

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of teaching self-care behaviors on reducing insulin consumption in patients with type 2 diabetes covered by the health insurance

#### Protocol summary

##### Study aim

- Determination and comparison of HBA1C index in type 2 patients between intervention group and control group
- Determination and comparison of FBS index in type 2 patients between intervention group and control group and comparison of serum two hour blood sugar index in type 2 patients between model group and control group
- Determination and comparison of body mass index in type 2 patients between the intervention group and the control group
- Determining and comparing the amount of pen insulin used in type 2 patients between the intervention group and the control group

##### Design

Clinical trial, parallel groups, double-blind, randomized, phase 2 on 70 patients with type 2 diabetes. Rand function of Excel software was used for randomization.

##### Settings and conduct

In this study, 70 diabetic patients covered by health insurance aged 35-65 who receive pen insulin are divided into two intervention groups (35 people) and control (35 people) using a random block method. In the intervention group, training on the correct method of pen insulin injection and healthy eating, prescribing a diet of 500 kcal less than the calculated energy and walking with an intensity of 60% heart rate for 45 minutes is recommended.

##### Participants/Inclusion and exclusion criteria

Entry criteria: patients with type 2 diabetes, both men and women, in the age range of 35-65 covered by health insurance. Exclusion criteria: lack of consent to participate or continue the project, migration, hospitalization, suffering from mental disorders and movement disorders, and suffering from debilitating cardiovascular disease.

##### Intervention groups

Pen insulin injection training and healthy eating The diet is 500 kcal less than the energy intake walking

##### Main outcome variables

The level of recovery of the disease will be possible by measuring two-hour blood sugar, HbA1c, FBS, BMI and the dose of pen insulin before and after 12 weeks.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210808052106N2**

Registration date: **2023-02-27, 1401/12/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-27, 1401/12/08**

Update count: **0**

##### Registration date

2023-02-27, 1401/12/08

##### Registrant information

##### Name

leila javadi

##### Name of organization / entity

Health Insurance Organization

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 5104 0223

##### Email address

javadi.l@ihio.gov.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-05-21, 1402/02/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of teaching self-care behaviors on reducing insulin consumption in patients with type 2 diabetes covered by the health insurance

**Public title**

Investigating the effect of education in reducing insulin consumption in patients with type 2 diabetes

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with type 2 diabetes should be both men and women in the age range of 35-65 Patients are covered by health insurance

**Exclusion criteria:**

Lack of consent to participate or continue the plan  
Migration Having mental disorders and movement disorders Having an underlying disease such as debilitating cardiovascular disease

**Age**

From **35 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **62**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible participants will be randomly assigned to intervention and control groups using random block method by RAS (Random Allocation Software) and 1:1 allocation ratio by a person not involved in the research. In order to hide the allocation of groups based on a random sequence, the allocation is written by a person not involved in the research in terms of numbers on a paper and sealed in a matte envelope. So that the researcher and the analyst will not know about the allocation of groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to hide the allocation of groups based on a random sequence, the allocation is written by a person not involved in the research in terms of numbers on a paper and sealed in a matte envelope. So that the researcher and the analyst will not know about the allocation of groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

thics committee of Tabriz University of Medical Sciences

**Street address**

NO.35, Roshdie Alley, Saadi Ave, valiasr

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157936534

**Approval date**

2023-01-09, 1401/10/19

**Ethics committee reference number**

IR.TBZMED.REC.1401.938

**Health conditions studied****1****Description of health condition studied**

Type 2 diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

**Primary outcomes****1****Description**

fasting blood sugar

**Timepoint**

The beginning and end of the study

**Method of measurement**

Spectrophotometric method

**2****Description**

Two-hour blood sugar

**Timepoint**

The beginning and end of the study

**Method of measurement**

Spectrophotometric method

### 3

#### **Description**

HbA1c

#### **Timepoint**

The beginning and end of the study

#### **Method of measurement**

Spectrophotometric method

### **Secondary outcomes**

#### 1

#### **Description**

Pen insulin dosage

#### **Timepoint**

The beginning and end of the study

#### **Method of measurement**

Electronic prescription system

#### 2

#### **Description**

The average score of anthropometric indices (weight and body mass index) in the study groups

#### **Timepoint**

The beginning and end of the study

#### **Method of measurement**

Weighed by a Saka scale with an accuracy of 0.1 Kg, height with stadiometer and body mass index are obtained by dividing a person's weight in kilograms by the second power ( $x^2$ ) of his height in meters.

### **Intervention groups**

#### 1

#### **Description**

The group receiving lifestyle, diet and physical activity education. The people of the intervention group will be prescribed a diet containing 60% carbohydrates, 25% fat and 15% protein, 500 kilocalories less than the calculated daily energy, along with general healthy nutrition education based on increasing the consumption of vegetables and legumes and reducing the consumption of sweets and saturated fats. . This group will participate in aerobic exercise for 12 weeks and three sessions per week. The exercise will include brisk walking with 60% heart rate intensity for 45 minutes. The training sessions will include how to inject insulin by a diabetes doctor, healthy nutrition by a nutrition consultant, and physical activity by a sports consultant at the beginning of the study for 6 hours.

#### **Category**

Lifestyle

#### 2

#### **Description**

Control group: During the study, this group will not receive diet and training, but at the end of the study, a training session along with a lifestyle training brochure will be provided to them.

#### **Category**

N/A

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health Insurance Organization

##### **Full name of responsible person**

Leila Javadi

##### **Street address**

General Health Insurance, Office Golha St, Ail Goli

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5167858525

##### **Phone**

+98 41 5104 0100

##### **Email**

Info.as@ihio.gov.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

National Research Center of Iran Health Insurance Organization

##### **Full name of responsible person**

Mohammad Efatpanah

##### **Street address**

No.1, North Flamack Street, Ivanak Blvd, Gods town

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1467863433

##### **Phone**

+98 21 9688 1000

##### **Email**

info@ihio.gov.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

National Research Center of Iran Health Insurance Organization

#### **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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Health Insurance Organization

#### Full name of responsible person

Leila Javadi

#### Position

Health Services Evaluation Expert

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Responsible for the Health Committee

#### Street address

No.35, Rushdieh Alley, Saadi St., Valiasr

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5157936534

#### Phone

+98 41 3333 1633

#### Email

Javadi.l@ihio.gov.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Health Insurance Organization

#### Full name of responsible person

Leila Javadi

#### Position

Health Services Evaluation Expert

#### Latest degree

Ph.D.

#### Other areas of specialty/work

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#### Email

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Health Insurance Organization

#### Full name of responsible person

Leila Javadi

#### Position

Health Services Evaluation Expert

#### Latest degree

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#### Other areas of specialty/work

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#### Phone

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#### Email

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Part of the data, such as information about the main outcome

### When the data will become available and for how long

Access period starts 6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Research using our study from another dimension

### From where data/document is obtainable

Ms. Soraya Moradi Analyst of the study  
Tel:009851040444 moradi.s@ihio.gov.ir

### What processes are involved for a request to access data/document

E-mail from the academic researcher and with the authentication of the researcher is possible within one month

### Comments