Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intervention based on health belief model on dietary behavior promotion among pregnant women with iron deficiency anemia attending to health center

Protocol summary

Summary

This study aimed to determine the effect of intervention based on health belief model on nutritional behaviors anemic pregnant women that referred to health centers in Orumieh, 1395. The statistical population were 90 pregnant women with iron deficiency anemia diagnosed based on having HB<11 mg/dl in the first pregnancy care (6-10 gestational weeks). In this study, six health centers were selected based on the three level division (level 1, 2 and 3) of the Deputy of Health and in each level, 30 available people attended two centers in that level were randomly selected according to inclusion and exclusion criteria. In each level, people were randomly assigned to the intervention and control groups using sealed envelopes. After completing a researcher-made questionnaire based on the Health Belief Model by the intervention group on anemia and nutrition during pregnancy, the educational and counseling sessions for the intervention group were held through 4 sessions of 60-90 minutes (one session every week) and the control group will receive routine care. Inclusion criteria included age between 18-35 years; nonspecific underlying disease; iron deficiency anemia; normal BMI. Exclusion criteria included high risk pregnancy. Two months after the ending of intervention in both groups, questionnaires will be completed in the presence of researcher and changes of hemoglobin, knowledge, nutritional behavior and structures pattern will be analyzed between and within the two intervention and control groups before and after consultation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121824340N10**
Registration date: **2017-08-25, 1396/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-25, 1396/06/03

Registrant information

Name
Hamideh Mohaddesi
Name of organization / entity
Urmia University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Orumieh University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intervention based on health belief model on dietary behavior promotion among pregnant women

with iron deficiency anemia attending to health center

Public title
The impact of counseling on dietary behaviors among anemic pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria : aged between 35-18 years; no specific underlying disease :chronic renal failure and infection of HI, parasitic infections, malaria, schistosomiasis and hookworm infections; iron deficiency anemia :Hemoglobin less than 11 mg per deciliter and willingness to enter the study; ability to read and write; experiencing last pregnancy less than last three years. Exclusion criteria: Pre-eclampsia and eclampsia; gestational diabetes; preterm delivery; hyperemesis gravidarom; high and low BMI below 18.5 and over 25.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
After selecting the people of each center based on the criteria of entry and exit , randomly using a packet in a blind and blind envelope, the control group will be 30 and the intervention group will be 30 people.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
(postal code:571478334), Urmia University of Medical Sciences, Orghance Street, Resalat blvd, Urmia
City
Urmia
Postal code
5714783734
Approval date
2016-08-19, 1395/05/29
Ethics committee reference number
IR.UMSU.REC.13950218

Health conditions studied

1

Description of health condition studied
anemia
ICD-10 code
Nutritiona
ICD-10 code description
D50.9 Iron deficiency anaemia, unspecified

Primary outcomes

1

Description
Dietary behavior
Timepoint
Pretest (Before intervention) and post test (Two months after intervention)
Method of measurement
Questionnaire created based on Health Belief Model

2

Description
Knowledge
Timepoint
Pretest (Before intervention) and post test (Two months after intervention)
Method of measurement
Questionnaire created based on Health Belief Model

3

Description
Perceived susceptibility
Timepoint
Pretest (Before intervention) and post test (Two months after intervention)
Method of measurement
Questionnaire created based on Health Belief Model

4

Description
Perceived severity
Timepoint
Pretest (Before intervention) and post test (Two months after intervention)
Method of measurement
Questionnaire created based on Health Belief Model

5

Description

Perceived benefits

Timepoint

Pretest (Before intervention) and post test (Two months after intervention)

Method of measurement

Questionnaire created based on Health Belief Model

6

Description

Perceived barriers

Timepoint

Pretest (Before intervention) and post test (Two months after intervention)

Method of measurement

Questionnaire created based on Health Belief Model

7

Description

Cues to action

Timepoint

Pretest (Before intervention) and post test (Two months after intervention)

Method of measurement

Questionnaire created based on Health Belief Model

8

Description

Self efficacy

Timepoint

Pretest (Before intervention) and post test (Two months after intervention)

Method of measurement

Questionnaire created based on Health Belief Model

Secondary outcomes

1

Description

Hemoglobin

Timepoint

One month after iron therapy and 26th-30th week of pregnancy

Method of measurement

Health records

Intervention groups

1

Description

Intervention group: After completing a researcher-made questionnaire based on the Health Belief Model by the intervention group on anemia and nutrition during pregnancy, the educational and counseling sessions for the intervention group were held through 4 sessions of 60-90 minutes (one session every week) and these educational contents were given to the patients via lecture, Group discussion, question and answer as well as individual nutrition counseling according to the health belief model and according to the country's guidelines.

Category

Prevention

2

Description

Control group: After completing a researcher-made questionnaire based on the health belief model, the control group did not undergo any educational interventions on anemia and nutrition during pregnancy. The control group received only routine health care from their care providers.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Alborz street, Urmia

City

Urmia

2

Recruitment center

Name of recruitment center

Behdari Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Behdari street, Urmia

City

Urmia

3

Recruitment center

Name of recruitment center

Dizaje siavash Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Marefat alley,Shora street, Urmia

City

Urmia

4

Recruitment center

Name of recruitment center

17 Shahrivar Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Shahid Ebrahimi alley, 17 Shahrivar street, Urmia

City

Urmia

5

Recruitment center

Name of recruitment center

SHohada Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Babasaei street, Urmia

City

Urmia

6

Recruitment center

Name of recruitment center

Nikkhah Health Center

Full name of responsible person

Hamideh Mohaddesi

Street address

Rajaii street, Urmia

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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Urmia University of Medical Sciences ,Orjhans Street ,Resalat Boulevard

City

Urmia

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Urmia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia University Of Medical Sciences

Full name of responsible person

Hamideh Mohaddesi

Position

Assistant Professor, Nursing and Midwifery Department

Other areas of specialty/work

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Hamideh Mohaddesi

Position

Assistance professor, Nursing and Midwifery department

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty