Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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+98 21 8803 8972

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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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1996835119
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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