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. Finaly 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 اسفاده 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)×fasting insulin (mU/L)/405].

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2

Description
change in plasma omentin-1
Timepoint
before and after interventiond
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
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Shiraz University of Medical Sciences Department of Epidemialogy
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Ali puostforoush
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Shiraz
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