Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 Mohammadniamothagh

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
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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
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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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