# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of family-centered theory-based intervention to increase preventive behaviors iron deficiency anemia on the primary students in Torbat Heydariyeh City

## Protocol summary

**Study aim**
The effect of theory-based family-based educational intervention on promoting mothers' preventive behaviors of maternal iron deficiency anemia

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 300 patients. PASS software was used for randomization.

**Settings and conduct**
The study population is the mothers of families living in Torbat-e Heydarieh. The researcher first studies valid scientific books and articles and collects the necessary information related to the research topic. According to the respected professors, the researcher of a preliminary study to examine the cognitive and behavioral status of mothers, will be performed on mothers in the city of Torbat Heydariyeh who represent the real community.

**Participants/Inclusion and exclusion criteria**
The condition for entering the participants' research is knowledge of the research objectives, satisfaction with participation, as well as having a first-year girl in primary school and an average age of 23 to 35 years.

**Intervention groups**
Educational intervention group: A group of mothers with the first daughter of the primary school is studied. An 8-member educational class is held in 9 different groups with group discussion and brainstorming to improve the intervention mapping approach. Control group: There is a group of selected mothers from families living in Torbat-e Heydarieh city who are included in the study as mothers with first graders, but no educational intervention will be performed on them and as a control group to compare with the intervention group. , Will be examined.

**Main outcome variables**
The rate of improvement of iron deficiency anemia prevention behaviors of first grade female students in Torbat-e Heydarieh is determined and compared by mothers before and six months after the intervention.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160824029512N2**
Registration date: **2022-04-05, 1401/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-05, 1401/01/16**
Update count: **0**

**Registration date**
2022-04-05, 1401/01/16

**Registrant information**

**Name**
mohammad hossien delshad

**Name of organization / entity**
Torbat Heydariyeh University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-11-14, 1400/08/23

**Expected recruitment end date**
2022-04-12, 1401/01/23

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of family-centered theory-based intervention to increase preventive behaviors iron deficiency anemia on the primary students in Torbat Heydariyeh City

**Public title**

Family-centered educational intervention on iron deficiency anemia prevention behaviors

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Knowledge of research objectives, satisfaction with participation, having a first year girl in primary school, having 23 to 35 years of age in mothers

**Exclusion criteria:**

Dissatisfaction to participate in research Incomplete completion of questionnaires

**Age**

From **23 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **300**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method and descriptions of each method: Layered randomization method with random assignment to intervention and control groups, followed by simple random sampling method with proportional assignment in each of the clusters of participants (mothers of first-year female students elementary School) Randomization unit: Cluster Randomization layers: First, all mothers of families with the first elementary school daughter of the study are classified among the invited participants in the study into subgroups with the same characteristics or characteristics, which are known as classes. From the classification groups, simple random sampling is performed, in which each element in the same subgroup is neutrally selected. During each stage of the sampling process, randomly and completely randomly. Randomization tools: are selected with PASS statistical software randomization tools. How to make a random sequence: To create a random sequence in the experiments of the two groups, one of the study groups is considered a lion and the other group is considered a line. They find it by accident. Explanation of concealment: It is a double-blind randomization.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Mothers with a first-year girl in primary school with an average age of 23 to 35 years because they are the booklet of the control group or the intervention is blinded and do not know and also the researcher does not know about the intervention and control group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Data collection is done in the form of a questionnaire that was interviewed by the researcher from mothers. It is a theory-based planning framework that evaluates and intervenes in health-related issues through an ecological approach. Intervention mapping to make the necessary changes at different ecological levels focuses on how to change the behavior of people at risk and environmental factors to make behavioral changes that lead to changes in health and quality of life

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Torbat Heydariyeh Medical Sciences

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Torbat Heydariyeh, North Ferdowsi St., Razi Razi 2, No. 14, 2nd floor

**City**

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**Province**

Razavi Khorasan

**Postal code**

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**Approval date**

2021-09-26, 1400/07/04

**Ethics committee reference number**

IR.THUMS.REC.1400.024

## Health conditions studied

### 1

**Description of health condition studied**

Anemia

**ICD-10 code**

D50

**ICD-10 code description**

Iron deficiency anemia

## Primary outcomes

### 1

**Description**

Primary outcome: Percentage of behaviors to prevent

anemia in first grade female students of Torbat-e Heydarieh by mothers ", score of blood iron level test of first-year primary school girls" and "Percentage of regular physical activity by first grade female students in Torbat-e Heydarieh" Be. Definition of the percentage of preventive behavior: Performing the predicted health behavior means performing a health task continuously and consecutively for at least 6 months, after which the person can perform the health task without any problems. Definition of Blood Iron Levels: The amount of iron in a person's serum or blood. Definition of physical activity: Any activity or movement of the body that is caused by the contraction and expansion of skeletal muscles and requires energy is called physical activity. The use of iron tablets during pregnancy in mothers means the complete use of iron tablets during pregnancy and also other consequences include attitude score, studying the attitude to the concept of a person's belief about the desirability or undesirable behaviors to prevent anemia in female students in the class It is the first to be assessed based on existing and related questions in the study tool. Awareness of preventive behaviors and mothers' behavior. The mothers' knowledge about preventive behaviors of students' anemia, which will be measured based on their answers to the relevant questions in the questionnaire.

**Timepoint**

Before, after and 6 months after intervention

**Method of measurement**

Self-reported questionnaire,Tools to prevent pediatric anemia behaviors according tointervention mapping protocol.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Educational intervention group: A group of mothers with the first daughter of the primary school is studied. An 8-member educational class is held in 9 different groups with group discussion and brainstorming to improve the intervention mapping approach.

**Category**

Behavior

### 2

**Description**

Control group: There is a group of selected mothers from families living in Torbat-e Heydarieh city who are included in the study as mothers with first graders, but no educational intervention will be performed on them and as a control group to compare with the intervention group. , Will be examined.

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Torbat Heydariyeh University of Medical Sciences

**Full name of responsible person**

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## Sponsors / Funding sources

### 1

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**Full name of responsible person**

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**Web page address**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Torbate-Heidaria 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**
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Torbate-Heidaria University of Medical Sciences
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
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**When the data will become available and for how long**
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**From where data/document is obtainable**

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

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**Comments**

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