Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect application of the transtheoretical model self-care outcomes and serum irisin level in the patients with type 2 diabetes and control.

Protocol summary

Summary

This study aimed to investigate application of the transtheoretical model to predict self-care outcomes and serum irisin level in the patients with type 2 diabetes and control. Summary of the project:134 patients with type 2 diabetes Ardabil, aged between 30-70 years, who use blood glucose lowering drugs, and without kidney disease, liver and mental problems and learning and literacy are , the population of the study . The fifth phase of the study (intervention): Evaluate biochemical, anthropometric and blood pressure will be before the intervention of both groups . To an educational model based on trans-theoretical model of change will be taught. The control group patients will receive standard training. For education based on individuals at any stage of change will be changed, At least 5 and a maximum of 7 sessions based on the number of stages of change and self-care needs of patients and the contents of the training session: Proper use of medications, dietary education and physical activity sessions accompanied by one family member, making decisions that affect diabetes, in some of the meetings will be held and self-care educational booklet at the end of each session, each session will be available to the subjects, Educational tool CD containing demo videos - training of the subjects will be in the last session. The sixth phase of the study (follow-up): They both study groups (intervention and control) will be followed for 6 months and during this period will not be any training program. At the end of the seventh week and 6 months after the intervention (follow-up) on the stages of change questionnaire, 24-hour food recall questionnaire and physical activity questionnaire back to the subjects in each stage will be completed and the evaluation of anthropometric and biochemical evaluation Fasting blood glucose , fasting blood glucose 2 hours after breakfast , glycosylated hemoglobin, triglyceride and total cholesterol and high-density cholesterol , low-density cholesterol and irisin concentrations will be in the three stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701165670N23**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-12-13, 1395/09/23

Expected recruitment end date

2017-01-12, 1395/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect application of the transtheoretical model self-care outcomes and serum irisin level in the patients with type 2 diabetes and control.

Public title
Diabetes Education
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients with type 2 diabetes, age range 30-70 years; patients with type 2 diabetes with a history of over a year; the use of blood glucose lowering drugs ;Satisfaction in the study; absence of kidney disease, liver and mental problems and learning, vision and hearing problems; A1C ≥ 7% or FPG≥ 126 mg / dL ; BMI>25 kg/m2 ;ability to read and write; regular attendance in classes Exclusion criteria: the use of insulin in patients with type 2 diabetes; pregnant women with type 2 diabetes / plan to become pregnant or breast-feeding; Persons who have already passed the training course healthy lifestyle as a model; patients who were undergoing surgery for weight loss.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Vice-Dean for Reserch and Technology Tabriz University of Medical Sciences
Street address
GOLGASHT Street;Tabriz
City
Tabriz
Postal code
Approval date
2016-12-26, 1395/10/06
Ethics committee reference number
IR.TBZMED.REC.1395.1012

Health conditions studied

1

Description of health condition studied
diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose (FPG)
Timepoint
Before intervention At the end of the seventh week and 6 months after the intervention
Method of measurement
Photometry with Commercial Kits (Pars azmon)

2

Description
Glycosylated hemoglobin(A1C)
Timepoint
Early intervention, the end of the seventh week and after 6 months follow-up
Method of measurement
Chromatography

3

Description
Blood glucose 2 hours after breakfast(2-h PG)
Timepoint
Early intervention, the end of the seventh week and after 6 months follow-up
Method of measurement
Photometry with Commercial Kits (Pars Azmoon)

4

Description
Tri glyceride(TG)
Timepoint
Early intervention, the end of the seventh week and after 6 months follow-up
Method of measurement
Photometry with Commercial Kits (Pars Azmoon)

5

Description
Total Cholesterol(TC)
Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Photometry with Commercial Kits (Pars Azmoon)

6

Description

HDL-C

Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Photometry with Commercial Kits (Pars Azmoon)

7

Description

LDL–C

Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Fried-Wald formula

8

Description

Irisin

Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

ELISA kit for measuring enzyme-linked immunosorbent (Zlbio, Germany)

9

Description

Serum insulin

Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

ELISA kit for measuring enzyme-linked immunosorbent (monobind, America)

10

Description

betatrophin

Timepoint

Early intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

ELISA kit for measuring enzyme-linked immunosorbent (Zlbio, Germany)

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

scale RASA

2

Description

Body mass index(BMI)

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

With formula

3

Description

Blood Pressure

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Manometer EmsiG

4

Description

The type and number of drugs

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

With Question

5

Description

Position on Stage of Change

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Questionnaire Stage of Change

6

Description

Energy

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Recall Food 24 -hour

7

Description

Macronutrients

Timepoint

Before the intervention, the end of the seventh week and

after 6 months follow-up

Method of measurement

Recall Food 24 -hour

8

Description

Exercise Intensity

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Questionnaire IPAQ

9

Description

Exercise Duration

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Questionnaire IPAQ

10

Description

Exercise Frequency

Timepoint

Before the intervention, the end of the seventh week and after 6 months follow-up

Method of measurement

Questionnaire IPAQ

Intervention groups

1

Description

Control group: During the intervention and six-month follow-up, the control group will not receive training program and after the end of study pamphlets and videos teaching demo will be available to them

Category

Lifestyle

2

Description

Intervention group: The intervention group will be trans-theoretical model of education based on stages of change model. Educational content for people who pre contemplation, contemplation and decision are: In training sessions for each of the people who are in pre-contemplation the content of education separately, for those who are contemplation stage the content of education separately, for those who are decision stage individually tailored education content and to people based on location will be trained in each of the steps. Training healthy lifestyle will be given (proper use of blood glucose lowering drugs, healthy diet and proper physical activity), short-term and long-term complications caused by poor control of blood glucose and the effects of diet and physical activity on control of blood glucose. Also at the meeting discussed the results of a group and motivational interviews (attention, relevance, confidence and satisfaction) will be used in the decision stage. After people during each stage of their education and arrived to action and maintenance, The next steps will be implemented in the following explained. Educational content for people who are action and maintenance: Self-care educational content sessions • educational content, blood glucose lowering drugs: Proper education about using medication, side effects of blood glucose lowering drugs, Introduction to Herbal Medicines lowering blood sugar training will be given using a video projector. • Educational content diet education sessions: In training sessions diet for people with diabetes, about food groups, my plate, food serving, carbohydrate, protein and fat, glycemic parameters and their effects on weight and also improperly cooked food and how to choose and buy food according to food groups and healthy cooking food, use artificial sweeteners and fats and salts in moderation will be given the necessary training using video projector. • The contents of sessions of physical activity: In people with type 2 diabetes in sessions of physical activity, aerobic exercise (walking, swimming, gardening and light aerobic exercises) the average duration and intensity resistance exercise with an interval of half an hour three times a week according to the stage of change model training process will be broadcast using video projector and training will be given to them. this means that people who are pre contemplation stage educational content and dramatic film - individually according to your needs and learning from educational content specified ,as well as for people who are in the process of contemplation, decision, action and maintaining improper behavior educational content and dramatic film - a separate training according to the needs and from the educational content of self-care, proper education about using medication lowering blood sugar, diet education and training physical activity The qualitative study with content that will be used in decision stage, Will be taught. training period will be 7 week, during the seven-week training session Will be held on the basis of stages of change and the number of patients' needs in meetings an hour to 2 hours, group training for the lecture with questions and answers and the explanations. Tools video projector will be used for education, some of the meetings will be formed accompanied by an influential family members, in the last session and a summary of their training Care and dramatic film - made training to people involved displayed and educational tool CD containing demo videos - training will be provided to subjects, after 7 weeks of primary and secondary outcomes will be measured and will follow-up 6-month and in six months there will be no intervention And again six months after the primary and secondary outcomes will be measured.

Category

Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Private Clinic
Full name of responsible person
Maryam Zare
Street address
No 27;Sarcheshmee Street ; Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Dean for Reserch and Technology Tabriz University Of Medical Science
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
GOLGASHT Street;Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Dean for Reserch and Technology Tabriz University Of Medical Science
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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Email
mzare753@ gmail.com
Web page address

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