Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of Benson Relaxation and Foot Reflexology on the Quality of Sleep in Patients with Heart Failure

Protocol summary

Study aim

Comparison of the effects of Benson relaxation and foot reflexology massage on the quality of sleep in patients with heart failure

Design

This study was a clinical trial with a control group and two blinded blinded study groups. In the case of patients referring to the Cardiology Clinic, randomized assignment with a sample size of 93 and a sample size in each group of 27 with parallel groups The BBR method will be divided into two groups of test and one control group with sixth permutation blocks.

Settings and conduct

This study is a randomized clinical trial. All patients with mild to moderate hemodynamic heart failure who referred to the specialized clinic of Javad Alamea 2 Torbat Heydariyeh are a clinical blinded clinical trial.

Participants/Inclusion and exclusion criteria

Intervention for the studied groups at the beginning of the visit after obtaining informed consent and suitable age, lack of admission to the psychiatric ward, lack of chronic disease, lack of use of sedative medications, lack of history of foot injury, confirmation of diagnosis of heart failure and poor sleep quality. And complete patient alertness are included in the study, and in case of patient dissatisfaction, patient death and any unexpected complications, history of neuropathy and a history of missing patients in the past two months, and compensated for heart failure, they will be excluded from the study phase

Intervention groups

1- Patients who are affected by the relaxation of the Benson method on their sleep quality.2. Patients who are affected by the effect of foot reflexology massage on their sleep quality.3. A control group that only undergoes routine treatment.

Main outcome variables

Improve the quality of sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039882N1**
Registration date: **2018-06-08, 1397/03/18**
Registration timing: **prospective**

Last update: **2018-06-08, 1397/03/18**
Update count: **0**

Registration date

2018-06-08, 1397/03/18

Registrant information

Name

Massoomeh Emami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Benson Relaxation and Foot Reflexology on the Quality of Sleep in Patients with Heart Failure

Public title

Comparison the effect of Benson Relaxation and Foot Reflexology on the Quality of Sleep in Patients with Heart Failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Having at least 30 years and maximum 60 years of age No admission to psychiatric wards and no known psychiatric disorders (schizophrenia, anxiety, depression, dementia). Not having chronic disease (cancer, musculoskeletal disorders, chronic renal failure) Have full vigilance and acceptable listening and speaking ability to answer questions and learn the relaxation method. Do not take sedative drugs such as benzodiazepines Having no history of injury, open wounds, and surgery in the legs during the last two years that prevent the massage of the back of the foot. Considering the history, the medical records and the researcher's observation Confirmation of diagnosis of systolic (mild to moderate) heart failure by a specialist who has been ill for at least six months Confirmation of undesirable sleep quality based on Peters Leaf questionnaire (score 5-21 is recognized as undesirable sleep quality) 10. The patient is completely alert and able to answer questions.

Exclusion criteria:

If the patient is unsatisfied, continue to participate in the study Patient's death The occurrence of any unexpected complications during an intervention that prevents the patient from continuing work (arrhythmia, CPR on the patient during an intervention, secondary myocardial infarction, or angioplasty). People with a history of diabetic neuropathy. Phase compensated heart failure entered the unconsolidated phase. Do not have a history of missing loved ones in the past two months.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Random random allocation ,method using balanced block randomization (BBR) ,with 6-point permutational blocks to 2 test groups and 1 control group

Blinding (investigator's opinion)

Single blinded

Blinding description

People who are invited to participate in the study and are classified in intervention groups after being informed consentfully are not aware of the allocation of study groups. Patients are not referred to the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Khorasan Razavi province, Gonabad city, Asian road border

City

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Province

Razavi Khorasan

Postal code

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Approval date

2018-02-21, 1396/12/02

Ethics committee reference number

IR.GMU.REC.1396.122

Health conditions studied

1

Description of health condition studied

Patients with systolic heart failure (mild to moderate)

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Improve sleep quality based on Peters Leaf questionnaire

Timepoint

Sleep quality measurement before intervention and after intervention, duration of intervention is 3 weeks.

Method of measurement

Petersberg Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, foot-reflecting massage is performed as a non-invasive intervention by hand after preparing the legs, and then the foot-foot reflection massage is done in the foot area at the point of the pinnacle at sixty feet. Before performing the back massage, the palms of the foot in the area At first, a minute of general massage of the foot is performed with the same precursor movements to warm the feet in the patient, and then the foot reflexology of the foot with direct thumb on the respective area of each foot for 15 minutes and a total of 30 minutes. The intervention is conducted 3 times a week for 4 weeks at the clinic by a researcher and researcher

Category
Treatment - Other

2

Description
Intervention group: Relaxation exercises are individually taught to the research units. Subsequently, the instruction manual accompanies a compact disc recorded by the training process or via mobile Bluetooth for home-based training to research units They were asked to perform the exercises for 2 days, for the first time in the morning (between 8-10 o'clock) and 2 o'clock in the evening (between 20 o'clock to 22 o'clock) for 20 minutes for 4 weeks

Category
Treatment - Other

3

Description
Control group: 3. A control group that only undergoes routine treatment.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialty Clinic Javad Alaem 2 Torbat Heydarieh

Full name of responsible person
Massoomeh Emami Bakawali

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8th gharani,gharani st,Specialized clinic of Jawad Alameh 2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Gonabad University of Medical Sciences

Proportion provided by this source
1

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
Gonabad University of Medical Sciences

Full name of responsible person
Massoomeh Emami

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work

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Person responsible for updating data

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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
Part of the data, such as information on the main outcome, is shared best practice.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
researchers
Under which criteria data/document could be used
For research on the topic of study
From where data/document is obtainable
Gonabad University of Medical Sciences
What processes are involved for a request to access data/document
Refer to the publisher site
Comments