

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of the Effect of Eight-Week Trx Exercise and Omega-3 Supplementation on Visfatin Level and Insulin Resistance in Women with Polycystic Ovary Syndrome.

#### Protocol summary

##### Study aim

The purpose of this study was to investigate the effect of eight weeks of trx training and omega-3 supplementation on serum visfatin levels and insulin resistance in women with PCOS.

##### Design

Twenty eight patients were randomly assigned to four complement, exercise, combination and control groups through lottery.

##### Settings and conduct

The participants were randomly divided into four groups by lottery and the complementary group was followed up through the complementary telegram channel and the intervention group of the training group and the combined gymnasium were conducted.

##### Participants/Inclusion and exclusion criteria

Women with polycystic ovarian syndrome aged 20-40 years, non-pregnancy, menopause, addiction, taking medications for blood pressure and hormone, diabetes, cardiovascular problems, renal failure, liver and thyroid problems, using omega-3 supplementation regularly in three Last month, as well as regular physical activity in the last three months.

##### Intervention groups

Exercise TRX and supplementation with omega-3

##### Main outcome variables

The implications of this study are to reduce insulin resistance and insulin levels and increase visfatin levels.

#### General information

##### Reason for update

##### Acronym

TRX

##### IRCT registration information

IRCT registration number: **IRCT20180824040856N1**

Registration date: **2018-09-08, 1397/06/17**

Registration timing: **retrospective**

Last update: **2018-09-08, 1397/06/17**

Update count: **0**

##### Registration date

2018-09-08, 1397/06/17

##### Registrant information

###### Name

Fariba Khoshkam

###### Name of organization / entity

Islamic Azad University Isfahan(Khorasgan)

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3568 4210

###### Email address

zeraati3679@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-02, 1396/01/13

##### Expected recruitment end date

2017-06-15, 1396/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effect of Eight-Week Trx Exercise and Omega-3 Supplementation on Visfatin Level and Insulin Resistance in Women with Polycystic Ovary Syndrome.

##### Public title

Effect of trx training and omega-3 supplementation in controlling polycystic ovary syndrome.

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Female with polycystic ovarian syndrome age 20-40 years

##### **Exclusion criteria:**

Pregnance alcoholism or drugs taking certain medications menopause cardiovascular problems Liver problems Renal failure diabetes taking omega-3 supplement regularly in the last three months regular exercise in the last three months

#### **Age**

From **20 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **28**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Randomized randomization, in which I wrote the names of the participants on separate papers and placed in a container, I asked one person to read them one by one and I was replaced by training in four groups.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

TRX exercises have been used in this research, which is completely new and has not been applied to these participants until now.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Islamic Azad University Khorasgan Branch (Isfahan)  
Ethical Committee

##### **Street address**

t, Arghavia, University Blvd. East Gay St

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8155139998

#### **Approval date**

2018-06-03, 1397/03/13

#### **Ethics committee reference number**

IR.IAU.KHUISF.REC.1397.018

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Polycystic ovary syndrome

#### **ICD-10 code**

E28.2

#### **ICD-10 code description**

Polycystic ovarian syndrome

## **Primary outcomes**

### 1

#### **Description**

insulin resistance

#### **Timepoint**

24 hours before intervention and two months after intervention

#### **Method of measurement**

Blood sampling

### 2

#### **Description**

Visfatin level

#### **Timepoint**

24 hours before intervention and two months after intervention

#### **Method of measurement**

Blood sampling

### 3

#### **Description**

Weight changes

#### **Timepoint**

24 hours before intervention and two months after intervention

#### **Method of measurement**

Scala Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Omega-3 supplementation. Receipt of 1000 mg capsule, daily dose of a capsule, after lunch, Zahravi Co.

#### **Category**

Lifestyle

## 2

### Description

Intervention group2: Omega-3 supplementation and TRX exercise Get a 1000 mg capsule, a daily dose of capsule, after lunch, Zahrawi's company, and 24 sessions of TRX training, each session is an hour

### Category

Lifestyle

## 3

### Description

Intervention group3: Practice, 24 training sessions for TRX, duration of each session for one hour

### Category

Lifestyle

## 4

### Description

Intervention group 4: Control group

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Ferdos Mehrabian

##### Street address

Shahid Beheshti Hospital , Motahhari Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8184855351

##### Phone

+98 31 3236 7001

##### Fax

##### Email

info@manoshahr.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University Khorasgan Branch (Isfahan)

##### Full name of responsible person

Ahmad Azin

##### Street address

, Arghavia, University Blvd. East Gay St

##### City

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8155139998

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+98 31 3535 4060

##### Email

info@khuisfac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Islamic Azad University Khorasgan Branch (Isfahan)

##### Proportion provided by this source

100

##### Public or private sector

Private

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Khorasgan (Isfahan) Branch, Islamic Azad University

##### Full name of responsible person

Fariba Khoshkam

##### Position

Student

##### Latest degree

Master

##### Other areas of specialty/work

Physiology

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## Person responsible for scientific inquiries

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available