Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of deep breathing on sleep quality, anxiety, and depression in patients undergoing coronary artery bypass graft surgery at Shafa Health Center affiliated to Kerman University of Medical Sciences

Protocol summary

Study aim

Determining the effect of deep breathing on sleep quality, anxiety and depression in patients undergoing open heart surgery at Shafa Health Center affiliated to Kerman University of Medical Sciences

Design

This research is a randomized trial of two parallel groups

Settings and conduct

Patients of cardiac surgery department will be placed in the control and intervention groups based on random codes. After receiving training, participants in the intervention and control groups will use deep breathing and receive usual care respectively. Sleep quality, depression and anxiety of participants will be evaluated before, immediately, 15 days later and one month after the intervention.

Participants/Inclusion and exclusion criteria

Age above 20 years Literacy in reading and writing Absence of neurological problems Hospitalization of the patient at least one day before surgery Excluding criteria Having a history of mental disorders and sleep disorders before surgery (declared by the patient) Using sleeping pills or sleeping scents Having a hearing impairment Having a history of progressive chronic diseases such as kidney failure and uncontrolled diabetes and... Death of the patient after surgery

Intervention groups

patients after training, breathe through the nose in a deep breath. Then stop breathing for 2 to 5 seconds and then exhale slowly through the mouth. Intervention start after the patient's hemodynamic condition is confirmed. It should be noted that the number of breathing exercises is once every three hours and 10 breaths are performed each time.

Main outcome variables

Sleep quality is measured using the Pittsburgh Questionnaire with scores between 0-21, with a lower score indicating better sleep quality. Depression and anxiety are measured by hospital depression and anxiety questionnaire with scores between 0-21. A score less than 11 indicates a degree of depression and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231208060294N1**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Mansooreh Azizzadeh Forouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3213 4106

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

2024-02-04, 1402/11/15

Actual recruitment end date

2024-07-20, 1403/04/30

Trial completion date

2024-07-22, 1403/05/01

Scientific title

The effect of deep breathing on sleep quality, anxiety, and depression in patients undergoing coronary artery bypass graft surgery at Shafa Health Center affiliated to Kerman University of Medical Sciences

Public title

Effect of deep breathing on sleep quality, anxiety and depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to read and write and use a mobile phone Stability of hemodynamic symptoms Absence of neurological problems Hospitalization of the patient at least one day before surgery

Exclusion criteria:

Having a history of mental disorders (depression, anxiety), sleep disorders before surgery (reported by the patient Using sleeping pills or sleeping scents Having a hearing impairment Having a history of progressive chronic diseases such as kidney failure and uncontrolled diabetes

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**
More than 1 sample in each individual
Number of samples in each individual: **42**
Patients undergoing heart transplant surgery
Actual sample size reached: **42**
More than 1 sample in each individual
Actual sample size in each individual: **42**
Patients undergoing heart transplant surgery

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used using free software (Random Allocation Software). Because the general population of patients is not known and the study is prospective, the best method of randomization for this research was block randomization. Blocking is used in order to balance the number of samples allocated to each of the studied groups. The size of the blocks is equal, but more than the number of sample volume is produced so that if it is necessary to enter a larger number of samples, the sequence will not be disturbed. Entry into the study will continue until the completion of the set number for both groups, and if a person is removed from one group during the study, intervention and follow-up will be replaced by the next person from the sequence of blocks. The production of random blocks was done by one of the researchers of the project who has no direct relationship with the patients and their assignment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Intervention and control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Commite of Kerman University of Medical Sciences

Street address

No. 2. Haft Bagh Alavi Bolv, Kerman university of medical sciences

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kerman

Province

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Postal code

7619813555

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

400001191

Health conditions studied

1

Description of health condition studied

Cardiac surgery

ICD-10 code

Z95.1

ICD-10 code description

Presence of aortocoronary bypass graft

Primary outcomes

1

Description

The score of sleep quality that is less than 5 is between 0 and 21.

Timepoint

In this study, the quality of sleep and anxiety and

depression of open heart surgery patients will be evaluated before the intervention, immediately after the intervention, 15 days later and one month after the end of the intervention.

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after receiving training, patients perform Amin's breathing before the operation, immediately after the operation, 15 days after the operation, and one month after the operation for 10 minutes every three hours.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman University of Medical Sciences

Full name of responsible person
Mansooreh Azizzadeh Forouzi

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

No

Title of funding source

معاونت تحقیقات دانشگاه علوم پزشکی کرمان

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
Kerman University of Medical Sciences

Full name of responsible person
Mansooreh Azizadeh Forouzi

Position
faculty member

Latest degree
Master

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After publishing the results of the study , the authors can send their request to the responsible author so that they can use the data of the study. All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

After publishing the results of the study , the authors can send their request to the responsible author so that they can use the data of the study.

To whom data/document is available

After publishing the results of the study , the authors can send their request to the responsible author so that they can use the data of the study. All data is potentially shareable after de-identifying individuals. The data will be accessible only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can use the study questionnaires by sending an email to the responsible author, and they can also receive the SPSS file of the data by maintaining confidentiality.

From where data/document is obtainable

Corresponding author, Mrs. Mansooreh Azizzadeh Frouzi email: forozy@gmail.com

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

After the publication of the study results, the authors can send their request to the responsible author so that they can use the study data. The requested information will be sent within two weeks.

Comments