

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Leila Jahangiry

Name of organization / entity

Tabriz University of Medical Sciences

Country

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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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Tahere Shamizadeh

Position

educator

Other areas of specialty/work

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PhD

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Position
Assistant Professor
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Health Education and Promotion departement, Public
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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