

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparing the acute effects of resistance exercise with intensity of 50%1RM and 75%1RM on heart rate variability in patients with heart failure

#### Protocol summary

##### Study aim

comparing the acute effects of resistance exercise with the intensity of 50%1RM and 75%1RM on autonomic function, cardiac function and functional status of patients with heart failure

##### Design

Three-arm parallel-group randomized-controlled trial with blinded patients, concealed randomization sequence

##### Settings and conduct

Due to the fact that the Persian form of the subjective exercise experience scale is not available, the validity and reliability of this scale were examined among a healthy matched control population of 128 volunteer adults who will request to walk for 30 minutes after consent. The eligible patients refer to the hospital after signing informed consent and will be evaluated for autonomic function, cardiac function, functional status, and their psychological response to exercise, then allocate to one of the 3 groups randomly. The intervention consists of a single session resistance exercise and at the end of the intervention again will be evaluated for the above-mentioned variables.

##### Participants/Inclusion and exclusion criteria

class II, III of stable patients with heart failure, duration of disease:1-4 years, BMI: 25-32kg/m<sup>2</sup>, optimal medical treatment, the ability of communication; pacemaker, cardiac surgery during last 6 months, myocardial infarction during last year, personal withdrawal

##### Intervention groups

1-resistance training with intensity of 50%1RM + aerobic training  
2--resistance training with intensity of 75%1RM+ aerobic training  
3-control group(aerobic training)

##### Main outcome variables

Heart rate variability(time and frequency dominants), hemodynamics (heart rate, blood pressure, rate pressure product), subjective exercise experiences scale, six minute walking test distance

#### General information

##### Reason for update

We have to change the project to some extent because of the Coronavirus and stopping the project due to the traffic ban for high-risk patients like heart failure.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190605043821N1**  
Registration date: **2019-08-06, 1398/05/15**  
Registration timing: **prospective**

Last update: **2021-01-04, 1399/10/15**

Update count: **1**

##### Registration date

2019-08-06, 1398/05/15

##### Registrant information

###### Name

Marzieh Saeidi

###### Name of organization / entity

Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-07, 1398/05/16

##### Expected recruitment end date

2021-03-06, 1399/12/16

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the acute effects of resistance exercise with intensity of 50%1RM and 75%1RM on heart rate variability in patients with heart failure

**Public title**

effects of resistance training on heart rate variability in patients with heart failure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

class II, III of stable heart failure patients stable and optimal medical treatment BMI 25-35 kg/m<sup>2</sup> Hemoglobin >12(women) and >13(men) duration of heart failure: 1-4 years Ejection Fraction: <40% age : 45-75 year

**Exclusion criteria:**

unstable conditions such as complex ventricular arrhythmia, unstable angina pacemaker myocardial infarction during last year cardiac surgery during last 6 months impairment in which exercise is not safe such as orthopedic ... cognitive impairments

**Age**From **45 years** old to **75 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**Target sample size: **19****Randomization (investigator's opinion)**

Randomized

**Randomization description**

simple randomization by closed envelopes A person blinded to the research provide 57 envelopes for 3 groups (19 envelopes for each group) in a box and then exclude one envelope randomly for each patient without replacement

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data analyzer is not aware of the treatment performed for individuals

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

ethics committee of Tarbiat Modares University of Medical Sciences

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Jalal ale ahmad highway

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**Postal code**

14115111

**Approval date**

2019-08-03, 1398/05/12

**Ethics committee reference number**

IR.MODARES.REC.1398.071

**Health conditions studied****1****Description of health condition studied**

heart failure

**ICD-10 code**

I50.2

**ICD-10 code description**

Systolic (congestive) heart failure

**Primary outcomes****1****Description**

heart rate variability(time and frequency domain)

**Timepoint**

before and immediately after the intervention

**Method of measurement**

ECG Holter monitoring

**2****Description**

Quality of Life

**Timepoint**

before the intervention

**Method of measurement**

Minnesota Living with Heart Failure(MLHF) Questionnaire

**3****Description**

Dyspnea

**Timepoint**

before the intervention

**Method of measurement**

Modified Medical Research Council Dyspnea Scale(MRC)

#### 4

**Description**

Fatigue severity

**Timepoint**

before the intervention

**Method of measurement**

Fatigue Severity Scale (FSS)

#### 5

**Description**

blood pressure

**Timepoint**

before and immediately after the intervention

**Method of measurement**

sphygmomanometer

#### 6

**Description**

heart rate

**Timepoint**

before and immediately after the intervention

**Method of measurement**

Qardio-core and ECG Holter monitoring

#### 7

**Description**

muscle strength

**Timepoint**

before and immediately after the intervention

**Method of measurement**

Digital dynamometry

#### 8

**Description**

Rate Pressure Product

**Timepoint**

before and immediately after the intervention

**Method of measurement**

heart rate × systolic blood pressure

#### 9

**Description**

psychological response to the exercise stimulus

**Timepoint**

before and immediately after the intervention

**Method of measurement**

subjective exercise experience scale (SEES)

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group1: resistance exercise with the

intensity of 50%1RM: a single exercise session includes 5 minutes warm-up, 15 minutes of aerobic exercise with the intensity of 50% heart rate reserve, 30 minutes of resistance training (50%1RM) using weights for upper and lower limbs (10 exercises, 2 sets of 6-8 repetitions with 1-minute rest between sets and exercises), and 5 minutes cool down

**Category**

Rehabilitation

#### 2

**Description**

Intervention group2: resistance exercise with the intensity of 75%1RM: a single exercise session includes 5-minutes warm-up, 15 minutes of aerobic exercise with the intensity of 50% heart rate reserve, 30 minutes of resistance exercise (75%1RM) using weights for upper and lower limbs (10 exercises, 2 sets of 6-8 repetitions with 1-minute rest between sets and exercises), and 5 minutes cool down

**Category**

Rehabilitation

#### 3

**Description**

Control group: a single session exercise includes 5 minutes warm up, 15 minutes aerobic exercise with intensity of 50% heart rate reserve, and 5 minutes cool down

**Category**

Rehabilitation

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Tehran Heart Center

**Full name of responsible person**

hamid Reza Pourhoseini

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

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**Web page address****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**

assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Marzieh Saeidi Kelishadi

**Position**

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**Latest degree**

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## 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

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

There is not any more information

### When the data will become available and for how long

There is not any more information

### To whom data/document is available

There is not any more information

### Under which criteria data/document could be used

There is not any more information

### From where data/document is obtainable

There is not any more information

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

There is not any more information

### Comments

There is not any more information