

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of the theory-based education on promoting healthy lifestyle in pre-diabetic women referring to arak health care centers

#### Protocol summary

##### Study aim

To determine the effect of the theory-centered education on the promotion of healthy lifestyle in pre-diabetic women

##### Design

The present study was conducted on a control-controlled educational intervention in about 104 pre-diabetic people referring to comprehensive health centers in Arak city (in two groups of control and control, each of 52). Thus, residents of Arak city according to the opinion of the staff of the deputy Health is divided into four classes based on the socioeconomic status. Then, from each of the two health centers, it is selected randomly, so that the selected center belongs to the test group and the second center selected belongs to the control group, so in total 4 centers are assigned to the test group and 4 centers to the control group, and samples are from each The center is available for selection.

##### Settings and conduct

Steps: Measurement of fasting blood glucose Perform pre-test by distributing the questionnaire Educational content development Educational intervention for intervention group Perform post-test by redistributing the questionnaire three months after the intervention Measurement of fasting blood glucose after intervention Place:arak health care centers

##### Participants/Inclusion and exclusion criteria

Entry requirements: having a minimum fifth degree of primary education, a person's willingness to participate in research, a fasting blood sugar level of more than 100 and less than 125, age from 30 to 59 years

##### Intervention groups

Control group: receive routine training Test group: Suitable training programs are received for structured models of planned behavior.

##### Main outcome variables

Prevent diabetes and its complications, having healthy and effective lives in society

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190304042921N1**

Registration date: **2019-07-22, 1398/04/31**

Registration timing: **prospective**

Last update: **2019-07-22, 1398/04/31**

Update count: **0**

##### Registration date

2019-07-22, 1398/04/31

##### Registrant information

##### Name

Kolsoum Mohammadniyamothagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3368 6443

##### Email address

k.mohammadniya@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-06, 1398/05/15

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the theory-based education on promoting healthy lifestyle in pre-diabetic women referring to arak health care centers

#### Public title

The effect of the theory-based education on promoting healthy lifestyle in pre-diabetic women referring to arak health care centers

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having a fifth grade elementary level of education a person's willingness to participate in research a fasting blood sugar level of more than 100 and less than 125 age from 30 to 59 years

##### Exclusion criteria:

exclusion criteria is women are not willing to participate in this research

#### Age

From **30 years** old to **59 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **104**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method: Simple randomization Residents of Arak city according to the opinion of the staff of the deputy health department are divided according to the socioeconomic status in the four classes. These four categories include centers with a population of almost good (5 centers), medium (3 centers), medium-low (2 centers) and poor (4 centers). Then, from each secondary health center, a simple random selection is made, so that the selected center belongs to the test group and the second center selected belongs to the control group, so in total 4 centers are assigned to the test group and 4 centers to the control group and samples from each center Available at affordable prices. The number of samples selected from each center is also 6 in each group. Random unit: cluster Randomization tool: SPSS software Hiding allocation concealment: The name of the comprehensive health center is hidden to the person who carries out randomization.

#### 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 Arak University of Medical Sciences

##### Street address

Department of Research and Technology, University of the Great Prophet, Basij Square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

#### Approval date

2019-06-02, 1398/03/12

#### Ethics committee reference number

IR.ARAKMU.REC.1398.073

## Health conditions studied

### 1

#### Description of health condition studied

Pre-diabetes

#### ICD-10 code

R73.0

#### ICD-10 code description

Abnormal glucose tolerance test

## Primary outcomes

### 1

#### Description

Healthy lifestyle (behavior)

#### Timepoint

Before the intervention and 3 months after the intervention

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

Knowledge

#### Timepoint

Before the intervention and 3 months after the intervention

#### Method of measurement

questionnaire

### 2

#### Description

Attitude

### **Timepoint**

Before the intervention and 3 months after the intervention

### **Method of measurement**

questionnaire

### **3**

#### **Description**

Intention

#### **Timepoint**

Before the intervention and 3 months after the intervention

#### **Method of measurement**

questionnaire

### **4**

#### **Description**

Subjective norms)

#### **Timepoint**

Before the intervention and 3 months after the intervention

#### **Method of measurement**

questionnaire

### **5**

#### **Description**

Perceived behavioral control

#### **Timepoint**

Before the intervention and 3 months after the intervention

#### **Method of measurement**

questionnaire

### **6**

#### **Description**

Fasting blood sugar

#### **Timepoint**

Before the intervention and 3 months after the intervention

#### **Method of measurement**

questionnaire

### **7**

#### **Description**

Body mass index

#### **Timepoint**

Before the intervention and 3 months after the intervention

#### **Method of measurement**

Tools

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Preventive training programs will be developed to promote a healthy lifestyle (including

healthy eating, physical activity, non-smoking, or hookah) and lowering blood glucose levels. The number of sessions and the content of the training and its duration will be determined after the need-assessment.

#### **Category**

Prevention

### **2**

#### **Description**

Control group: The control group does not receive any training during the study.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Arak Health Center

##### **Full name of responsible person**

Saeed Mohammad Doost

##### **Street address**

Phase Two, Shahid Beheshti Town, Arak

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

۳۸۱۸۱۴۶۸۵۱

##### **Phone**

+98 86 3313 9037

##### **Email**

behdasht@arakmu.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr. Alireza Kamali

##### **Street address**

Prophet's University Complex, Basij Square, Sardasht, Arak

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

38481-7-6341

##### **Phone**

+98 86 3417 3639

##### **Fax**

+98 86 3417 3639

##### **Email**

research@arakmu.ac.ir

##### **Web page address**

<https://arakmu.ac.ir/vcr/fa>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Kolsoum Mohammadniamothagh

**Position**

Masters student Health Education

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Ground Floor,Building No. 2,Golestan koy,Mustafa Khomeini Town

**City**

Arak

**Province**

Markazi

**Postal code**

38181-4-6851

**Phone**

+98 86 3368 6443

**Fax**

**Email**

k.mohammadniya@arakmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Kolsoum Mohammadniamothagh

**Position**

Masters student Health Education

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Ground Floor,Building No. 2,Golestan koy,Mustafa Khomeini Town

**City**

Arak

**Province**

Markazi

**Postal code**

38181-4-6851

**Phone**

+98 86 3368 6443

**Fax**

**Email**

k.mohammadniya@arakmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Kolsoum Mohammadniamothagh

**Position**

Masters student Health Education

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

**Street address**

Ground Floor,Building No. 2,Golestan koy,Mustafa Khomeini Town

**City**

Arak

**Province**

Markazi

**Postal code**

38181-4-6851

**Phone**

+98 86 3368 6443

**Fax**

**Email**

k.mohammadniya@arakmu.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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