Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the cost and effectiveness analysis of combined exercises on insulin consumption and some related factors on type 2 diabetic patients

Protocol summary

Study aim

The main purpose was to compare the cost and effectiveness of combined exercises on insulin consumption and some related factors in type 2 diabetic patients.

Design

This study is a clinical trial.There is no possibility of blinding in this study.Initial measurements will be performed in the field of physical fitness, blood tests. Participants will practice according to the protocol. At the end of the quarterly period, final measurements will be performed similar to the initial measurements.

Settings and conduct

This study will be held in Zanjan. The metabolic training protocol will be performed by cardio exercises tailored to the athlete's condition for 12 weeks.The resistance training protocol will be the large muscles of the body.During the implementation of the training protocol, changes in insulin consumption will be in accordance with standard protocols and proportional to blood sugar levels.To assess the diet, a 24-hour diet recall questionnaire will be used before blood sampling. Important clinical considerations will be considered, including exercise intensity, food intake, and insulin.

Participants/Inclusion and exclusion criteria

Inclusion criteria are blood sugar levels have been controlled by insulin and participants who have the ability and interest to participate in training programs. Exclusion criteria are any illness or medical restriction for performing sports activities

Intervention groups

68 participants (40 to 60 years old) whose diabetes was controlled by insulin use will participate in this study.The intervention group will participate in a 12-week training protocol with an intensity of 50 to 75% HRmax and resistance training with 50 to 85% (1RM).The control group will have a normal life.

Main outcome variables

The main outcome is examine the changes in insulin consumption, treatment costs due to exercise in order to modify health insurance policies on the diabetes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180530039909N1**
Registration date: **2021-09-03, 1400/06/12**
Registration timing: **prospective**

Last update: **2021-09-03, 1400/06/12**
Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Mahmoud Hakami Zanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3341 1577

Email address

mahmoud1ir@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the cost and effectiveness analysis of combined exercises on insulin consumption and some related factors on type 2 diabetic patients

Public title

Comparison of the cost and effectiveness analysis of combined exercises on insulin consumption and some related factors on type 2 diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetic patients whose blood sugar levels are controlled by insulin Diabetic patients have the ability and interest to participate in exercise programs.

Exclusion criteria:

Patients have any illness or medical restrictions for participating in the exercise

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the coin toss method will be used. In this method, the lion side of the experimental group and the line side of the control group will be used to create a random sequence. Depending on the size of the sample, the coin will be flown and individuals will be divided into two randomly assigned groups.

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

Zanjan University of Medical Sciences (Research Ethics Committee)

Street address

Zanjan University of Medical Sciences,Professor Prof. Boulevard,Zanjan

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2021-07-04, 1400/04/13

Ethics committee reference number

IR.ZUMS.REC.1400.135

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

ICD-10-E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

The main variables measured in this study are the amount of changes in the dose and cost of insulin consumption

Timepoint

Measurement sections will be pre-test and post-test

Method of measurement

The method of measuring the main outcome variable will be measuring the sugar profile and Insulin consumption as well as a researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will participate in a combined exercise program for 12 weeks and 3 sessions per week. This combination exercise program will include metabolic exercises with a gradual increase in intensity between 50 and 70% of the MaxHR. The resistance training section will also be between 50 and 85% of 1RM for large muscle groups with gradually increasing intensity.

Category

Lifestyle

2

Description
Control group: The control group will have a normal life.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Health Insurance Research Unit
Full name of responsible person
Fatemeh Mohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Health Insurance Research Center
Full name of responsible person
Parvaneh Keyhani
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Entrance A, No. 1, Corner of Derakhshan St, North Flamek St, Ivanak Blvd, Farahzadi Blvd, Sanat Square, Gharb Town, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Health Insurance Research Center
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mahmoud Hakami
Position
Faculty member
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The sections that contribute to the production of science in the title of this study will be shared

When the data will become available and for how long
The data access period will start 6 months after the results are published

To whom data/document is available
The data of this study will be available to all researchers

Under which criteria data/document could be used
The data will only be usable for citation

From where data/document is obtainable
mahmoud1ir@yahoo.com This email will be the communication channel for receiving documents

What processes are involved for a request to access data/document
When the request was received via email. That request will be considered. If it was in accordance with the conditions of this study. Submission data will be sent within one month

Comments