Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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
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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

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Postal code

5157936534

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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

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Health Insurance Organization

Full name of responsible person

Leila Javadi

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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