

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Survey of the Effect of Nutrition Education Based on Health Belief Model on Nutritional Behavior In Afghan Immigrant's Pregnant Women

Protocol summary

Study aim

Determining the impact of nutrition education based on the health belief model on the nutritional behavior of Afghan immigrant pregnant women

Design

It will be a non-randomized clinical trial with a pre-test and post-test design. Two centers were selected from the number 2 health centers of Mashhad city and one of the centers will be randomly assigned as the intervention group and the other center will be assigned to the control group. In each center, there are 58 women who meet the entry criteria based on the list available in the selection centers and finally 116 Afghan pregnant women are included in the study. The intervention group will receive 4 nutrition training sessions based on the health belief model with an interval of one week. Nutritional behavior questionnaires, made by the researcher based on the structures of the HBM model and a 24-hour food reminder checklist, will be completed immediately and one month after the intervention. They will receive a training booklet.

Settings and conduct

Health Center No. 2 of Mashhad((Considering that most of the Afghan immigrant population of this city lives in the areas covered by this center)

Participants/Inclusion and exclusion criteria

Afghan immigrant pregnant women 6-20 weeks with informed consent and with entry criteria and exit criteria: unwillingness to continue the research, absence from more than one training session and occurrence of severe emotional or mental problems during the research

Intervention groups

The intervention group includes 58 pregnant Afghan immigrant women who will receive 4 sessions of nutrition education based on the health belief model during a period of one month. The control group, consisting of 58 pregnant Afghan immigrant women, will not receive this intervention.

Main outcome variables

Nutritional behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220629055312N1**

Registration date: **2022-07-25, 1401/05/03**

Registration timing: **prospective**

Last update: **2022-07-25, 1401/05/03**

Update count: **0**

Registration date

2022-07-25, 1401/05/03

Registrant information

Name

Somaye Riazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3341 9333

Email address

riazis992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-11, 1401/05/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Ethics committee
Survey of the Effect of Nutrition Education Based on Health Belief Model on Nutritional Behavior In Afghan Immigrant's Pregnant Women	Name of ethics committee Ethics Committee of Nursing and Midwifery Faculty of Mashhad University of Medical Sciences
Public title	Street address Nursing and Midwifery Faculty, Ibne Sina Ave, Doctora intersection, Daneshgah Ave
Survey of The Effect of Nutrition Education on Afghan Immigrants Pregnant Women	City Mashhad
Purpose	Province Razavi Khorasan
Education/Guidance	Postal code 9137913199
Inclusion/Exclusion criteria	Approval date 2022-07-05, 1401/04/14
Inclusion criteria: Conscious consent of the mother Being Afghan Gestational age 6-20 weeks based on first trimester ultrasound normal pregnant women with single pregnancy No unwanted pregnancy age above 18 years Having a minimum literacy rate(the ability of reading and writing) having a phone number No simultaneous participation in other research No affecting by disease requires intervention in the mother or fetus No affecting by chronic systemic disease No following a specific diet during the intervention Absence of severe emotional and mental problems in the mother No addiction to cigarettes and drugs Lack of education and health-related jobs	Ethics committee reference number IR.MUMS.NURSE.REC.1401.031
Exclusion criteria: Unwillingness to continue cooperation in research Failure to attend more than one training session Failure to answer more than 10% of the questions in the questionnaire Occurrence of severe emotional and mental problems during research (such as separation from a spouse or loss of a family member)	Health conditions studied
Age From 18 years old	1
Gender Female	Description of health condition studied Supervision of normal pregnancy
Phase N/A	ICD-10 code Z34.9
Groups that have been masked <i>No information</i>	ICD-10 code description Supervision of normal pregnancy, unspecified
Sample size Target sample size: 116	Primary outcomes
Randomization (investigator's opinion) Not randomized	1
Randomization description	Description Changes in Nutritional Behavior Score and Scores of health belief model constructs
Blinding (investigator's opinion) Not blinded	Timepoint Immediately and one month after the intervention
Blinding description	Method of measurement Nutritional Behavior Questionnaires in Low-Income Populations, Standard Form of 24-Hour Food Intake and Research Questionnaire Based on Health Belief Theory Structures
Placebo Not used	Secondary outcomes
Assignment Parallel	1
Other design features	Description Micronutrients and macronutrients intake
Secondary Ids	Timepoint Before the start of the intervention, immediately and one month after the intervention
empty	Method of measurement Standard recall 24 (Standard 24-hour feed reminder) form
Ethics committees	Intervention groups

1

Description

Intervention group: Teaching nutritional behaviors based on the Health Belief Model in 4 sessions of 45 minutes in groups of 8-12 people including the first session on the general principles of nutrition and proper nutritional behavior and its importance, the second session on perceived sensitivity and intensity, the third session of barriers and benefits of perception And the fourth session of self-efficacy and guidelines for act. This group will also receive routine pregnancy care.

Category

Lifestyle

2

Description

Control group: Receiving routine pregnancy care and not participating in nutrition education sessions based on the health belief model

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 2 of Mashhad

Full name of responsible person

Dr Hamidraza Ghorbanzadeh

Street address

Rezayieh, Vahdat Ave

City

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Province

Razavi Khorasan

Postal code

9153913153

Phone

+98 51 3365 3000

Email

ghorbanzadehhr1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayour

Street address

Ghoreshi building, next to Hoveyze Cinema,
Daneshgah Ave

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Province

Razavi Khorasan

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9138813944

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+98 51 3841 1538

Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Kobra Mirzakhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Nursing and Midwifery Faculty, Ibne Sina Ave, Doctora
intersection, Daneshgah Ave

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9137913199

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Email

MirzakhaniK@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Kobra Mirzakhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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

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

Potential data can be shared after de-identifying individuals.

When the data will become available and for how long

Access starts one month after publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data is sent by official request through academic or organizational e-mail of the researchers after confirming and identifying the identity of the sender.

From where data/document is obtainable

Dr. Kobra Mirzakhani MirzakhaniK@mums.ac.ir

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

The data is sent by official request through academic or organizational e-mail of the researchers after confirming and identifying the identity of the sender.

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Kobra Mirzakhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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