

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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

##### Province

Razavi Khorasan

##### 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 of Ferdowsi University of Mashhad, Azadi Square , Mashhad, Razavi Khorasan, Iran.

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##### **Email**

tahereh.sadeghi@yahoo.com

## **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 of 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**  
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## Person responsible for scientific inquiries

### Contact

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

### Contact

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Mashhad University of Medical Sciences  
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Associate professor  
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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