

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of three-months of exercise intervention on the levels of inflammatory factors in women with low socioeconomic status

Protocol summary

Study aim

In general, people with a lower socioeconomic status are more likely to be exposed to risky behaviors such as physical inactivity, poor diet, and not participating in health examinations, as well as psychological stress. One of the causes of inactivity is the lack of targeted sports programs for this group of people. The purpose of this research is to implement a regular program for this group of people.

Design

Two groups of 40 people each (experimental-control)

Settings and conduct

Islamshahr Imam Khomeini Stadium Shatre

Participants/Inclusion and exclusion criteria

Among the eligible volunteers and based on the desired criteria for entry: marriage, living in Islamshahr and suburbs, at least 30 years old and at most 50 years old, at least a diploma, not having any diseases affecting exercise intervention such as orthopedic diseases, Neuromuscular or cardiovascular diseases and not prohibiting sports activities by a doctor. Exclusion criteria: celibacy, under-diploma education, residence outside of Tehran, lack of regular participation of the subject in training, illness before and during the training protocol.

Intervention groups

The exercise protocol (exercise instructions) will be based on the recommendations of ACSM in the form of three sessions per week and for 60 minutes, which will be designed by a researcher. The exercise protocol will include three stages of warming up the main part of the exercise and cooling down.

Main outcome variables

The effects of a three-month period of sports activity on the levels of inflammatory factors in sedentary women with low socioeconomic status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230803059019N1**

Registration date: **2023-08-20, 1402/05/29**

Registration timing: **retrospective**

Last update: **2023-08-20, 1402/05/29**

Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Seyed Mohsen Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7730 4261

Email address

mohsentrainer@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-15, 1402/04/24

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of three-months of exercise intervention on the levels of inflammatory factors in women with low socioeconomic status	
Public title	The effects of three-months of exercise intervention on the levels of inflammatory factors in women with low socioeconomic status
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Sedentary healthy women low socioeconomic status
Exclusion criteria:	Diseases affecting exercise intervention such as orthopedic diseases, neuromuscular or cardiovascular diseases Prohibition of sports activities by the doctor
Age	From 30 years old to 50 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	SHAHED UNIVERSITY
Street address	Shahid University, Shahid Reza Ali Street, Shahid Oliya Blvd., Aftab City, Tehran
City	TEHRAN
Province	Tehran
Postal code	3319118651
Approval date	2023-07-10, 1402/04/19
Ethics committee reference number	

IR.SHAHED.REC.1402.044	
Health conditions studied	
<u>1</u>	
Description of health condition studied	Intense physical activity, despite its various benefits for general health, can cause possible damage to various body tissues due to the increase in oxidative stress through the increase in the production of reactive species. How to regulate inflammatory responses in exercise protocols is different in different people. the existing research shows that sports activity can have different results based on the intensity and duration.
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	TNF-alpha: anti-inflammatory cytokines are secreted in response to inflammation and are limiting and reversing the progressive process of inflammation.
Timepoint	In two stages, pre-test and post-test
Method of measurement	Blood sampling and measurement by ELISA device
<u>2</u>	
Description	IL-10 : anti-inflammatory cytokines are secreted in response to inflammation and are limiting and reversing the progressive process of inflammation.
Timepoint	In two stages, pre-test and post-test
Method of measurement	Blood sampling and measurement by ELISA device
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	In this research, we will have two groups of subjects with a pre-test and post-test design, which will include an experimental group and a control group, the experimental group includes 40 healthy sedentary women with low socioeconomic status and the control group includes 20 healthy sedentary women with economic status It is of low social status in Islamshahr city. The exercise protocol (exercise instructions) will be based on ACSM's recommendations in the form of three sessions per week for 60 minutes, which will be designed by a researcher. The exercise protocol will include three

stages of warming up the main part of the exercise and cooling down. The first stage 15 1 minute of warm-up (10 minutes of walking with moderate intensity, 5 minutes of stretching and rhythmic movements and movement exercises), the second stage of the main part of the exercise is 30 minutes (including selected exercises to improve cardiorespiratory endurance, muscular endurance, flexibility in a combination with equipment and with weight body) and the final 15-minute third stage (including 10 minutes of group games and entertainment to improve the spirit and collective vitality of the subjects and 5 minutes of light aerobic activity and stretching exercises will be performed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
SHAHED UNIVERSITYT
Full name of responsible person
AMIN ISANEJAD
Street address
Shahid University, Shahid Reza Ali Street, Shahid Oliya Blvd., Aftab City, Tehran
City
TEHRAN
Province
Tehran
Postal code
3319118651
Phone
+98 21 5522 8800
Email
ict@shahed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University
Full name of responsible person
AIMN ISANEJAD
Street address
Shahid University, Shahid Reza Ali Street, Shahid Oliya Blvd., Aftab City, Tehran
City
TEHRAN
Province
Tehran
Postal code
3319118651
Phone
+98 21 5522 8800
Email
ict@shahed.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

Proportion provided by this source

5

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
Shahed University
Full name of responsible person
Seyed Mohsen Hoseini
Position
STUDENT
Latest degree
Bachelor
Other areas of specialty/work
Physiology
Street address
Unit 2,Plates 6,ThreeOrchid Alley, Behesht Gharabi St.Hakimiya
City
TEHRAN
Province
Tehran
Postal code
1651875579
Phone
+98 21 7730 4261
Email
mohsentrainer@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Seyed Mohsen Hoseini
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Exercise Physiology
Street address
Hakimiya, Behesht Gharabi St., Orchid Alley, Three Plates 6, Unit 2

City
tehran
Province
Tehran
Postal code
1651875579
Phone
+98 21 7730 4261
Email
mohsentrainer@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Seyed Mohsen Hoseini
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Exercise Physiology
Street address
Hakimiya, Behesht Gharabi St., Orchid Alley, Three
Plates 6, Unit 2
City
tehran
Province
Tehran
Postal code
1651875579
Phone
+98 21 7730 4261
Email
mohsentrainer@gmail.com

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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be viewed after checking and coding and identifying individual information

When the data will become available and for how long

The start of access is 6 months

To whom data/document is available

Supervisor and internal and external referees of the thesis

Under which criteria data/document could be used

In order to improve the quality of future research

From where data/document is obtainable

To the university library

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

First, the university archive, then the supervisor or the library

Comments