

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 Boker

#### 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 select (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

Bukan Comprehensive Health Service Centers

#### City

Bukan

#### Province

West Azarbaijan

#### Postal code

6681718568

#### Phone

+98 87 3623 3327

#### Email

farokhi.behdad89@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Iraj Mohebbi

##### Street address

Urmia, Resalat Blvd., Emergency Alley

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 4897

##### 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

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Bukan Comprehensive Health Service Centers

**City**

Bokan

**Province**

West Azarbaijan

**Postal code**

6681718568

**Phone**

+98 87 3623 3327

**Email**

rashidi.zhila81@gmail.com

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Bukan city Comprehensive Health Service Centers

**City**

Bukan

**Province**

West Azarbaijan

**Postal code**

6681718568

**Phone**

009887362367

**Email**

rashidi.zhila81@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Zhila Rashidi

**Position**

Bukan Comprehensive Health Service Centers Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Bukan Comprehensive Health Service Centers

**City**

Bukan

**Province**

West Azarbaijan

**Postal code**

6681718568

**Phone**

+98 87 3623 3327

**Email**

rashidi.zhila81@gmail.com

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Zhila Rashidi

**Position**

Midwife

**Latest degree****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**