

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of rehabilitation at home compared to rehabilitation at standard center on risk factors, quality of life and adherence to treatment in patients with cardiac disease

Protocol summary

Study aim

Determining the effect of cardiac rehabilitation at home on risk factors, quality of life and adherence to treatment in comparison with cardiac rehabilitation in the rehabilitation center in patients with cardiac disease

Design

Clinical trial with out control group, with parallel groups, randomized using random allocation software

Settings and conduct

The study is performed on 62 patients with heart disease referred to Afshar Hospital in Yazd, 31 patients are rehabilitated in the standard center and 31 patients are rehabilitated at home, and the effect of exercise on quality of life, risk factors and adherence to treatment is evaluated and compared. The study is single blind in which subjects do not know what group they belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 75 years, clinically stable condition Non-inclusion criteria: Arrhythmia, uncontrolled blood pressure and diabetes, physical disability, dissatisfaction to participate in the study

Intervention groups

Intervention group 1: Exercise is done in Afshar Rehabilitation Center using treadmills and bicycles.
Intervention group 2: Doing exercise at home by walking.

Main outcome variables

Reduction of blood lipids, blood sugar, improvement of quality of life, adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210927052610N1**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **retrospective**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Najmeh Dehghanizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 9100 2550

Email address

n.dehghanizadeh@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

2020-09-22, 1399/07/01

Actual recruitment end date

2020-12-21, 1399/10/01

Trial completion date

2021-03-21, 1400/01/01

Scientific title

Investigating the effect of rehabilitation at home compared to rehabilitation at standard center on risk factors, quality of life and adherence to treatment in patients with cardiac disease

Public title

Effect of exercise in patients with cardiac disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Cardiac out put more than 40% No ventricular arrhythmias and atrial fibrillation Having a normal answer to exercise test Age of 30_75 years Clinically stable

Exclusion criteria:
Arrhythmia and uncontrolled blood pressure Uncontrolled Diabetes Systemic and pulmonary diseases limiting exercise Physical disabilities and any restrictive exercise conditions Severe valvular cardiac disease and known or suspected aortic dissection Patient dissatisfaction

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To perform random allocation and divide the samples between two groups A (exercise in the center) and group B (exercise at home), first using random allocation software version 1, we generate a random sequence by simple random allocation method. Each of numbers 1 to 62 is assigned to the intervention group A or B. When patients are referred, the first person eligible for number 1 is taken, and the last person eligible for number 62 is assigned, respectively, and assigned to the group. A and B It is determined that in order to be blind to the random allocation of clients, the random allocation table is given to a third person who is out of the study and the researcher of the intervention group calls the third person by phone or text message before specializing.

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 Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam blvd, Professor Hesabi blvd.

City

Yazd

Province

Yazd

Postal code

8915173149

Approval date

2020-08-02, 1399/05/12

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.093

Health conditions studied

1

Description of health condition studied

Cardiac patients rehabilitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life score

Timepoint

The quality of life questionnaire sf36 is completed before the start of the rehabilitation program and after the completion of rehabilitation sessions

Method of measurement

Quality of Life Questionnaire short form 36

2

Description

Lipid profile and fasting blood glucose

Timepoint

Lipid profile and fasting blood glucose is measured before the start of the rehabilitation program and after the completion of rehabilitation sessions

Method of measurement

Level of fasting blood glucose and lipid profile is measured in labratory via Through blood sampling

3

Description

Treatment adherence

Timepoint

The treatment adherence form is completed at the beginning and end of the rehabilitation program

Method of measurement

Treatment adherence medanlo questionnaire

Secondary outcomes

1

Description

Quality of life score
Timepoint
Sf36 form is completed before exercise and after 36 exercise sessions
Method of measurement
Short Form 36 quality of life questionnaire

2

Description
Treatment adherence score
Timepoint
Modanloo questionar form is completed before exercise and after 36 exercise sessions
Method of measurement
Treatment Adherence madanloo questionnaire

3

Description
Lipid profile level
Timepoint
Lipid profile is measured before the start of exercise and after 36 sessions of rehabilitation
Method of measurement
Blood lipids are measured in the laboratory through a blood sample

4

Description
Fasting blood glucose
Timepoint
Fasting blood sugar levels are measured before exercise and after 36 sessions of rehabilitation
Method of measurement
Fasting blood glucose is measured in the laboratory through a blood sample

5

Description
Blood pressure level
Timepoint
At the beginning of the rehabilitation program and at the end of the rehabilitation sessions
Method of measurement
Use a sphygmomanometer

Intervention groups

1

Description
Intervention group 1:Doing exercise in a standard center Using treadmills and bicycles ,3 sessions per week, each session 50 minutes, a total of 36 sessions over 3 months
Category
Rehabilitation

2

Description

Intervention group 2: Exercise at home, 30 minutes of walking daily, 5 days a week for 3 months
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Afshar rehabilitation center
Full name of responsible person
Mohammad Reza Vafai Nasab
Street address
Afshar hospital; Jomhoori blvd
City
Yazd
Province
Yazd
Postal code
8917945556
Phone
+98 35 3525 5011
Fax
+98 35 3525 3335
Email
Afsharhospital@ssu.ac.ir
Web page address
<https://web.ssu.ac.ir/>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud mirzai
Street address
Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam blvd, Professor Hesabi blvd
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3410
Fax
+98 35 3820 3414
Email
dr.n.dehghanizadeh@gmail.com
Web page address
<https://web.ssu.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Najmeh Dehghanizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Unit 4, Floor 5, phase 5, Ahmadi Roshan residential complex, Ebne Sina blvd

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Phone

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Najmeh Dehghanizadeh

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

Yazd University of Medical Sciences

Full name of responsible person

Najmeh Dehghanizadeh

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Confirming the responsible person

From where data/document is obtainable

Dr najmeh dehghanizadeh

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

By sending a request to the email of the person in

charge dr.n.dehghanizadeh@gmail.com
Comments