

# 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**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913112

**Phone**

+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

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617213112

**Phone**

+98 51 4401 8440

**Fax**

+98 51 4401 8424

**Email**

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

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873136

**Phone**

+98 51 4401 8352

**Email**

radmostafa633@gmail.com

## Person responsible for scientific 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

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873136

**Phone**

+98 51 4401 8352

**Email**

radmostafa633@gmail.com

radmostafa633@gmail.com

**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 obtainable**

Dr. 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**

Nursery

**Street address**

Shahrak Tawheed Road

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873136

**Phone**

+98 51 4401 8352

**Email**