

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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)

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Email address

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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

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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhossein Nasirmoghadas

Position

M.Sc Student

Latest degree

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Other areas of specialty/work

Nursery