

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of three months of exercise training intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status

Protocol summary

Study aim

The main objective: the effect of a physical activity intervention course on the level of physical activity, health indicators and quality of life

Design

We will have a semi-experimental research with two pre-test and post-test groups, which will include an experimental group and a control group. In this research, 80 women with low socio-economic status and low mobility will be included. The experimental group includes 40 sedentary healthy women with low socioeconomic status and the control group includes 40 healthy sedentary women with low socioeconomic status in Islamshahr city (inclusion criteria). All statistical operations are performed in spss and the differences between groups, their significance and the difference between pre-test and post-test are calculated.

Settings and conduct

The experimental group will perform physical activity with body weight in Imam Khomeini Stadium in Islamshahr, and the control group will continue their normal life.

Participants/Inclusion and exclusion criteria

Conditions for the entry of healthy middle-aged women with low socio-economic status/conditions for the non-entry of women with chronic diseases and high economic status

Intervention groups

sports activity

Main outcome variables

- Physical activity 2 - Quality of life 3 - Risk factors for vascular diseases 4 - Inflammatory indices (IL-6, CRP) 5 - Body composition 6 - Fasting blood sugar 7 - Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230804059023N1**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

Registration date

2023-08-10, 1402/05/19

Registrant information

Name

Bitra Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 5080

Email address

bitaranjbar1278@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of three months of exercise training

intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status		Province Tehran Postal code 3319118651 Approval date 2023-07-10, 1402/04/19 Ethics committee reference number IR.SHAHED.REC.1402.046
Public title The effects of three months of exercise training intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: The desired criteria for the entry and selection of subjects are selected for the study of healthy women The criteria for their entry is that they have a low socioeconomic status Exclusion criteria: Women should not have an acute disease such as cardiovascular disease, metabolic disease, etc These women do not have a high economic status Age No age limit Gender Female Phase N/A Groups that have been masked No information Sample size Target sample size: 80 Randomization (investigator's opinion) N/A Randomization description Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Single Other design features		Health conditions studied <u>1</u> Description of health condition studied Sports activity ICD-10 code ICD-10 code description Primary outcomes <u>1</u> Description Sports intervention Timepoint Investigating the effects of a three-month period of sports intervention on the amount of physical activity, quality of life, risk factors of cardiovascular diseases and some inflammatory indicators in women with low socioeconomic status Method of measurement International Physical Activity Questionnaire
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahed university Street address Block A, Floor 13.Medical Treatment and EducationShahrak Qods, Simai St. of Iran, Central Headquarters of the Ministry of Health,,Tehran, City Theran		Secondary outcomes <u>1</u> Description Quality of Life Timepoint The effects of three months of exercise training intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status. Method of measurement World Health Organization Quality of Life Questionnaire <u>2</u> Description Inflammatory indices (IL-6, CRP) Timepoint The effects of three months of exercise training intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status. Method of measurement Laboratory kits

Intervention groups

1

Description

Intervention group: exercise exercises will be performed on people, they will fill in quality of life questionnaires, physical activity level, household status information, barriers to sports participation. A checkup test is performed. The training time is 3 months (12 weeks) and the number of training sessions per week is 3 sessions and the class time is one hour, the exercises are done with body weight, the groups are randomly selected

Category

Other

2

Description

Control group: The control group does not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed University

Full name of responsible person

Amin Esanezhad

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Persian Gulf Highway, Shahed University

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Shahriyar Birjani

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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

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

Shahed University

Full name of responsible person

Bitar Ranjbar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Others

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professor

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

Yes - There is a plan to make this available

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

vThe effects of three months of exercise training intervention on physical activity levels, quality of life, cardiovascular disease risk factors and some inflammatory indices in women with low socioeconomic status.

When the data will become available and for how long

Access starts from 1402

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

true

From where data/document is obtainable

bitaranjbar1278@gmail.com

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

Request to the mentioned email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Bitar Ranjbar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Others

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