

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of balance exercises on sleep quality in patients with heart failure

Protocol summary

Balance exercises, sleep quality

Study aim

to determine the effect of balance exercises on the quality of sleep of patients with heart failure

Design

A randomized clinical trial on 55 patients

Settings and conduct

Heshmatieh Sabzevar Hospital Cardiopulmonary rehabilitation department. The questionnaire divides patients into two groups with good sleep quality and poor sleep quality. Then, using the random assignment method and R software, and using 4 permutation blocks, we divide the patients who have poor sleep quality into two intervention and control groups. Then the intervention group is taught balance exercises. The total duration training will be four times a week for eight weeks. At the end of this familiarization session, they are asked to do exercises at home 2-3 hours before sleeping at night. After two months of the intervention, the sleep quality questionnaire is again given to the control and intervention groups and their sleep quality is evaluated.

Participants/Inclusion and exclusion criteria

Entry criteria: at least one month has passed since their heart failure diagnosis, being in the 1st, 2nd and 3rd class of heart failure. suffering from sleep disorders, interested in participating in the study and having full consciousness. Non-entry criteria: patients with severe insufficiency who are in grade 4, patients with movement and physical limitations, patients with joint and skeletal diseases, patients diagnosed with respiratory apnea, patients who are willing. Patients who suffer from deterioration of their physical condition and intolerance during the study and symptoms such as shortness of breath, dizziness, extreme fatigue, etc

Intervention groups

We teach the intervention group balance exercises, they do them for 2 months, and then we measure their sleep quality. In the control group we only measure their sleep quality after 2 months.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230725058925N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

Hossein Motamedi manesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3341 9158

Email address

hoseinpars817@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2023-10-02, 1402/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of balance exercises on sleep quality in patients with heart failure

Public title

The effect of balance exercises on sleep quality in patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least one month has passed since their heart failure diagnosis being in class 1, 2 and 3 of heart failure $EF \geq 40$ suffering from sleep disorders interested in participating in the study having full consciousness

Exclusion criteria:

Patients with severe insufficiency who are in grade 4 patients with movement and physical limitations patients with joint and skeletal diseases patients diagnosed with respiratory apnea patients unable to complete the questionnaire patients who did not want to participate in the study Patients who experience worsening physical condition and intolerance and symptoms such as shortness of breath, dizziness, severe fatigue, etc. during the study patients who die during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the criteria for entering the study are selected and interviewed in person to participate in the research if they wish. Then the questionnaire is distributed among the patients and the patients are requested to complete the questionnaires in person and the confidentiality of their information is explained to the patients and if the patients wish, they will be informed of the research results. The questionnaire divides patients into two groups with good sleep quality and poor sleep quality. Regarding the study, sufficient explanations will be given to patients with poor sleep quality, and then consent forms will be given to these patients and these forms will be completed in person by the patients. Then, using the random allocation method and R software, and using 4 permutation blocks, we divide the patients who have poor sleep quality into two intervention and control groups

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 Sabzevar University of Medical Sciences

Street address

Shahrak Tawheed Road

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617213112

Approval date

2023-07-26, 1402/05/04

Ethics committee reference number

IR.MEDSAB.REC.1402.058

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50

ICD-10 code description

complicating:abortion or ectopic or molar pregnancy (O00-O07, O08.8)obstetric surgery and procedures (O75.4)due to hypertension (I11.0)with renal disease (I13.-)following cardiac surgery or due to presence of cardiac prosthesis (I97.1)neonatal cardiac fai

Primary outcomes

1

Description

sleep quality

Timepoint

The beginning of the study. end of study

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before the intervention, the sleep quality questionnaire is taken from the intervention group. Then balance exercises are taught to the patients. The exercise program is given to them. 2 months later, the sleep quality questionnaire will be taken from them and compared.

Category

Rehabilitation

2

Description

Control group: The sleep quality questionnaire is taken from the patients, and then 2 months later, this work is repeated and the primary and secondary results are compared.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatieh Sabzevar Hospital

Full name of responsible person

Hamid Marefai

Street address

Asadabadi St

City

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9617913112

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+98 51 4401 1600

Email

hh.medsab.ac.ir@domain.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Kazem Hasanpour

Street address

Shahrak Tawheed Road

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Province

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Fax

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info@medsab.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mustafa Rad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahrak Tawheed Road

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

The results of the study will be reported to the patients if they wish

When the data will become available and for how long

Access starts 6 months after the announcement of the results

To whom data/document is available

Academic staff

Under which criteria data/document could be used

For more research

From where data/document is obtainableDr. Mustafa Rad 09159720970
radmostafa633@gmail.com Hossein Motamedi mansesh
09024189917 hoseinpars817@gmail.com**What processes are involved for a request to access data/document**

Requests should be sent to hoseinpars817@gmail.com.

The request will be reviewed. Your answer will be sent by email

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

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mustafa Rad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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