Clinical Trial Protocol
Iranian Registry of Clinical Trials

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

Public title
Survey of The Effect of Nutrition Education on Afghan Immigrants Pregnant Women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
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
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)
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Ethics Committee of Nursing and Midwifery Faculty of Mashhad University of Medical Sciences
Street address
Nursing and Midwifery Faculty, Ibne Sina Ave, Doctora intersection, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.MUMS.NURSE.REC.1401.031

Health conditions studied

1

Description of health condition studied
Supervision of normal pregnancy
ICD-10 code
Z34.9
ICD-10 code description
Supervision of normal pregnancy, unspecified

Primary outcomes

1

Description
Changes in Nutritional Behavior Score and Scores of health belief model constructs
Timepoint
Immediately and one month after the intervention
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

Secondary outcomes

1

Description
Micronutrients and macronutrients intake
Timepoint
Before the start of the intervention, immediately and one month after the intervention
Method of measurement
Standard recall 24 (Standard 24-hour feed reminder) form

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
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۵۳۹۱۳۱۵۳

Phone
+98 51 3365 3000

Email
ghorbanzadehhr۱@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

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+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

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

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
Street address
Nursing and Midwifery Faculty, Ibne Sina Ave, Doktora intersection, Daneshghah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
MirzakhaniK@mums.ac.ir

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
Street address
Nursing and Midwifery Faculty, Ibne Sina Ave, Doctora intersection, Daneshghah Ave
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Email
MirzakhaniK@mums.ac.ir

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