Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of aerobic and resistance exercise program on sleep quality in the elderly patients with heart failure

Protocol summary

Summary

(1) Objectives: “Effects of aerobic and resistance exercise program on sleep quality in the elderly male patients with heart failure”. (2) Design: This study is a true-experimental, clinical trial design that population is the male elderlies with CHF (type 2&3). Sample size is 60 Patients in interventional and control groups (30 patients in one group). Sampling method is consecutive that will be randomized to an experimental (intervention) group or a wait-list control group by blocking method. Field of study was Echocardiography unit and exercise hall of Ramsar Imam Sadjad hospital. (3) Setting and conduct: In order to collect data will be used of Questionnaire consisted of demographic variables and sleep quality questionnaire. Sleep quality questionnaire will be completed in before and after intervention and will be compared. (4) Participants including major eligibility criteria: Male Participants must be at least 60 years of age and 74 years maximum with history minimum of 6 month. Exclusion criteria: A history of coronary artery disease on cardiac angiogram of > 70% ؛sustained ventricular arrhythmias؛ Heart Rate >120 bpm (5):) Intervention: The experimental group received the intervention 4 week 3؛ times in week for 30 minute combined aerobic and resistance training exercise program). In intervention group patients received the Aerobic and resistance exercises program in 3 months, 3 times in week. the wait-list control group: received usual care for heart failure patients. (6) Main outcome measures: The primary outcome improved quality of sleep Secondary outcomes improve quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120430930N2**
Registration date: **2017-05-27, 1396/03/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Babol University of Medical Sciences.

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2016-12-15, 1395/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of aerobic and resistance exercise program on sleep quality in the elderly patients with heart failure

Public title

The effect of exercise on sleep of elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Participants male must be at least 60 years of age and 74 years maximum diagnosed with systolic heart failure with an ejection fraction of less than or equal to 40% confirmed by echocardiogram cardiologists Imam Sadjad was stablished in Ramsar؛ participants with history minimum of 6 month؛ ability to Persian language speaking and comprehension.
Exclusion criteria: A history of coronary artery disease on cardiac angiogram of > 70% physically limiting angina usual daily activity؛ sustained ventricular arrhythmias requiring antiarrhythmic medications , 2nd or 3rd degree heart block؛ Heat Rate >120 bpm, neurologic or orthopedic condition that limits physical ability to exercise.

Age

From **60 years** old to **74 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized trial by blocking method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran

City

Babol

Postal code

4717647745

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

MUBABOL.REC.1395.166

Health conditions studied

1

Description of health condition studied

Congestive heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

Primary outcomes

1

Description

Improve sleep quality

Timepoint

before and after intervention at the end of week 12

Method of measurement

Questionnaire consisted of demographic variables؛ sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

1. Intervention group: The experimental group received the intervention (12-week combined aerobic and resistance training exercise program). In intervention group patients received the Aerobic and resistance exercises program in 3 months, 3 times in week.

Category

Lifestyle

2

Description

2. Control group: The wait-list control group with no intervention does not take place.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ramsar Imam Sadjad hospital

Full name of responsible person

Zahra Fotoukian

Street address

Infront of the Post office - Mottahari street

City

Ramsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Babol University of Medical Sciences Babol University

Full name of responsible person
Doctor Ali Akbar Moghadamnia

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Babol University of Medical Sciences, Ganjafrooz Street , Babol , Mazandaran

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Babol

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research of Babol University of Medical Sciences Babol University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty