

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Breathing Exercises on Fatigue Severity, Dyspnea, and Functional Classification in Patients with Heart Failure

#### Protocol summary

##### Study aim

Determining the effect of breathing exercises on the severity of fatigue, dyspnea, and functional classification of heart failure patients

##### Design

Three-arm parallel groups randomized trial without blinding on 100 patients. The sealed envelope method will be used for simple random division

##### Settings and conduct

The study is conducted at Shahid Modarres Hospital of Tehran affiliated with Shahid Beheshti University of Medical Sciences. The patients will be selected by convenience sampling and placed in three groups in a simple random method. Breathing exercises in two different ways (incentive spirometry; diaphragmatic and pursed-lip breathing exercises) will be performed three times a day for 10 days in the patients of the two intervention groups. In the control group, usual treatments and care are performed. Before the start of the intervention and after its completion, variables of fatigue, dyspnea, and functional classification are measured in all patients.

##### Participants/Inclusion and exclusion criteria

Heart failure patients of both sexes at least 20 years old; ability to read and write; EF lower than 55%; NYHA functional classification between classes II to IV; No history of psychological disorders, cancer, anemia, renal failure, diabetes, and neurological disorders

##### Intervention groups

A control group; a group of diaphragmatic and pursed lip breathing exercises; a group of flow oriented incentive spirometry

##### Main outcome variables

Fatigue severity; dyspnea; functional classification

#### General information

##### Reason for update

According to the end of the intervention, the start and

end dates of sampling were updated.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240306061197N1**

Registration date: **2024-04-14, 1403/01/26**

Registration timing: **prospective**

Last update: **2024-07-17, 1403/04/27**

Update count: **2**

##### Registration date

2024-04-14, 1403/01/26

##### Registrant information

##### Name

Amirhossein Nasirmoghadas

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8803 8972

##### Email address

amir.h.nasirmoghadas@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-08, 1403/01/20

##### Expected recruitment end date

2024-06-09, 1403/03/20

##### Actual recruitment start date

2024-04-15, 1403/01/27

##### Actual recruitment end date

2024-06-14, 1403/03/25

##### Trial completion date

2024-06-14, 1403/03/25

##### Scientific title

The Effect of Breathing Exercises on Fatigue Severity, Dyspnea, and Functional Classification in Patients with

Heart Failure

### Public title

The Effect of Breathing Exercises on Fatigue Severity, Dyspnea, and Functional Classification in Patients with Heart Failure

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Heart failure patients with Ejection Fraction (EF) lower than 55% NYHA functional classification between classes II to IV Ability to read and write Informed consent

#### Exclusion criteria:

No history of psychological disorders, cancer, anemia, renal failure, diabetes, and neurological disorders Simultaneous participation in any study that includes breathing exercises or any intervention effective on fatigue and dyspnea

### Age

From **20 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

Actual sample size reached: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The sealed envelope method will be used for simple random division. Each participant will draw a sealed envelope containing a number between 1 and 3. Patients who draw number 1 will be placed in the control group, number 2 in the diaphragmatic and pursed-lip breathing exercises group (DG), and number 3 in flow-oriented incentive spirometry.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

### Assignment

Parallel

### Other design features

The study will have three groups, including a control group, a group of diaphragmatic and pursed-lip breathing exercises, and an incentive spirometry group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University

#### Street address

Nursing and Midwifery Faculty, Intersection of Valiasr St. and Niayesh Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1996835119

#### Approval date

2022-10-25, 1401/08/03

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.161

## Health conditions studied

### 1

#### Description of health condition studied

Heart failure

#### ICD-10 code

I50

#### ICD-10 code description

Heart failure

## Primary outcomes

### 1

#### Description

Fatigue severity score based on FSS questionnaire

#### Timepoint

Before and after the intervention

#### Method of measurement

Fatigue Severity Scale (FSS) questionnaire

### 2

#### Description

Dyspnea severity based on modified Borg dyspnea scale

#### Timepoint

Before and after the intervention at rest and on exertion

#### Method of measurement

score of modified Borg dyspnea scale

### 3

#### Description

New York Heart Association (NYHA) Functional Classification

#### Timepoint

Before and after the intervention

#### Method of measurement

New York Heart Association (NYHA) Functional Classification based on severity of symptoms especially fatigue and dyspnea

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: diaphragmatic and pursed-lip breathing exercises, thrice a day for 10 days and each time for 10 minutes. take a 2-minute rest for every 1 minute of performing the breathing exercises (10 breaths/minute)

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: use of flow-oriented spirometry three times a day for 10 days. Each time, two rounds of 10 breaths and a few minutes of rest between each round

#### Category

Rehabilitation

### 3

#### Description

Control group: Continue the usual treatments and care

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Modarres Hospital

##### Full name of responsible person

Amirhossein Nasirmoghadas

##### Street address

Yadegar emam highway, saadat abad intersection

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 23515

##### Email

amir.h.nasirmoghadas@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Afshin Zarghi

##### Street address

Arabi Ave, Bldg No.2, 7th Floor, Velenjak, Tajrish

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835119

##### Phone

+98 21 2243 9780

##### Email

info@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Amirhossein Nasirmoghadas

##### Position

M.Sc Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

No. 26, West Zayandeh roud Alley, North Shirazi Ave., Mollasadra Ave.

##### City

Tehran

##### Province

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##### Phone

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amir.h.nasirmoghadas@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Amirhossein Nasirmoghadas

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

Shahid Beheshti University of Medical Sciences

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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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available