

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparing the effect of Benson relaxation and nature sound on anxiety and fatigue of the patients with heart failure

Protocol summary

Summary

1) The objective of present study is Comparing the effect of Benson relaxation and nature sound on anxiety and fatigue of the patients with heart failure 2) Design: The study is a randomized clinical trial with both control and intervention group 3) Setting and conduct: 105 patients with heart failure admitted in the CCU of Imam Reza (AS) and Fatima (SA) hospitals will be randomly placed in the intervention and control groups. 4) Participants including major eligibility criteria: They are patients with heart failure 5) Intervention: The intervention group will be trained Benson muscle relaxation. In Benson muscle relaxation with headphones for 20 minutes twice a day, morning and evening during of 3 days they perform relaxation. In the intervention group the sounds of nature, nature sounds through headphones patients 2 times a day for 20 minutes each morning and evening during 3 days listening. The control group did not receive anything 6) Main outcome measures: The primary outcomes variable are anxiety and fatigue.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121425528N1**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-09, 1394/12/19

Registrant information

Name

Leila Seifi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical science

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Benson relaxation and nature sound on anxiety and fatigue of the patients with heart failure

Public title

Comparing the effect of Benson relaxation and nature sound on anxiety and fatigue of the patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include: The diagnosis of heart failure by a doctor : An ejection fraction less than 35% : Patient said the fatigue and anxiety: Alert and able to collaborate with researchers: Lack of cognitive and mental disorders: Lack of neuromuscular disorders: Lack

of addiction to drugs- sedatives and alcohol! No history of relaxation methods. Exclusion criteria: Patients who do not tolerate intervention! After education and investigation of procedure ability if they do not learn relaxation skills! With acute situation(Connecting to ventilator): They die during the intervention

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Iran university of medical sciences and health services

Street address

Iran university of medical sciences, Shahid Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

IR.IUMS.rec.1394.9311449002

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure Cardiac asthma Left heart failure

Oedema of lung Pulmonary oedema

Primary outcomes

1

Description

Anxiety

Timepoint

Before and immediately after the intervention

Method of measurement

Speilberger Anxiety questionnaire

2

Description

Fatigue

Timepoint

One day before, The third day after the intervention

Method of measurement

Fatigue Severity Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this group, patients listen to a nature sounds by headphone a like waterfalls, the sound of rain ,birds,etc twice in each day in 20 minutes ,2times for 3 days.

Category

Rehabilitation

2

Description

In the intervention group of Benson muscle relaxation, patients received twice a day .morning and evening for three days. In this method ,moreover the patients listen to a relaxation CD, they relax their muscle from toe to muscles of upper body .

Category

Rehabilitation

3

Description

Routin procedures are done for the control group only ,the patient had not received intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital
Full name of responsible person
Leila Seifi
Street address
Emam Reza st, Emam Reza hospital, Amol
City
Amol

2

Recruitment center
Name of recruitment center
Fatemeh Zahra hospital
Full name of responsible person
Leila Seifi
Street address
Emam KHomeini Square, Jam-e Jam St, Fateme Zahra hospital
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran university of medical science
Full name of responsible person
Seyed Ali Javad Moosavi
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Iran university of medical sciences, Shahid Hemmat highway, Tehran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran university of medical science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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School of nursing & midwifery of Iran university
Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty