

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of scheduled program based on the theory of planned behavior on the level of Iron deficiency anemia in pregnant women

Protocol summary

Study aim

determining the effect of planned program based on the theory of planned behavior on iron deficiency anemia of pregnant women

Design

This study is an intervention study of randomized clinical trial After approving the proposal and obtaining a license from the Research Ethics Committee of Tarbiat Modares University, the researcher received a letter of introduction from the faculty and presented it to the relevant officials of the health network in the city. And by obtaining their consent, they will take a sample. The research population includes all pregnant women with iron deficiency anemia who refer to health centers in the city of Khoy in the province of West Azerbaijan. Sampling is clustered and random. Written consent is obtained from all research samples to participate in the study. By referring to the centers, 200 pregnant women with iron deficiency anemia will be selected first by simple random sampling method. They are then assigned to the study group and control group for random allocation by 4-block block randomization. Using statistical methods, groups should be homogeneous in terms of demographic characteristics and pregnancy status. Pregnant women who apply for maternity care will be considered as a sample if they have the entry and desire details to participate in the study and complete the written written consent form. Finally, the samples are randomly assigned to two intervention and control groups.

Settings and conduct

Khoy Health Centers, which includes 10 centers located in Khoy and is covered by Khoy University of Medical Sciences.

Participants/Inclusion and exclusion criteria

pregnant women

Intervention groups

The interventions will be designed as 4 training sessions, each lasting 45 to 55 minutes over 4 weeks. control group will receive routine care.

Main outcome variables

Iron deficiency anemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170218032635N1**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **retrospective**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

Afsaneh Sadooghiasl

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4875

Email address

asadooghi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of scheduled program based on the theory of planned behavior on the level of Iron deficiency anemia in pregnant women

Public title
scheduled program based on the theory of planned behavior on the level of Iron deficiency anemia in pregnant women

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 3 to 6 months of pregnancy Definite diagnosis of Iron deficiency anemia Minimum literacy and ability to read and understand educational material No evidence of chronic disease
Exclusion criteria:
 Absolute illiteracy Using antidepressants and Psychedelic medicine problem in communicating Lack of fluency in Persian

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization unit in this study is the Patient Referral Center, which is assigned to groups using a coin toss.

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither participants nor data analyst know the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University

Street address

Chamran highway-Jalal al ahmed-

City

Teharn

Province

Tehran

Postal code

14115-331

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.MODARES.REC.1398.031

Health conditions studied

1

Description of health condition studied

Iron Deficiency Anemia

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anemia, unspecified

Primary outcomes

1

Description

Iron deficiency Anemia

Timepoint

before intervention- 3 months later

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Interventions will be designed as 4 training sessions each for 45 to 55 minutes over 4 weeks. Behavioral goals will be determined for each training session and we will strive to achieve these goals using various methods such as lecture, instructional videos, Q&A, group discussion and individual counseling. Two sessions to raise awareness, one session to change the attitudes of pregnant women towards anemia prevention and treatment and their positive evaluation of iron deficiency diet, and a last session on behavioral control of pregnant women and their intention to choose the best method. Health care (iron pills or diet change) will take place.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care center of Khoy, Urmia

Full name of responsible person

mansour mahmoodzadeh

Street address

resalat bulvard

City

Khoy

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

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Email

elnazzamanlu456@gmail.com

Web page address

<https://khoy.umsu.ac.ir/index.aspx?fkeyid=&siteid=42&pageid=5072>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Mohammad Javan

Street address

chamran high way- jalal al ahmed

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edu@modares.ac.ir

Web page address

<https://www.modares.ac.ir/med>

Grant name

Grant code / Reference number

79706

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

Elnaz Zamanlu

Position

MSc student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Afsaneh Sadooghiasl

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Yes - There is 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

Not applicable

Title and more details about the data/document

The data will be released in groups without identification code.

When the data will become available and for how long

After the journal's decision to accept and publish the results in paper form is finalized

To whom data/document is available

Editors of scientific journals

Under which criteria data/document could be used

No new analysis of the data is permitted and can only be used to inform or verify the quality and scientific accuracy of the study

From where data/document is obtainable

Afsaneh Sadooghiasl

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

After receiving a request from the editor in chief, a meeting will decide which piece of information they can publish and will be e-mailed or faxed after deleting any identifying code

Comments