

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of educational intervention on the health literacy of secondary school girls in Fouladshahr in the field of iron deficiency anemia

Protocol summary

Study aim

Determining the effect of educational intervention on the health literacy of female high school students in Fouladshahr in the field of iron deficiency anemia

Design

Clinical trial with intervention and control group (60 people in each group), unblinded, randomized by lottery method

Settings and conduct

Clinical trial with intervention and control group (60 people in each group), unblinded, randomized by lottery method

Participants/Inclusion and exclusion criteria

Female high school students living in Mehr Fouladshahr Maskan District who meet the following conditions: 1) 15 to 18 years old age group 2) Registration in second secondary schools in Mehr Fouladshahr Housing District 3) Informed and written consent of the student and one of the parents They are to participate in the study

Intervention groups

After selecting the samples, the researcher collects information about the intervention and control groups using a questionnaire. After analyzing the data, designing an educational program according to the interests of the students, analyzing the primary data, the conditions of the school and the opinion of the research team, and this will be decided during the research. In the next stage, the intervention group will be given the necessary training regarding health literacy and iron deficiency anemia. During this period, the control group does not receive any training. After the end of the educational intervention, according to the recommendation of scientific sources, the students will be given the opportunity to use the necessary training for one month, and after this time interval, we will provide the questionnaire to the same people again. to complete again. Finally, after two months of the educational intervention, the questionnaire will be given to the same people to complete the questionnaire.

Main outcome variables

Health literacy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220925056037N1**

Registration date: **2023-04-08, 1402/01/19**

Registration timing: **prospective**

Last update: **2023-04-08, 1402/01/19**

Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name

Sahar Saeedi

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

Phone

+98 31 5236 1363

Email address

sahar.saeedi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-14, 1402/01/25

Expected recruitment end date

2023-07-16, 1402/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of educational intervention on the health literacy of secondary school girls in Fouladshahr in the field of iron deficiency anemia

Public title
The effect of educational intervention on the health literacy of secondary school girls in the field of iron deficiency anemia

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Registering in second secondary schools of Fouladshahr
Mehr Housing District Age group of 15 to 18 years
Informed and written consent of the student and one of their parents to participate in the study
Exclusion criteria:

Age
From **15 years** old to **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
After receiving the letter of recommendation from Tarbiat Modares University and obtaining a permit from the Vice-Chancellor of Health of Isfahan University of Medical Sciences, as well as with the coordination of the Fouladshahr Education Department, we will select the two schools of Resalat and Parvin Etisami, which are the only secondary schools in Mehr Fouladshahr housing area. And we randomly consider one of the schools as the intervention group (Parvin Etisami School) and one as the control group (Resalat School). Then, we randomly select 60 students from each of the schools (lottery method) as the sample size of each of the intervention and control groups.

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

Tarbiat Modares University (Research Ethics Committee)

Street address

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Hamad and Chamran intersection, Tehran

City

Tehran

Province

Tehran

Postal code

14115-331

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.MODARES.REC.1401.182

Health conditions studied

1

Description of health condition studied

health literacy

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50

ICD-10 code description

Iron deficiency anemia

Primary outcomes

1

Description

The health literacy score in the researcher-made questionnaire

Timepoint

before the start of the study, one month and two months after the intervention

Method of measurement

researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After receiving a letter of introduction from Tarbiat Modares University and obtaining a permit from the Vice-Chancellor of Health of Isfahan University of Medical Sciences and also with the coordination of Fouladshahr Education Department, 60 students of Parvin Etsami School (2nd secondary) who meet the study entry criteria We choose them randomly. After selecting the samples, the researcher introduces himself and the objectives of the research to the students and provides the necessary explanations about answering the questions, collects information using a questionnaire and collects them after completing the questionnaire. After analyzing the data, a suitable training program will be prepared by the researcher and according to the opinion of the research team. It should be noted that in the design and manner of holding educational sessions, students' interests, primary data analysis, the conditions of the school and respected teachers, and the opinion of the research team are considered, and this will be decided during the research. In the next stage, the intervention group will be given the necessary training regarding health literacy and iron deficiency anemia. After the end of the educational intervention, according to the recommendation of scientific sources, the students will be given the opportunity to use the necessary training for one month, and after this time interval, we will provide the questionnaire to the same people again. to complete again. Finally, after two months of the educational intervention, the questionnaire will be given to the same people to complete the questionnaire.

Category

Other

2

Description

Control group: After receiving a letter of introduction from Tarbiat Modares University and obtaining a permit from the Vice-Chancellor of Health of Isfahan University of Medical Sciences, as well as with the coordination of Fouladshahr Department of Education, 60 students of Resalat School (Second Secondary Section) who meet the entry criteria for our study are randomly selected. After selecting the samples, the researcher provides the necessary explanations regarding answering the questions for the students and collects them after completing the questionnaire. But in the future, we do not conduct any educational intervention for the control group, and finally, once after one month of the educational intervention we did for the intervention group, we give the questionnaires to the control group and again after two months. From the educational intervention of the intervention group, we give the questionnaires to the control group. It should be mentioned that the control group does not receive any intervention and only completes the questionnaires in certain time intervals.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Parvin E'tesami school

Full name of responsible person

Bitra Sepahi

Street address

No. 52, Narges Alley, Valiasr Street, Janbazan Blvd

City

Varnamkhast

Province

Isfahan

Postal code

8473158386

Phone

+98 937 005 3835

Fax

Email

sahar98saeedi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Seyed Gholamreza Mousavi

Street address

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Hamad and Chamran intersection, Tehran

City

Tehran

Province

Tehran

Postal code

33114115.

Phone

+98 21 8288 3827

Email

moussavi@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Shamsuddin Niknami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Hamad and Chamran intersection, Tehran

City

Tehran

Province

Tehran

Postal code

14115-331

Phone

+98 21 8288 3549

Email

sahar98saeedi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shamsuddin Niknami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Hamad and Chamran intersection, Tehran

City

Tehran

Province

Tehran

Postal code

14115-331

Phone

+98 21 8288 3549

Email

sahar98saeedi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

Sahar Saeedi varnamkhasti

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

No. 52, Narges Alley, Vali Asr St., Shariati St.

City

Varnamkhast

Province

Isfahan

Postal code

8473158386

Phone

+98 31 5236 1363

Fax

Email

sahar98saeedi@gmail.com

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

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

Clinical Study Report

Yes - There is 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

This study is a thesis and its results will be published in the thesis and articles.

When the data will become available and for how long

This study is a thesis and its results are published in the thesis and articles.

To whom data/document is available

Apart from the personal and confidential information of the participants, which only the researcher has access to, other information is published in articles and theses. In addition, people working in academic and scientific institutions can access the information by submitting a letter of introduction and coordinating with the responsible author of the article.

Under which criteria data/document could be used

This study is a thesis and definitive decisions in this field will be published in the future. In general, people who intend to use the results of this research in their studies should refer to our article or study as a source. Also, at each stage, check the necessary arrangements and more detailed instructions with the responsible author or other authors.

From where data/document is obtainable

To receive information, refer to the email address of the

responsible author or other authors of the article.

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

After sending a letter of introduction from the relevant institution to the email address of the responsible author of the article or the thesis supervisor (if she/he is not available, send an email to other authors), she/he will make the necessary arrangements with them.

Comments