

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

##### Name

Ali Tarighat-Esfanjeni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 300 5895

##### Email address

tarighata@tbzmed.ac.ir

##### 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.

2016-12-26, 1395/10/06

**Ethics committee reference number**  
IR.TBZMED.REC.1395.1012

**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  $\geq$  7% or FPG $\geq$  126 mg / dL ; BMI>25 kg/m<sup>2</sup> ;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**

**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

**Name of organization / entity**

Nutrition faculty, Tabriz university Of Medical sciences

**Full name of responsible person**

Maryam Zare

**Position**

Master Of Science in Nutrition / Dietitian Razi Health  
Centre

**Other areas of specialty/work**

**Street address**

Ardabil

**City**

Ardabil

**Postal code**

**Phone**

+98 45 3326 0575

**Fax**

**Email**

mzare753@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Nutrition Faculty, Tabriz University of Medical  
Sciences

**Full name of responsible person**

Dr.Ali Tarighat-Esfanjeni

**Position**

Ph.D of Nutrition

**Other areas of specialty/work**

**Street address**

Nutrition Faculty, Attarneyshabouri street, Golgasht  
street

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3335 7310

**Fax**

**Email**

tarighata@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Nutrition faculty, Tabriz University Of Medical  
Sciences

**Full name of responsible person**

Maryam Zare

**Position**

Master of Science in nutrition / Dietitian Razi Health  
Centre

**Other areas of specialty/work**

**Street address**

No27,sarchshme street,Ardabil

**City**

Ardabil

**Postal code**

**Phone**

+98 45 3326 0575

**Fax**

**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*