Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 musle 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

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2885

Email address

seifi.l@tak.iums.ac.ir

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 than35% ؛ 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

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

City
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

Name of organization / entity
School of nursing & midwifery of Iran university

Full name of responsible person
Leila Seifi

Position
Post graduate student in nursing

Other areas of specialty/work

Street address
School of nursing & midwifery, Rashid Yasemi St, Valiasr St, Tehran

City
Tehran

Postal code
Iran

Phone
+98 21 8888 2886

Fax

Email
mitraseifimehr@yahoo.com; seifi.l@tak.iums .ac.ir

Web page address
mitraseifimehr@yahoo.com; seifi.l@tak.iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of nursing & midwifery of Iran university

Full name of responsible person
Tahere Najafi

Position
Ph.D in nursing

Other areas of specialty/work

Street address
School of nursing & midwifery, Rashid Yasemi st, (after Vanak square), Vali-e- Asr st, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 8888 2885

Fax

Email
najafi.t@iums.ac .ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of nursing & midwifery of Iran university

Full name of responsible person
Leila Seifi

Position
Post graduate student in nursing

Other areas of specialty/work

Street address
School of nursing & midwifery, Rashid Yasemi St, (after Vanak square), Vali-e-Asr st, Tehran, Iran

City
Tehran

Postal code
Iran

Phone
+98 21 8888 2886

Fax

Email

mitraseifimehr@yahoo.com; seifi.l@tak.iums. ac .ir

Web page address

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