

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 51 5222 1508

Email address

h.delshad@modares.ac.ir

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
Street address
Torbat Heydariyeh, North Ferdowsi St., Razi Razi 2, No. 14, 2nd floor
City
Torbat Heydariyeh Medical Sciences
Province
Razavi Khorasan
Postal code
9519633885
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 Heydariyeh 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 Heydariyeh" 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 to intervention 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 Heydariyeh 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

Mohammad Hossien Delshad

Street address

North Ferdowsi ,Razi ,Razi 2, No. 14, 2nd floor

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9519633885

Phone

+98 51 5222 1508

Email

delshad264@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohammad Ahmadi Soleimani

Street address

Torbat Heydariyeh razi razi1

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9519633787

Phone

+98 51 5228 6065

Email

ahmadim1@thums.ac.ir

Web page address

<https://edu-res.thums.ac.ir/%D9%BE%DA%98%D9%88%D9%87%D8%B4>

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****Name of organization / entity**

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad Hossien Delshad

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Health Promotion

Street address

North Ferdowsi Razi Razi 2, No. 14, 2nd floor

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9519633885

Phone

+98 51 5222 1508

Email

delshadmh1@thums.ac.ir

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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad hossien Delshad

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Health Promotion

Street address

Ferdowsi St. Razi Razi St. 2, No. 14, 2nd Floor

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9519633885

Phone

+98 51 5222 1508

Fax

+98 51 5222 1508

Email

h.delshad@modares.ac.ir

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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad hossien Delshad

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

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Phone

+98 51 5222 1508

Fax

+98 51 5222 1508

Email

h.delshad@modares.ac.ir

Web page address

<http://delshad264.blogfa.com/>

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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To whom data/document is available

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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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