

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Aerobic and Resistance Exercise Program on Physical_Psychological Adaptation in the Male elderly patients with Heart Failure

Protocol summary

Summary

1. Objectives: Effects of Aerobic and Resistance Exercise Program on Physical_Psychological Adaptation in the elderly patients with Heart Failure. 2. Design: A randomized, clinical trial design. The study population is the male elderlies with heart failure (type 2&3). Sample size: 60 Patients in experimental and control groups (30 patients in the group). Sampling is consecutive that will be randomized to an experimental or a control group by blocking method. Study Field: Echocardiography unit and exercise hallway located at Ramsar Imam Sadjad hospital. Methods: It will be used of a 3-dimentional Questionnaire consisted of; demographic variables, Psychological health Questionnaire of patients with heart failure and 6-Minute Walk Test (MWT) for measuring psychological and physical adaptation. 3.Participants: The male elderly patients with CHF must be at least 60 years of age and 74years maximum; the participants with history minimum of 6 months. Exclusion criteria: Patients with a history of Coronary Artery Disease on cardiac angiogram of >70%, sustained ventricular arrhythmias, and HR >120 bpm. 4. Interventions: Experimental group; It will do the aerobic exercise (slow walking) at the 12 weeks, 3 times per week within 30 minutes. After the end of 4 weeks, Light Resistance exercise program (using Dumbbell 500gr; within 30 minutes, 3 times per week) will do until the end of week 12. The control group: Participants in the control group will not receive any exercise intervention. 5. The main outcome variables: The primary outcome; improved physical and psychological adaptation. The secondary outcome; improved quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111630930N1**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

پورحبیب علی

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

a.pourhabib@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, 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 Physical_Psychological Adaptation in the Male elderly patients with Heart Failure

Public title

The effect of exercise on Physical_Psychological Adaptation in the Male elderly patients with Heart Failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The elderly patients with Heart Failure must be at least 60 years of age and 74years maximum; diagnosed with systolic heart failure with an ejection fraction of less than or equal to 40%, confirmed by echocardiogram and have approval from the primary cardiologist; participants with history minimum of 6 month; ability to Persian language speaking and comprehension. Exclusion criteria: History of coronary artery disease with the stenosis of >70% on cardiac angiogram; sustained ventricular arrhythmias requiring anti-arrhythmic medications; 2nd or 3rd-degree heart block, and HR >120 bpm; the patients with neurologic or orthopedic conditions that limits their 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

47176-47745

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 Physical adaptation

Timepoint

before and after intervention at the end of week 12

Method of measurement

Questionnaire consisted of demographic variables, Questionnaire Psychological adaptation of cardiac disease, 6 Minute Walk test (MWT)

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: Implementation of exercise interventions in the experimental group; the patients will do slow walking (light aerobic exercises) in the 12 weeks, 3 times per week within 30 minutes. In addition, participants in the intervention group will be instructed; "Before and after exercise do heating and cooling exercises for 5 to 10 minutes." They should walk for 30-minute after the warm-up exercise. After 4 weeks, in addition to walking, light resistance exercise program (using Dumbbell 500gr; 3 times per week, within 30 minutes) will be implemented until the end of the week 12.

Category

Lifestyle

2

Description

2. Control group: The control group will not receive any interventions.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ramsar Imam Sadjad hospital

Full name of responsible person

Ali Pourhabib

Street address

Enghelab Square

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

Street addressBabol University of Medical Sciences, Ganjafooz
Street , Babol , Mazandaran**City**

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding sourceVice 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****Name of organization / entity**

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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