Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of two different modes of concurrent training on heart performance, biochemical and functional factors associated with sarcopenia in patients with heart failure

Protocol summary

Study aim

Comparison of the effect of two different modes of concurrent training on heart performance, biochemical and functional factors associated with sarcopenia in patients with heart failure

Design

A clinical trial with control group, with parallel groups, randomized, phase 3 on 30 patients. For randomization, restricted randomization with the random allocation rule is used.

Settings and conduct

In order to get familiar with the research implementation process, completion of the consent form and initial assessment, 2 meetings will be held. Then patients participate in 8 weeks of 2 concurrent training methods in Ghalb Al-Zahra Hospital. After 8 weeks of training intervention, 2 more sessions will be held with an interval of 48 hours from the last training session in order to measure the secondary level.

Participants/Inclusion and exclusion criteria

The participants are male and female heart failure patients. The conditions for entering include the age range of 55 to 65 years, ejection fraction equal to and less than 49, and hemodynamic stability for at least 3 months before participating in the research. Also, the conditions of not entering include infection, pulmonary restriction, smoking, significant cardiac arrhythmia, restriction and prohibition of sports activities due to angina or peripheral artery occlusion disease.

Intervention groups

Concurrent training on the same days (resistance training and high intensity interval training on the same day), concurrent training on different days (resistance training and high intensity interval training on different days) and control (they don't do any exercise training).

Main outcome variables

Peak oxygen consumption; 6-minute walking distance test; Appendicular skeletal muscle index; Handgrip strength; Gait speed; Static balance; Left ventricular ejection fraction; Fractional shortening; C-reactive protein; Testosterone; Cortisol

General information

Reason for update

Acronym

HF با اختصار Heart Failure نارسایی قلبی یا

IRCT registration information

IRCT registration number: **IRCT20240124060802N1**
Registration date: **2024-02-07, 1402/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-07, 1402/11/18**
Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

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Name of organization / entity

The University of Shiraz

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-03, 1402/11/14

Expected recruitment end date

2024-03-17, 1402/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two different modes of concurrent training on heart performance, biochemical and functional factors associated with sarcopenia in patients with heart failure

Public title

Comparison of the effect of two different modes of concurrent training on heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 55 to 65 years Ejection fraction equal to and less than 49 Hemodynamic stability for at least 3 months before participating in the research

Exclusion criteria:

Infection Pulmonary restriction Smoking Significant cardiac arrhythmia Limiting or prohibiting exercise due to angina or peripheral arterial occlusive disease

Age

From **55 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization method with random allocation rule is used. The randomization unit is an individual that is done using a ball in a container. Also, the allocation concealment method is used with sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Psychology and educational Sciences- Shiraz University

Street address

2nd Unit Right Side, 5/12 Alley, Ahmadabad Soghad Town, Allah Sq., Modarres Blvd.

City

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Province

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Postal code

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Approval date

2023-11-08, 1402/08/17

Ethics committee reference number

IR.US.PSYEDU.REC.1402.080

Health conditions studied

1

Description of health condition studied

Heart failure, Sarcopenia

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Peak oxygen consumption: In this research, peak oxygen consumption is the maximum aerobic power, which is measured by the modified Bruce test and the respiratory gas analysis device.

Timepoint

Measuring peak oxygen consumption before the intervention and 48 hours after the end of the intervention

Method of measurement

Treadmill and respiratory gas analysis device

2

Description

6-minute walking distance: In this research, 6-minute walking distance means the distance traveled in 6 minutes, which is evaluated by the 6-minute walking test.

Timepoint

Measuring the distance of 6 minutes of walking before the intervention and 48 hours after the end of the intervention

Method of measurement

Stopwatch

3

Description
Appendicular skeletal muscle index: In this research, appendicular skeletal muscle index refers to the mass of upper and lower body skeletal muscles in terms of height, which is measured by DEXA.
Timepoint
Measuring the appendicular skeletal muscle index before the intervention and 48 hours after the end of the intervention
Method of measurement
DEXA device

4

Description
Hand grip strength: It means the maximum hand grip strength, which is measured with a hand grip dynamometer.
Timepoint
Measuring the hand grip strength before the intervention and 48 hours after the end of the intervention
Method of measurement
Handgrip device

5

Description
Gait speed: It means the most comfortable walking speed on the 8-meter path, which is measured by recording the time.
Timepoint
Measuring the gait speed before the intervention and 48 hours after the end of the intervention
Method of measurement
Stopwatch

6

Description
Static balance: means the ability or lack of ability to perform the static balance test of one leg for 10 seconds.
Timepoint
Measuring the static balance before the intervention and 48 hours after the end of the intervention
Method of measurement
Stopwatch

7

Description
Left ventricular ejection fraction: In this study, left ventricular ejection fraction is a percentage of the end-diastolic volume that is ejected from the heart in each beat and is measured by echocardiography.
Timepoint
Measurement of left ventricular ejection fraction before the intervention and 48 hours after the end of the intervention
Method of measurement
Echocardiography device

8

Description
Fractional shortening: Fractional shortening refers to the percentage change in the dimensions of the left ventricle during systole, which is measured by echocardiography.
Timepoint
Measurement of fractional shortening before the intervention and 48 hours after the end of the intervention
Method of measurement
Echocardiography device

9

Description
C-reactive protein: It means its serum concentration, which is measured by ELISA method using a special kit.
Timepoint
Measurement of C-reactive protein before the intervention and 48 hours after the end of the intervention
Method of measurement
Special kit for measuring C-reactive protein amount and required blood collection equipment

10

Description
Testosterone: It means its serum concentration which is measured by ELISA method using a special kit.
Timepoint
Testosterone measurement before the intervention and 48 hours after the end of the intervention
Method of measurement
A special kit for measuring the amount of testosterone and the necessary blood collection equipment

11

Description
Cortisol: It means its serum concentration which is measured by ELISA method using a special kit.
Timepoint
Cortisol measurement before the intervention and 48 hours after the end of the intervention
Method of measurement
A special kit for measuring the amount of cortisol and the necessary equipment for blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It is the concurrent training group on the same days, where a combination of resistance training and high intensity interval training are performed on the same day for 8 weeks. The resistance

training protocol includes 1 to 2 sets of 10 to 15 repetitions, with a 1-minute rest between sets and a 2-minute rest between movements. Exercises with dumbbells are performed with an intensity of 50 to 65% of 1 repetition maximum, and in exercises with elastic bands, start with low resistance elastic bands (yellow) and if the person can perform the exercise in question with the rate of perceived exertion below 5 on the modified Borg scale, it also goes to colors with more resistance (red, green and blue). High intensity interval training also includes 4 repetitions of 4 minutes of exercise with an intensity of 80-90% of the peak oxygen consumption on the ergometer cycle, which are separated by 3 active rests with an intensity of 50% of the peak oxygen consumption on the cycle ergometer.

Category

Rehabilitation

2

Description

Intervention group: It is the concurrent training group on different days, where resistance training and high intensity interval training are performed on different for 8 weeks. The resistance training protocol includes 1 to 2 sets of 10 to 15 repetitions, with a 1-minute rest between sets and a 2-minute rest between movements. Exercises with dumbbells are performed with an intensity of 50 to 65% of 1 repetition maximum, and in exercises with elastic bands, start with low resistance elastic bands (yellow) and if the person can perform the exercise in question with the rate of perceived exertion below 5 on the modified Borg scale, it also goes to colors with more resistance (red, green and blue). High intensity interval training also includes 4 repetitions of 4 minutes of exercise with an intensity of 80-90% of the peak oxygen consumption on the ergometer cycle, which are separated by 3 active rests with an intensity of 50% of the peak oxygen consumption on the cycle ergometer.

Category

Rehabilitation

3

Description

Control group: The control group is that in this group, patients do not do any type of exercise for 8 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghalb Al-Zahra hospital

Full name of responsible person

حجت الله روستا

Street address

Ghalb Al-Zahra Hospital, Astane Junction, Siboyeh Blvd., Shiraz

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۷۱۶۴۹۵۴۹۳۷

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghalb Al-Zahra hospital

Full name of responsible person

Hojjatollah Roosta

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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

Ghalb Al-Zahra hospital

Proportion provided by this source

80

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

Other

2

Sponsor

Name of organization / entity

The University of Shiraz

Full name of responsible person

Mohammad Moazeni
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Shiraz University, Eram Sq., Jomhoori Eslami Blvd., Shiraz
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https://shirazu.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
The University of Shiraz

Proportion provided by this source
20

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
The University of Shiraz
Full name of responsible person
Zahra Karimi Ahmadabadi
Position
PhD candidate
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Exercise physiology
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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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All subjects' data (non-identifiable), study protocol, statistical analysis map, informed consent form and clinical study report will be published.

When the data will become available and for how long

Access starts 6 months after results and article are published

To whom data/document is available

Researchers working in academic, scientific and medical institutions

Under which criteria data/document could be used

In order to be used for future research

From where data/document is obtainable

1. Zahra Karimi Ahmadabadi by email: setarekarimi374@gmail.com Faculty of Educational Sciences and Psychology, Shiraz University 2. Dr. Javad Nemati by email: nemati_phy@yahoo.com Faculty of Educational Sciences and Psychology, Shiraz University

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

Correspondence by email

Comments