

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Determining the effect of two protocols of high-intensity intermittent training (HIIT) and moderate-intensity continuous training (MICT) on aerobic performance, anthropometric indices and ejection fraction in patients with chronic heart failure

Protocol summary

Study aim

Determining the effect of two protocols of high-intensity intermittent training (HIIT) and moderate-intensity continuous training (MICT) on aerobic performance, anthropometric indices and ejection fraction in patients with chronic heart failure

Design

Clinical trial without control group, with parallel groups, without blinding, on 70 patients, randomization by computer numbers.

Settings and conduct

Eligible patients referring to the rehabilitation clinic of Fatemeh Zahra Sari Hospital are assigned to one group of HIIT exercises and another group with MICT exercises. The exercise program will be under cardiac monitoring 3 times a week for 4 weeks. The MICT session will consist of aerobic exercise starting at 40-50% and progressing to 70-80% HRR. Each HIIT session consists of work intervals of 30 sec to 4 min with a maximum intensity of 85%-90% HRR separated by 1-3 min rest intervals with an intensity of 50-70%.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) age 30 to 70 years 2) sinus rhythm 3) agreement and compliance with our study protocol 4) possibility to sign the informed consent form Exclusion criteria: 1) people with peripheral vascular disease, 2) ventricular premature beats or other arrhythmias 3) cardiac conduction defects 4) history of pacemaker placement 5) significant valvular heart disease 6) arterial blood pressure greater than 180/100 mm mercury, 7) functional limitations (such as physical limitations) and 8) concurrent participation in another clinical trial.

Intervention groups

Our study will be conducted on patients with chronic heart failure referred to the Cardiovascular Rehabilitation Center of Fatemeh Zahra Sari Heart Hospital.

Main outcome variables

Primary outcomes includes ejection fraction and 6-minute walk test and secondary outcomes includes LV size, RV size, LV Global Strain, RV Function and anthropometric indices.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240126060809N1**

Registration date: **2024-01-30, 1402/11/10**

Registration timing: **prospective**

Last update: **2024-01-30, 1402/11/10**

Update count: **0**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Najmeh Ghorbanian Bahnamiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 6552

Email address

njm.ghorbanian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-31, 1402/11/11

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the effect of two protocols of high-intensity intermittent training (HIIT) and moderate-intensity continuous training (MICT) on aerobic performance, anthropometric indices and ejection fraction in patients with chronic heart failure

Public title
Determining the effect of two protocols of high-intensity intermittent training (HIIT) and moderate-intensity continuous training (MICT) on aerobic performance, anthropometric indices and ejection fraction in patients with chronic heart failure

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age 30 to 70 years sinus rhythm Agreeing and complying with our study protocol The possibility of signing an informed consent form
Exclusion criteria:
People with peripheral vascular disease Ventricular premature beats or other arrhythmias Cardiac conduction defects History of cardiac pacemaker insertion Significant valvular heart disease Arterial blood pressure greater than 180/100 mm Hg Functional limitations (such as physical limitations) Concurrent participation in another clinical trial

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using computer generated random numbers from 1 to 70. Numbers will be placed in envelopes in the package. Participants with even numbers will be assigned to the HIIT exercise protocol group and odd numbers to the MICT exercise protocol group.

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
Ethics Committee of Mazandaran University of Medical Sciences, Fateme Zahra Hospital
Street address
Serah Joibar, the beginning of Vali Asr Highway, the headquarters of Mazandaran University of Medical Sciences and Health Services
City
Sari
Province
Mazandaran
Postal code
۳۳۹۷۱-۴۸۱۵۷
Approval date
2024-01-14, 1402/10/24
Ethics committee reference number
IR.MAZUMS.REC.1402.585

Health conditions studied

1

Description of health condition studied
Chronic Heart Failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Ejection fraction
Timepoint
Before the intervention and at the end of 12 cardiac rehabilitation sessions
Method of measurement
Echocardiography device

2

Description
Aerobic performance
Timepoint
Before the intervention and at the end of 12 cardiac rehabilitation sessions
Method of measurement
6-min Walking Test

Secondary outcomes

1

Description

Left ventricular size

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Echocardiography device

2

Description

left atrium size

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Echocardiography device

3

Description

Left ventricular global strain

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Echocardiography device

4

Description

Right ventricular function

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Echocardiography device

5

Description

Body mass index

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Body analyze device

6

Description

Skeletal muscle mass

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Body analyze device

7

Description

Body fat mass

Timepoint

Before starting cardiac rehabilitation and at the end of 12 rehabilitation sessions

Method of measurement

Body analyze device

Intervention groups

1

Description

Intervention group: the first group of MICT exercise rehabilitation includes 20-60 minutes of progressive aerobic exercise including; Treadmill running, free running, manual ergometer, and stationary bike will receive VO2 reserve (HRR (Heart rate reserve)) starting at 40%-50% and progressing to 70%-80%. If HRmax is unknown, RPE (Rate of Perceived Exertion) is used to guide exercise intensity. Light, RPE less than 12 or equivalent to 40% HRR. A little hard with RPE 12-13 or average with 40-59% HRR. Hard with RPE 14-16 or equivalent to 60-80% HRR.

Category

Rehabilitation

2

Description

Intervention group: The second group receives a HIIT rehabilitation session including work intervals of 30 seconds to 4 minutes with a maximum intensity of 85%-90% HRR with rest intervals of 1-3 minutes with an intensity of 50-70%. If HRmax is unknown, RPE (Rate of Perceived Exertion) is used to guide exercise intensity. Light, RPE less than 12 or equivalent to 40% HRR. A little hard with RPE 12-13 or average with 40-59% HRR. Hard with RPE 14-16 or equivalent to 60-80% HRR.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Zahra Hospital, Sari

Full name of responsible person

Najmeh Ghorbanian Bahnamiri

Street address

Cardiopulmonary Rehabilitation Center, Fatemeh Zahra Hospital, Army Boulevard, Imam Hossein Square

City

Sari

Province

Mazandaran

Postal code

4818813371

Phone

+98 11 3332 3023

Email

njm.ghorbanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnejad

Street address

Moalem Square, Sari City, Mazandaran Province,
Research and Technology Deputy Building

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3354 3081

Email

pebrahimnejad@mazums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

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

Mazandaran University of Medical Sciences

Full name of responsible person

Najmeh Ghorbanian Bahnamiri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

Street address

3rd floor, No. 97, 6 Allameh Hassanzadeh, 6 Rezvan

Alley, Imam Reza St., Amol

City

Amol

Province

Mazandaran

Postal code

4713964665

Phone

+98 11 3575 2775

Email

njm.ghorbanian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zhra Madani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

second floor, unit 4, corner of 3 Kushasang St.,
Kushasang St., Rodaki St. Sari

City

Sari

Province

Mazandaran

Postal code

4816786501

Phone

+98 11 3360 8570

Email

shd_madani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Najmeh Ghorbanian Bahnamiri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

Street address

3rd floor, No. 97, 6 Allameh Hassanzadeh, 6 Rezvan
Alley, Imam Reza St., Amol

City

Amol

Province

Mazandaran

Postal code

4713964665

Phone

+98 11 3575 2775

Email

njm.ghorbanian@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available