Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

A Clinical trial to assess the effectiveness of educating a social cognitive theory based physical activity program on fasting blood glucose in the pre diabetic population in rural area.

Protocol summary

Summary

The study will aim to investigate the effectiveness of educational intervention based on social cognitive theory to prevent pre-diabetes proceed to diabetes among Pre-diabetic rural population in Ahar. The participants will be eligible people aged 30-65 years old with pre-diabetes who will be recruited to the study through screening in health houses and have willingness to participate in the study. Ahar have four regions. Accordingly, 3 health centers in each area and a health houses affiliated by each health center will be selected (A total of 12 health houses) through cluster randomization. The health houses will be randomly assigned to the intervention and control groups (6 health houses with 136 participants in each group). All participants will receive general information about pre-diabetes. The intervention group will participate in educational sessions (16 sessions; 90 minutes per week). The educational interventions will be planned based on the social cognitive theory in order to control per-diabetes. Educational sessions include per-diabetes prevention and diabetes control by physical activity, increasing self-efficacy in order to gain the ability to improve diabetes prevention, and setting a goal to decrease fast blood sugar. The intervention planning will be carried out based on social cognitive theory, self-efficacy for pre-diabetes, physical activity, goal setting, and outcome expectations. The post- test will be conducted four months after baseline measurements using some questionnaires including International physical activity questionnaire (IPAQ), self-efficacy towards Pre-diabetes questionnaire, goal setting and outcome expectations. The control group will receive educational program after the study duration.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201607198132N4**
Registration date: **2017-08-01, 1396/05/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-01, 1396/05/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2017-03-08, 1395/12/18

Expected recruitment end date

2017-06-08, 1396/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Clinical trial to assess the effectiveness of educating a social cognitive theory based physical activity program on fasting blood glucose in the pre diabetic population in rural area.

Public title
Designing physical activity interventional program for prediabetic population
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Pre-Diabetic rural people living in Ahar county aged 30-65 years old; the consent to participate in the study. Exclusion criteria: Lack of interest in cooperation
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **272**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht street, Azadi Steet, Tabriz Tabriz East Azarbayjan Iran, Islamic Republic Of
City
Tabriz
Postal code
Approval date
2017-03-06, 1395/12/16
Ethics committee reference number
IR.TBZMED.REC.1395.1252.

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
fasting blood sugar
Timepoint
Before and 16 weeks after intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
physical activity
Timepoint
Before and 16 weeks after intervention
Method of measurement
International physical activity questionnaire (IPAQ)

2

Description
self-efficacy toward Diabetes prevention
Timepoint
Before and 16 weeks after intervention
Method of measurement
self-efficacy toward Diabetes prevention questionnaire

3

Description
Goal setting toward Diabetes prevention
Timepoint
Before and 16 weeks after intervention
Method of measurement
Goal setting questionnaire

4

Description
outcome expectation toward Diabetes prevention
Timepoint
Before and 16 weeks after intervention
Method of measurement
outcome expectation questionnaire

5

Description
Body mass index
Timepoint
Before and 16 weeks after intervention
Method of measurement
tools

Intervention groups

1

Description
Educational programs will be conducted in the rural community to increase Physical activity in order to reduce blood sugar. The intervention group will participate in such educational sessions, 90 minutes per week. Climbing the hill will take place once a week to increase physical activity.
Category
Prevention

2

Description
During the study, the control group will not receive any training.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Rural Health Houses
Full name of responsible person
Tahere Shamizadeh
Street address
Rural Health Houses of Ahar, Ahar county, East Azarbayjan
City
Ahar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Asghari Jafarabadi
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht street, Azadi Street, Tabriz, East Azarbayjan
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty