

Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate o Ferdowsi University of Mashhad, Azadi Square , Mashhad, Razavi Khorasan, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School , Martyr Dr. Kharazmi Educational Building, University Campus, East Gate o Ferdowsi University of Mashhad, Azadi Square , Mashhad, Razavi Khorasan, Iran

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Person responsible for scientific inquiries

Contact

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable