

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The Effect of 12 Weeks Aerobic, Resistance and Combined Exercises on Omentin-1 Levels and Insulin Resistance among Type 2 Diabetic Middle-Aged Women

Protocol summary

Summary

The purpose of this study was to examine the impact of 12 weeks of aerobic (cycle ergometer), resistance, and combined exercises on omentin-1 level, glucose and insulin resistance indices in overweight middle age women with type 2 diabetes. In this study, 60 overweight middle age diabetic women who having been suffering from T2DM (fasting blood sugar ≥ 126 mg/dl and 2-hour postprandial blood glucose ≥ 200 mg/dl) for at least 2 years were selected using simple random sampling and they were assigned to three groups of aerobic exercise (15), resistant exercise (15) and combined exercise (15), and one control group (15). Exercises were done in a 3 times per week sessions for a total of 12 weeks. Blood samples were collected before each exercise session and 24 hours after of the last session. Finally significant differences in the change of HOMA-IR from the baseline to the end of three interventions and the control group have seen.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050833869N1**

Registration date: **2017-05-29, 1396/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

The present study was financially supported by Shiraz University of Medical Sciences, Shiraz, Iran (No: 95-01-59-12487). and Grand no SC-95-15

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2017-04-01, 1396/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 12 Weeks Aerobic, Resistance and Combined Exercises on Omentin-1 Levels and Insulin Resistance among Type 2 Diabetic Middle-Aged Women

Public title

The Effect of 12 Weeks Aerobic, Resistance and Combined Exercises on Omentin-1 Levels and Insulin Resistance among Type 2 Diabetic Middle-Aged Women

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were: having been suffering from T2DM (fasting blood sugar ≥ 126 mg/dl and 2-hour

postprandial blood glucose ≥ 200 mg/dl) for at least 2 years; being female; aged 45 to 60 years exclusion criteria: diagnosed with any other diseases

Age

From **40 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences ethical comity

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

IR.SUMS.REC.1395.192

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

Insulin Resistance

Timepoint

At 2 stage. First day of the study (before any intervention) and second mesure after 12 weeks intervention.

Method of measurement

اندازه گیری با استفاده از کیت انسولین و فرمول روبرو
Insulin resistance = [fasting glucose (mg/dL) × fasting insulin (mU/L)/405].

Secondary outcomes

1

Description

before intervention, 5 mL blood samples were taken after 12 hours of fasting and the serum samples were separated using a centrifuge. The samples were frozen at -70° degrees centigrade until the time of serum analysis and omentin-1 and plasma glucose were then measured. Serum omentin-1 and fasting insulin concentrations were determined using enzyme-linked immunosorbent assay kits (Cristal day biotech, Shanghai, China) and (Monobind, Aachen, Germany). Fasting plasma glucose was measured using glucose kit (Pars Azmoon, Tehran, Iran) through the photometric method. Insulin resistance was determined through homeostasis model evaluation (HOMA-IR) and based on the following equation: $HOMA-IR = [fasting\ glucose\ (mg/dL) \times fasting\ insulin\ (mU/L)] / 405$.

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equation: $HOMA-IR = \frac{\text{fasting glucose (mg/dL)} \times \text{fasting insulin (mU/L)}}{405}$.

2

Description

change in plasma omentin-1

Timepoint

before and after intervention

Method of measurement

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Intervention groups

1

Description

All volunteers were examined by a general physician to assure that the intervention would not endanger patients. All participants gave their written informed consent. Group assignment: patients were divided into four groups each consisting of 15 participants. A group (control group) received no intervention and three groups underwent 'AEs,' 'REs,' group, and 'CEs' groups. For those in AE group, each exercise session consisted of three phases of warm up, the main stage and a cool-down period. The warm-up phase comprised of 20 minutes of stretching and jogging. The main phase of the study was consisted of 25 minutes exercise in order to achieve 50% to 55% of maximum heart rate as measured by cycle ergo-meter. Running, exercise and stretching made up the cooling-down phase.

Category

Other

2

Description

Each phase in the RE group had three sessions per week which consisted of three phases of warm-up, the main, and cooling-down. The warm-up involved 20 minutes of stretching exercises and jogging on the spot. The main phase consisted of three sets×eight repetitions of weight training including leg extension, prone leg curl, abdominal crunch, biceps, triceps, and seated calf. The exercise intensity was 50% to 55% of one repetition maximum or 1 repetition maximum (RM). The cooling-down also consisted of running, free exercises and

stretching.

Category

Other

3

Description

The group with CEs had the same schedule of other groups for warm-up and cooling-down. The main phase consisted of aerobic training integrated with RE, with half the execution time and the same intensity of resistance and aerobic groups. The trainings programs were performed within three sessions per week for 12 weeks. Every 2 weeks, in all exercise groups training was increased by 5 minutes and the intensity by 5%. The average intensity of main stage in every exercise group was 5.5 metabolic equivalent of task (MET) in first week and increased to 7.1 MET at the end of the study.

Category

Treatment - Other

4

Description

control group received no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Clinic, Shiraz

Full name of responsible person

Mostafa Dianati

Street address

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Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ali puostforoush

Street address

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City

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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

Shiraz University of Medical Sciences
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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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