Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Protocol summary

Study aim

Comparison of Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Design

The clinical trial has a control group, is single-blind, randomly selected with a concealed envelope, and is on 36 patients with chronic heart failure.

Settings and conduct

The study location is Emam Reza Educational, Research, and Treatment Center in Mashhad. Patients and physicians have been blinded. Informed consent, a six-minute walk test, blood pressure measurement, an ECG Holter monitor, a lipid profile test, and TNF alpha are taken from all samples.

Participants/Inclusion and exclusion criteria

Among the patients with chronic heart failure referred to Emam Reza Educational, Research, and Treatment Center in the age range of 50 to 70 years and with an ejection fraction of less than 50%, they are selected by the available sampling method.

Intervention groups

There are three groups in this study. Using a concealed envelope, the samples are simply randomly assigned to one of three groups. Group 1: Individuals only receive standard medication treatment. Group 2: Individuals In addition to standard medication treatment, perform routine breathing exercises. Group 3: Individuals In addition to standard medication treatment, perform gradual, slow breathing exercises guided by a respirometer Biofeedback.

Main outcome variables

Basic respiration rate; Inflammation; Heart Rate Variability

General information

Reason for update

increasing the sample size The description of the control group was modified, where subjects received only standard drug treatment. recording the completion of the sample Recording the date of the end of the study Changing the status of the responsible person

Acronym

IRCT registration information

IRCT registration number: **IRCT20210426051093N1**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**
Update count: **1**

Registration date

2021-12-04, 1400/09/13

Registrant information

Name
Mahdi Rahmati-Yami
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date
2022-01-08, 1400/10/18
Actual recruitment end date
2023-02-13, 1401/11/24
Trial completion date
2023-03-13, 1401/12/22

Scientific title
Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Public title
Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Class II and III heart failure based on NYHA criteria Having suffered from heart failure for the past 3–5 years Clinical status and stable hemodynamics at least one month before entering the study Ejection fraction less than 50% based on echocardiography Being treated with standard medication Age range: 50 to 70 years
Exclusion criteria:
Unstable angina and complex ventricular arrhythmias The occurrence of myocardial infarction in the past year having pacemaker During the last six months, have bypass surgery or angioplasty. Participate in other exercise programs six months before the start of the study. The existence of musculoskeletal disorders that prevent normal walking Existence of cognitive disorders Lack of personal desire to cooperate History of lung disease, smoking, angina, heart attack or heart surgery (less than six months), orthopedic or neurological diseases, steroid therapy, or chemotherapy
Age
From **50 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **36**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of the groups by a researcher using a Concealed envelope method.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is a one-way blinded controlled clinical trial, and the cardiologist and patients are not aware of being in the intervention or control group.
Placebo
Not used
Assignment
Parallel
Other design features
Design and construction of a respirometer biofeedback device for respiratory training of the subjects

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tarbiat Modares University Ethics Committee
Street address
Tehran Jalal AleAhmad Nasr
City
Tehran
Province
Tehran
Postal code
14115111
Approval date
2021-10-23, 1400/08/01
Ethics committee reference number
IR.MODARES.REC.1400.200

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
The basic rate of respiration
Timepoint
48 hours before the intervention and 48 hours after the end of four weeks of intervention
Method of measurement
Average rate of five minutes of respiration based on respirometer biofeedback.

2

Description
Inflammation
Timepoint
48 hours before the intervention and 48 hours after the

end of four weeks of intervention

Method of measurement

According to the report of TNF-alpha in an enzyme-linked immunosorbent assay device

3

Description

Heart Rate Variability

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Holter monitoring device

Secondary outcomes

1

Description

Quality of Life

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Minnesota Quality of Life Questionnaire Score

2

Description

Cholesterol

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Based on an autoanalyzer device's report from a person's blood serum

3

Description

Triglyceride

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

4

Description

High-Density Lipoprotein (HDL)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

5

Description

Low-Density Lipoprotein (LDL)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

6

Description

Systolic blood pressure at rest

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the average Holter blood pressure report

7

Description

Diastolic blood pressure at rest

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the average Holter blood pressure report

8

Description

Rate of perceived exertion

Timepoint

48 hours before and after the six-minute walk test and 48 hours after the end of four weeks of intervention before and after the six-minute walk test

Method of measurement

Based on the Borg scale

9

Description

Standard Deviation of NN Intervals (SDNN)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

10

Description

Root Mean Square of Successive Differences between normal heartbeats (RMSSD)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

11

Description

The Percentage of adjacent NN intervals that differ from each other by more than 50 ms (pNN50)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

12

Description

Physical Functional Performance

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Based on the 6-Minute Walk Test (6MWT)

Intervention groups

1

Description

Control group: Individuals only receive standard medication treatment.

Category

Treatment - Drugs

2

Description

Intervention group; in the second group, or Routine Breathing Exercises group, for four weeks, in the first week for 20 minutes, and with an increase of 3.5 minutes at the beginning of the second, third, and fourth weeks, in the fourth week for 30 minutes, the person does these exercises. The patient is asked to lean back in the chair and sit in a comfortable chair. The patient then holds an incentive spirometry in his hand and, after a normal exhalation, places the spirometry mouthpiece in his or her mouth and performs inhalation slowly and deeply as much as possible. The patient performs this operation three times at the beginning of each week, and its average is recorded as the maximum respiratory capacity. The patient is then asked to perform a deep breathing exercise with 60% of the base volume obtained. This exercise is given twice a day, 10 times each time, with 30 to 60 seconds of rest between each exercise. At the beginning of each week, two exercises will be added to the exercises, so that at the end of the fourth week, this exercise will be performed 16 times.

Category

Rehabilitation

3

Description

Intervention group, In the third group, or Gradual Device-guided Slow Breathing Exercises, for four weeks, in the first week for 20 minutes, and with an increase of 3.5 minutes at the beginning of the second, third, and fourth weeks, in the fourth week for 30 minutes. Under the guidance of Respirometer Biofeedback, observing the overload principle, a total reduction of 50% of the respiratory rate is applied, which in four stages is 12.5% compared to the basic respiratory rate, which is measured at the beginning of each week. The basal rate of respiration and the rate of decrease in the rate of respiration relative to the basal rate obtained at the beginning of each week are recorded and reported for each individual.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Educational, Research, and Treatment Center

Full name of responsible person

Farveh Vakilian

Street address

Emam Reza Educational, Research, and Treatment Center, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
Roya ravanbod
Position
Associate Professor
Latest degree
Ph.D.
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Person responsible for scientific inquiries

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Roya ravanbod
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

Part of the data

When the data will become available and for how long

8 months after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

For medical and research purposes

From where data/document is obtainable

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

Approval of supervisors

Comments