

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

**The effects of different exercise training modalities as a treatment and prevention strategies on body composition measures in association with semen parameters in married middle-age fertile and at-risk infertile patients.**

### Protocol summary

#### Study aim

To investigate the effects of different exercise training modalities as a treatment and prevention strategies on body composition measures in association with semen parameters in married middle-age fertile and at-risk infertile patients.

#### Design

2,500 infertile men will be classified into various subgroups of infertility, including asthenozoospermic, asthenotratzoospermic, oligospermic, oligoasthenospermic, and oligoasthenotratzoospermic. Also, 600 inactive middle-aged married men with no fertility problems will participate in the present study as subjects (healthy or fertile group). After screening and in the first step, the subjects in different subgroups of infertility and also healthy tests will randomly be allocated (based on the table of random numbers) to one of the 5 groups including 1- moderate-intensity aerobic exercise, 2- high-intensity intensity continues, 3- high-intensity interval training, 4- resistance training, and 5- combined activities (moderate and resistance training). Then in the second step, the subjects in each of the mentioned groups will be randomly divided into physical activity groups or control groups.

#### Settings and conduct

This project will be implemented in Tehran with the cooperation of official reproductive medicine centers as well as clubs and sports centers in different parts of Tehran and under the supervision of the Faculty of Physical Education of the Allameh Tabatabai University of Tehran.

#### Participants/Inclusion and exclusion criteria

Physically active men  
Single men  
Men with chronic illnesses  
Smokers and men with alcohol consumption

#### Intervention groups

Moderate-intensity continuous training  
High-intensity continuous training  
High-intensity interval training  
Resistance training  
Combined aerobic and resistance training  
Non-exercise group (control)

#### Main outcome variables

Body composition; semen quality parameters, blood levels of hormones

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160605028270N2**  
Registration date: **2020-08-07, 1399/05/17**  
Registration timing: **prospective**

Last update: **2020-08-07, 1399/05/17**

Update count: **0**

#### Registration date

2020-08-07, 1399/05/17

#### Registrant information

##### Name

Behzad Hajizadeh Maleki

##### Name of organization / entity

Department of Sports Medicine, Institute of Sports Sciences, Justus-Liebig-University

##### Country

Iran (Islamic Republic of)

##### Phone

+49 641 9925210

##### Email address

behzad.hajizadeh-maleki@sport.uni-giessen.de

#### Recruitment status

**Recruitment complete**

#### Funding source

**Expected recruitment start date**

2020-08-10, 1399/05/20

**Expected recruitment end date**

2021-03-10, 1399/12/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of different exercise training modalities as a treatment and prevention strategies on body composition measures in association with semen parameters in married middle-age fertile and at-risk infertile patients.

**Public title**

The effects of different exercise training modalities as a treatment and prevention strategies on body composition measures in association with semen parameters in married middle age fertile and at-risk infertile patients.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Sedentary Married Free from chronic illnesses Non smokers and no alcohol dependency

**Exclusion criteria:**

Physically active men Single men Men with chronic illnesses Smokers and men with alcohol consumption

**Age**

From **25 years** old to **40 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **3100**

More than 1 sample in each individual

Number of samples in each individual: **5**

The initial semen sample will drawn 24 h before the training session (baseline; T1). Additional samples will collect 24 h after the last training session in week 12 (T2), 24 h after the last training session in week 24 (T3), and at 7 (T4) and 30 days (T5) post-intervention

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed by random number generation and group assignment will be placed in a sealed envelope, which will be opened by the study coordinator at the time of randomization.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Allameh Tabatabai University

**Street address**

Dehkadeh-ye-Olympic, Tehran, Tehran Province, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1489684511

**Approval date**

2020-07-21, 1399/04/31

**Ethics committee reference number**

IR.ATU.REC.1399.012

**Health conditions studied****1****Description of health condition studied**

Male factor infertility

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Body composition, semen quality and blood hormonal levels

**Timepoint**

At baseline, 12 weeks, 24 weeks and 7 and 30 days after training.

**Method of measurement**

Body composition variables including weight and height of subjects will be assessed using ZT-120 Weighing Machine Floor Type - made in Germany. Fat percentage and body mass index will be assessed using Omron portable fat meter made in Germany and waist circumference will be assessed by a tape measure. Semen variables will be evaluated according to World Health Organization (WHO) guidelines for the examination of human semen. Blood hormones will be measured using special kits by ELISA method.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: moderate-intensity continuous exercise training

#### Category

Treatment - Other

### 2

#### Description

Intervention group: high-intensity interval training

#### Category

Treatment - Other

### 3

#### Description

Intervention group: high-intensity continuous

#### Category

Treatment - Other

### 4

#### Description

Intervention group: resistance training

#### Category

Treatment - Other

### 5

#### Description

Intervention group: combined aerobic and resistance training

#### Category

Treatment - Other

### 6

#### Description

Control group: Non-exercise group

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Physical Education, Allameh Tabatabai University

##### Full name of responsible person

Bakhtyar Tartibian

##### Street address

Dehkade-ye Olampik, West Hemmat Highway, Tehran, Iran

#### City

Tehran

#### Province

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#### Postal code

1489684511

#### Phone

+98 21 4839 4112

#### Email

ba.tartibian@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Allameh Tabataba'i University

##### Full name of responsible person

Bakhtyar Tartibian

##### Street address

Dehkade-ye Olampik, West Hemmat Highway, Tehran, Iran

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##### Email

ba.tartibian@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Allameh Tabataba'i University

#### 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

Allameh Tabataba'i University

##### Full name of responsible person

Bakhtyar Tartibian

##### Position

Professor

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Physiology

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Position**

Professor

**Latest degree**

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**Email**

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**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

To respect their privacy.

**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**

Only part of the data, such as information about the main outcome or the like, can be shared after participants are unidentified.

**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**

Our data will only be available to researchers working in academic and research centers

**Under which criteria data/document could be used**

Upon request and at the discretion of the researchers, the information will be sent to applicants through legal channels.

**From where data/document is obtainable**

Applicants can send their application to ba.tartibian@gmail.com or Allameh Tabatabai University Administrative Correspondence Center.

**What processes are involved for a request to access data/document**

The request for access to the data will be answered within 5 to 7 days after the researchers review it.

**Comments**