Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of yoga breathing on quality of sleep and life in heart failure patients

Protocol summary

Study aim
Investigating the effect of breathing yoga pranayama on the quality of sleep and life of patients with heart failure.

Design
This study is a randomized clinical trial without blinding. Sampling is done by convenience with block randomization. The sample size includes 88 patients with class II and III heart failure.

Settings and conduct
This study is a randomized clinical trial to investigate the effect of breathing yoga on the quality of sleep and life of heart failure patients, which will be conducted in the Heart Clinic of Imam Khomeini Hospital in Tehran in 1404. In this study, patients are divided into two groups: control and intervention. The control group is encouraged to follow a medication regimen and a healthy lifestyle, and the intervention group, in addition to these recommendations, also practices breathing yoga. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
1. Diagnosis of heart failure class 2 and 3 according to the New York Heart Association scale 2. Specific age range of 18 to 60 years 3. Patients must be physically able to perform yoga exercises and breathing techniques 4. Willingness to participate in the study 5. Not using similar treatment methods 6. Access to mobile phone and internet. 7. Not taking sedatives or sleep disorders. 8. Not having had myocardial infarction or recurrent angina within the past six months. 9. No pregnancy or breastfeeding.

Intervention groups
The intervention group will receive training and practice of yoga breathing techniques (pranayama) in 30-minute daily online sessions via Google Meet and WhatsApp for 7 weeks. The control group will receive standard heart failure care and education based on the 2017 AHA/ACC guidelines for pharmacological interventions and lifestyle changes.

Main outcome variables
Sleep quality; Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251229068488N1**
Registration date: **2026-02-02, 1404/11/13**
Registration timing: **prospective**

Last update: **2026-02-02, 1404/11/13**
Update count: **0**

Registration date
2026-02-02, 1404/11/13

Registrant information

Name
Shabnam Rashidi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3741 5085

Email address
estshanur@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-17, 1404/11/28

Expected recruitment end date
2026-05-18, 1405/02/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of yoga breathing on quality of sleep and life in heart failure patients

Public title
Investigating the effect of yoga breathing on quality of sleep and life in heart failure patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Heart failure diagnosis: Patients must have been officially diagnosed by a specialist as having heart failure class 2 or 3 according to the New York Heart Association scale. Age: Patients must be within a certain age range (18 to 60 years). Physical fitness: Patients must be physically able to perform yoga exercises and breathing techniques and have no specific medical restrictions in this regard. Willingness to participate in the study: Patients must give their informed consent to participate in the study and be able to participate in the educational program for a specified period of time (7 weeks). Access to mobile phone and internet. Not taking sedatives or medications for sleep disorders on a regular basis. No history of myocardial infarction or recurrent angina within the past six months. No pregnancy or breastfeeding. No use of similar therapeutic methods: Patients must not have used similar methods, such as yoga or breathing techniques, for at least 3 months before the start of the study.

Exclusion criteria:
Unwillingness to continue participating in the study. Exacerbation of the disease. Death of the patient. Not responding to more than ten percent of the questionnaire items.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample members will be divided into two groups: control and intervention using a block random allocation method with blocks of 4. For this purpose, blocks of 4 will be selected, so that the intervention group will be assigned the letter A and the control group will be assigned the letter B. Each block should include 2 people in the intervention group (A) and 2 people in the control group (B). The 22 possible allocation scenarios will be written on separate cards and each card will be assigned a number from 1 to 22, as follows: BBAA(1 AABB(2 BAAB(3 ABBA(4 BABA(5 AABB(6 ABBA(7 BBAA(8 ABAB(9 BAAB(10 ABAB(11

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 the Faculty of Nursing and Midwifery and the Faculty of Rehabilitation - Tehran

Street address
Dr. Mirkhani Street (East Nusrat), Towhid Square

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2025-12-27, 1404/10/06

Ethics committee reference number
IR.TUMS.FNM.REC.1404.216

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
Quality of life score in the World Health Organization Quality of Life Questionnaire Short Form (WHOQOL-BREF); Sleep quality score in the Pittsburgh Sleep Quality Index.

Timepoint
In this study, sleep and quality of life are measured in two stages, once before the start of the intervention and before randomizing patients, and once a week after the end of the study.

Method of measurement
World Health Organization Quality of Life Questionnaire Short Form (WHOQOL-BREF); Sleep quality score in the

Pittsburgh Sleep Quality Index.

Secondary outcomes

1

Description
Self-reported symptoms of heart failure patients, including shortness of breath, fatigue, cough, and daily activity tolerance
Timepoint
These outcomes are assessed in two time periods: once before the intervention begins and once a week after the intervention ends.
Method of measurement
Self-report

Intervention groups

1

Description
Intervention group: Intervention group: The intervention included training and implementation of yoga breathing techniques (pranayama), in the form of daily 30-minute online sessions, on Google Meet and WhatsApp, for 7 weeks. The exercises used have been previously approved and content reviewed by yoga and Iranian medicine specialist Dr. Azadeh Zarei. The student researcher provides the training live and the patients practice simultaneously. If the movements are performed incorrectly, necessary corrections are made. Patient adherence is monitored through attendance at sessions and correct execution of the exercises. The intervention group is also given an educational booklet that includes an introduction to heart failure and yoga, scientific and safety basics, instructions for preparing the person and the environment, a description of breathing exercises, a weekly program with a monitoring chart, frequently asked questions, a final note, and a blank page for recording patient notes or symptoms. One week after the end of the intervention (7 weeks), in the eighth week, the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) and the Pittsburgh Sleep Quality Questionnaire (PSQI) will be completed again by the participants, and the results will be compared with pre-intervention data. The yoga exercises used in this study include the following: Naadi Shodhan Pranayam; Om Chanting; Ujjayi Pranayam; Bhramari Pranayam; Sheetali/Sheetkari; Yog Nidra in Shavasan
Category
Rehabilitation

2

Description
Control group: Patients in the control group were advised usual heart failure care and standard treatment based on the 2017 AHA/ACC guidelines, including pharmacological interventions and lifestyle changes. Control group participants were encouraged to walk briskly for at least 40 minutes daily; limit alcohol and sodium intake; follow the DASH diet; avoid smoking; and continue their medication.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Heart Clinic of Imam Khomeini Hospital
Full name of responsible person
Shabnam Rashidi
Street address
End of Keshavarz Boulevard, Tehran Province, Iran
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Province
Tehran
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Fax
+98 21 6658 1625
Email
Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Central University Organization, corner of Qods Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
141765383761
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+98 21 8163 3698
Fax
+98 21 8898 9664
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shabnam Rashidi
Position
Master's degree student in medical-surgical nursing
Latest degree
Bachelor
Other areas of specialty/work
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Email
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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
The de-identified data for this study includes general demographic information and results from research instruments (such as questionnaires, checklists, or clinical measurements). These data are stored in SPSS or Excel software files. Access to data after publication of the original results will be possible only for non-commercial research purposes and upon submitting a written request along with a brief research plan to the principal investigator. Any use requires acknowledgement of the original source. All shareable data is completely anonymized. All direct identifying information (such as name, contact number, national code, address) has been removed from the original

dataset and replaced with a random numeric code. The file linking these codes to the real identities of individuals will be kept separately and confidentially by the main researcher and will not be made available to others under any circumstances.

When the data will become available and for how long

The data from this study will be available for legitimate research requests 6 months after the acceptance and electronic publication of the first original article in a reputable journal.

To whom data/document is available

Access to this research dataset will be granted only to applicants who meet the following criteria: 1. Researchers and graduate students affiliated with an accredited academic or research institution. 2. The purpose of the request is to conduct non-commercial scientific research (such as a thesis, review article, meta-analysis, or research project). 3. A written request (official email) along with a brief research plan (Proposal) that clearly explains the goals, methods, and necessity of using these data has been submitted to the principal investigator. 4. Commit to using the data only for the purpose specified in the application and to refrain from any attempt to re-identify participants. 5. Commit to fully and appropriately citing the original source of the data (this thesis/article) in any publication resulting from these data. 6. Written consent from the principal investigator and, if necessary, re-approval from the ethics committee issuing the project has been received.

Under which criteria data/document could be used

The data from this study may be used for scientific, research, and non-commercial purposes only. Permitted uses include: · Conducting secondary analyses to answer new research questions. · Conducting meta-analyses or systematic reviews. . Replication or validation of the findings of the original study. · Use as teaching data or samples in research methods courses (with confidentiality). Basic Terms and Conditions of Use: 1. Ethical commitment: The user undertakes to never use the data to identify or contact participants and to respect their privacy. 2. Use restrictions: The data must not be used for commercial, marketing, insurance, legal or any discriminatory purposes. 3. Indexing and Citation: Any publication (article, report, thesis) that uses these data is required to properly cite and mention the original source (including the trial registration number in IRCT and the original article/thesis). 4. Prohibition of transfer: The user does not have the right to transfer the data to a third party or upload them to another public repository, except with the written permission of the principal investigator.

From where data/document is obtainable

Applicants for data access should send their formal request in the form of an email to the address of the author of this proposal. · Name and surname: Shabnam Rashidi · (Email): EstShaNur@gmail.com Required documents to accompany the email application: 1. A brief research proposal containing the title, objectives, methodology, and justification for the need for the data of this study. 2. A brief CV of the applicant. 3. A written commitment to comply with the conditions mentioned in this proposal (non-commercial purposes and confidentiality).

What processes are involved for a request to access data/document

The data access request will be processed through the following steps: 1. Submitting the initial request: The applicant sends a formal email containing the following to the designated contact point: · Self-introduction and institutional affiliation · Description of the research objective and scientific justification for the need for the data · Brief research proposal · Scientific CV

Comments