Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of education intervention based on health belief model on knowledge ,belief and performance of weight management of women with high body mass index in the before pregnancy period in patients referred to comprehensive health centers in Bokan

Protocol summary

Study aim

Determining the effect of educational intervention based on health belief model on knowledge ,belief and performance of weight management of women with high body mass index in the before pregnancy period in Bukan city

Design

The clinical trial has an experimental group and a control group that will be performed with the participation of 68 people by random sampling. Randomization will be based on even and odd numbers.

Settings and conduct

The study will be conducted at Bukan Comprehensive Health Service Centers. Participants in this study are women of Reproductive age who want to become pregnant. First, Bukan city in terms of socio-economic status will be divided into three parts : upper, middle and lower. Then, in each level, two centers will randomly selec (even number for the experimental group and odd for the control group).

Participants/Inclusion and exclusion criteria

*Inclusion criteria: Indigenous regional Having written consent Have a fifth grade and higher literacy Having a smartphone and whats app messenger Body mass index above 25 No chronic diseases No stressful events in the last six months in the individual or family *No entry conditions: Pregnancy Illiteracy Over 50 years old Having physical activity related diseases such as cardiovascular disease Having weight management activities

Intervention groups

Holding 4 training classes on pre-pregnancy weight management based on the Health Belief Model via WhatsApp Messenger in the intervention group Delivery of the training booklet to the control group after the end of the intervention

Main outcome variables

BMI Awareness Attitude Function Health Belief Model Structures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210824052278N1**
Registration date: **2021-10-23, 1400/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-23, 1400/08/01**
Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Zhila Rashidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3623 3327

Email address

rashidi.zhila81@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-24, 1400/06/02

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

2021-09-10, 1400/06/19

Actual recruitment end date

2022-09-10, 1401/06/19

Trial completion date

2022-09-10, 1401/06/19

Scientific title

Evaluation of the effect of education intervention based on health belief model on knowledge ,belief and performance of weight management of women with high body mass index in the before pregnancy period in patients referred to comprehensive health centers in Bokan

Public title

The effect of education based on health belief model on knowledge ,belief and performance of weight management of women with high body mass index in the before pregnancy period .

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Indigenous Having written consent Have a fifth grade and higher literacy Having a smartphone and whats app messenger Body mass index above 25 kg per cubic meter No chronic diseases No stressful events in the last six months in the individual or family

Exclusion criteria:

Pregnancy Illiteracy Over 50 years old Having physical activity related diseases such as cardiovascular disease Having weight management activities

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Before sampling, comprehensive urban health service centers will be classified into three levels: high, medium and low based on social and economic status. The sampling method will be multi-step. First, based on socio-economic levels, two health centers will be selected from each level. One center for the experimental group and one center for the control group will be randomly selected. Randomization is based on even and odd numbers and through lotteries. The even number is considered for the experimental group and the odd number is considered for the control group. We will have a total of 6 centers. Then, in each of the centers, 11 women who refer to the Comprehensive Health Service Center, who are in the pre-pregnancy stage and have the criteria to enter the intervention, will be available. 12 people will be selected in two centers. A total of 68 people (34 in the control group and 34 in the experimental group) will be included in the study based on the inclusion criteria.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, the control group was kept blind from receiving educational intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of urmia university of Medical sciences

Street address

no.36,Shafaet Alley ,Shohada street

City

saqqez

Province

Kurdistan

Postal code

6681718568

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.UMSU.REC.1400.199

Health conditions studied

1

Description of health condition studied

Obesity and overweight in women in the before pregnancy stage

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

Description

Weight management in women with higher-than-normal pre-pregnancy body mass index

Timepoint

One month and three months after the intervention

Method of measurement

Using a researcher-made questionnaire based on health belief model and three-factor eating questionnaire and short form physical activity questionnaire

Secondary outcomes

1

Description
Weight Loss
Timepoint
Three months after the intervention
Method of measurement
Weight measurement with accurate and controlled scales with control weights

Intervention groups

1

Description
In the intervention group, 4 training sessions will be held in groups of 6-7 people once a week. The duration of the sessions will be 90-60 minutes. Educational content will be prepared based on credible sources based on needs assessment of the subjects.The trainings will be provided online once a week at a pre-determined time in the form of chat, voice, video and video, and questions and answers. People in the control group will receive only routine pre-pregnancy care. The first session, introduction to the definition of obesity and overweight, explaining some of the major causes of weight gain and obesity. Session 2, Familiarity with the effects of obesity and overweight for the mother, fetus and pregnancy consequences. Session 3, Familiarity with the benefits of weight control in reducing the complications of obesity and weight gain; Obstacles to weight control and solutions to overcome these obstacles. The fourth session, the existing recommendations to change the diet and increase physical activity will be presented according to the National Curriculum Guide to Nutritional Care before Pregnancy of the Ministry of Health.
Category
Behavior

2

Description
Control group: Receive routine care in comprehensive health service centers
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Bukan Comprehensive Health Service Centers
Full name of responsible person
Zhila Rashidi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
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Urmia, Resalat Blvd., Emergency Alley
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Urmia
Province
West Azarbaijan
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5714783734
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Email
mohebbi_iraj@yahoo.co.uk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Zilla Rashidi
Position
Midwife

Latest degree
Bachelor
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Extract the results related to the main outcome and compile the final design report and write the article
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
If you need a questionnaire or an educational intervention file, provided you refer to the article
From where data/document is obtainable
Author of the article or final report, Jila Rashidi, rashidi.zhila81@gmail.com
What processes are involved for a request to access data/document
After receiving the email stating that the data has been sent and coordinating with the research team, the data will be sent for at least one month.
Comments