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, asthenotratozoospermic, oligospermic, oligoasthenosospermic, and oligo asthenotratosospermic. 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

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Country

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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 inweek 12 (T2), 24 h after the last training session in week 24 (T3), andat 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Allameh Tabataba'i University
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+98 21 4473 7636
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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 updating data

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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