Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effects of Acupressure on Sleep Quality, Anxiety, and Physiological Indicators in Patients with Heart Failure

Protocol summary

Study aim

The effects of acupressure at points SP6, PC6, and HT7 on sleep quality, anxiety, and physiological indicators in patients with heart failure will be investigated.

Design

A randomized controlled clinical trial with parallel groups, conducted on 76 patients from a convenience sample.

Settings and conduct

Patients with heart failure referred to Farshchian Educational and Medical Center in Hamadan and Imam Hossein Hospital in Malayer will be randomly assigned to intervention and control groups. For the acupressure intervention, patients will be positioned appropriately, and pressure will be applied gradually and rhythmically with the fingertips at points SP6, PC6, and HT7. The researcher will identify the exact points and apply pressure in a controlled, rhythmic manner, sufficient for participants to feel warmth, heaviness, or numbness in the target area without causing physical discomfort.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Willingness to participate in the study; 2) Signing the informed consent form; 3) Diagnosed heart failure (EF < 40%); 4) Ability to speak and understand Persian. Exclusion criteria: 1) Addiction to alcohol, illicit drugs, or sedative medications; 2) Known speech, hearing, or cognitive impairments; 3) Use of sedative or anti-anxiety medications within the past 24 hours

Intervention groups

Intervention group: Patients in the intervention group will receive acupressure at points SP6, PC6, and HT7 twice daily, 30 minutes per session, for three consecutive days. Control group: Patients in the control group will receive superficial pressure at neutral points surrounding the main points, following the same protocol as the intervention group. Primary outcomes: Sleep quality, anxiety levels, and physiological indicators will be assessed in both groups.

Main outcome variables

Sleep quality, anxiety levels, and physiological indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190524043687N6**
Registration date: **2025-12-19, 1404/09/28**
Registration timing: **prospective**

Last update: **2025-12-19, 1404/09/28**
Update count: **0**

Registration date

2025-12-19, 1404/09/28

Registrant information

Name

Ali Safdari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

Expected recruitment end date

2026-04-30, 1405/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effects of Acupressure on Sleep Quality, Anxiety, and Physiological Indicators in Patients with Heart Failure

Public title
Investigating the Effects of Acupressure on Sleep Quality, Anxiety, and Physiological Indicators in Patients with Heart Failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to Participate in the Study Signing of Informed Consent Form Ability to speak and understand the Persian language Diagnosed heart failure (EF < 40%), as confirmed by the treating physician

Exclusion criteria:
Presence of conditions such as intellectual disability, mental or behavioral disorders, hearing impairment, or speech disorders Presence of a previously diagnosed psychiatric disorder and/or sleep disorder Use of complementary therapies prior to the study Presence of addiction to alcohol, illicit drugs, or sedative medications Use of sedative or anti-anxiety medications within the past 24 hours Presence of any contraindication at the pressure application site (e.g., wounds, skin diseases, etc.)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated in equal numbers to the intervention and control groups using block randomization. To ensure the unpredictability of group assignment, allocation concealment will be performed by a statistical collaborator, and the randomization sequence will remain concealed until the time of intervention. For this purpose, opaque, sealed, and sequentially numbered envelopes containing the random allocation sequence will be used. Accordingly, after generating an appropriate random sequence based on the method described above and according to the study sample size, a number of opaque envelopes will be prepared. Each randomly generated sequence will be recorded on a card, and the cards will be placed sequentially inside the envelopes. To preserve the random sequence, the envelopes will be numbered consecutively on their outer surface. Finally, the envelopes will be sealed and placed in order inside a box. At the start of participant enrollment, based on the order in which eligible participants enter the study, one envelope will be opened sequentially, and the group assignment for that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, clinical caregivers, outcome assessors, and the statistical collaborator will be blinded to the allocation of patients to the intervention and control groups. The research collaborator responsible for outcome assessment will conduct evaluations without knowledge of participants' group assignments. To maintain blinding during data analysis, study data will be provided to the statistical collaborator in a coded format (A: intervention group, B: control group), without revealing the actual group identities. To assess the effectiveness of blinding, at the end of the intervention period, participants will be asked to guess the group to which they were assigned (intervention or control). The success of blinding will then be evaluated and reported by comparing the guesses between groups using appropriate statistical tests.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethical Committee of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran

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Hamadan

Province
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Postal code
6517838736

Approval date
2025-12-13, 1404/09/22

Ethics committee reference number
IR.UMSHA.REC.1404.769

Health conditions studied

1

Description of health condition studied
Heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Sleep Quality
Timepoint
Before the start of the study and on the second, third, and fourth days of hospitalization
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

2

Description
Anxiety
Timepoint
Spielberger Anxiety Questionnaire
Method of measurement
Before, immediately after, and 30 minutes after the daily intervention

3

Description
Arterial oxygen saturation
Timepoint
Before, immediately after, and 30 minutes after the daily intervention
Method of measurement
Pulse oximetry

4

Description
Systolic blood pressure
Timepoint
Before, immediately after, and 30 minutes after the intervention
Method of measurement
Digital sphygmomanometer

5

Description
Diastolic blood pressure
Timepoint
Before, immediately after, and 30 minutes after the intervention
Method of measurement
Digital sphygmomanometer

6

Description
Heart rate
Timepoint
Before, immediately after, and 30 minutes after the intervention
Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Patients with heart failure in the intervention group will first complete questionnaires assessing sleep quality and anxiety, and their physiological parameters, including systolic and diastolic blood pressure, heart rate, respiratory rate, and arterial oxygen saturation, will be measured. Then, acupressure will be applied at SP6, PC6, and HT7 points by a trained researcher. Patients will be positioned in a quiet environment with minimal noise, light, and temperature distractions, and their privacy will be maintained. The researcher will locate the precise points and gradually apply fingertip pressure in a smooth, rhythmic manner until participants report sensations of warmth, heaviness, or numbness in the targeted area without experiencing physical discomfort. This intervention will be performed twice daily, each session lasting 30 minutes, over three consecutive days. After each session, questionnaires and physiological parameters will be reassessed and recorded. To ensure the accuracy of the acupressure protocol and compliance with standard guidelines for acupressure and acupuncture research, a pilot study will be conducted prior to the main trial. Findings from this preliminary study will guide the timing of outcome measurements and finalize the intervention protocol, including session duration and frequency.
Category
Other

2

Description
Control Group: Patients in this group will first complete questionnaires assessing sleep quality and anxiety. Their physiological parameters, including systolic and diastolic blood pressure, heart rate, respiratory rate, and arterial oxygen saturation, will also be measured. Then, to maintain procedural consistency and blinding, they will receive gentle, superficial pressure at neutral points surrounding the main acupressure sites, following the same protocol as the intervention group. After each session, the questionnaires and physiological parameters will be reassessed and recorded.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Heart and Vascular Subspecialty Educational and Treatment Center

Full name of responsible person
Ali Afshari

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Farshchian Heart and Vascular Subspecialty Educational and Treatment Center, Shahid Fahmideh Blvd., Chahar Rah-e Pazhouhesh, Hamadan

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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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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Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Ali Afshari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available