

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of diaphragmatic breathing technique training along with range of motion exercises using animation on the sleep quality of heart failure patients

Protocol summary

Study aim

Determining the effect of diaphragmatic breathing technique training along with range of motion exercises using animation on the sleep quality of heart failure patients

Design

Randomized controlled clinical trial, with parallel groups, second phase, without blinding, number of 110 patients using permutation blocks of 4 using Excel software.

Settings and conduct

The setting of this research will be the heart specialist office and the cardiac wards of Emam Reza and Ghaem hospitals in Mashhad. In the intervention group, the researcher asks the patient to watch the animation and perform the exercises based on it in the presence of the researcher, then the patient is asked to complete the sleep quality questionnaire in the first morning and then twice a day for one month. Do diaphragmatic breathing techniques and range of motion exercises (shoulder, hip, and knee) in bed an hour after breakfast and at night before going to bed. And every day in the evening, every hour as desired, at least one hour after lunch for 15 minutes to walk at a slow pace. In the control group, patients will receive face-to-face training from nurses and the use of the department's educational pamphlets.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30 and 80, $54 > EF > 35$, Class 1 and 2 heart failure Exclusion criteria: Suffering from a mental disorder Suffering from COPD or any lung disorder Suffering from joint and muscle diseases

Intervention groups

Intervention group: using the diaphragmatic breathing technique along with range of motion exercises using animation for a period of one month twice a day along with a 15-minute walk. Control group: receiving the usual face-to-face training of nurses and prepared pamphlets

Main outcome variables

quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055605N1**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

massomeh abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3389 0169

Email address

abbasims3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of diaphragmatic breathing technique training along with range of motion exercises using animation on the sleep quality of heart failure patients

Public title

The effect of diaphragmatic breathing technique training along with range of motion exercises using animation on the sleep quality of heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age ranges between 30 and 80 45<EF>35 Class 1 and 2 Heart failure According to doctor

Exclusion criteria:

Suffering from muscle and joint disease Existence of obvious shortness of breath during physical or breathing exercises Having COPD or any pulmonary disorder Lack of co - ordination with more than 50 % of the total number of practice sessions Mental disorders require medical treatments

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to perform randomization in this study, first, using Excel software, 30 randomized permutation blocks of 4 pieces (using two characters A, B) will be retrieved. A will be considered for the intervention group and B for the control group. Then, by using 30 sealed envelopes, each of the randomized blocks will be placed in each envelope. After obtaining informed consent from each patient, if they meet the inclusion criteria, by referring to the sealed envelopes and based on any random character, the patient will be randomized to intervention or control group. Then the next envelope will be used. This process will be continued until 110 patients randomly placed in two intervention and control groups. To prevent the error, the researcher ask the office secretary to refer to the closed envelopes and report the random digits order.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Street, Ibne Sina Avenue, School of Nursing and Midwifery, Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

3944-91388

Approval date

2022-08-01, 1401/05/10

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.054

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

Heart failure patients

ICD-10 code

I50

ICD-10 code description

Heart failure

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

Sleep quality

Timepoint

Three times a day, Morning, Noon, And night

Method of measurement

Petersburg Sleep Quality Questionnaire

Secondary outcomes**1****Description**

Investigating the sleep quality of heart failure patients

Timepoint

Morning. Noon. Night

Method of measurement

Sleep quality questionnaire

Intervention groups

1

Description

Intervention group: First, in the present study, based on the search of literature and the opinion of experts, the diaphragmatic breathing technique and joint range of motion movements will be converted into two 5-minute animation films with the help of a professional animator. Then, in the intervention group, the researcher first asks the patient to watch the animation and perform the exercises based on it in the presence of the researcher. and then perform diaphragmatic breathing techniques and range of motion exercises (shoulder, hip, and knee) in bed twice a day for one month, one hour after breakfast and at night before going to bed. And every day in the evening, every hour as desired, at least one hour after lunch for 15 minutes to walk at a slow pace. Finally, after one month of exercises at home, the sleep quality questionnaire will be completed online by the patient and will be provided to the researchers.

Category

Rehabilitation

2

Description

Control group: In the control group, patients will receive face-to-face training from nurses and the use of the department's educational pamphlets. Finally, after one month, the patients are asked to complete the sleep quality questionnaire again

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyyedi Medical Clinic, Emam reza Hospital

Full name of responsible person

Masomeh Abbasi

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Daneshgah street, Ibn Sina avenue, Nursing and Midwifery School

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Mashhad University of Medical Sciences
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Person responsible for updating data

Contact

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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