Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Investigation of the effect of Buteyko breathing technique on sleep quality, fatigue, and Peripheral blood oxygen saturation in patients with acute coronary syndrome(ACS)

Protocol summary

Study aim

Determining the effect of the Buteyko breathing technique on sleep quality, fatigue, and peripheral blood oxygen saturation in patients with acute coronary syndrome hospitalized in the cardiac intensive care unit.

Design

This clinical trial is a randomized, triple-blind, controlled study with parallel groups. Patients with acute coronary syndrome are purposively selected and allocated to intervention (Buteyko breathing) and control (diaphragmatic breathing) groups using artificial intelligence. The sample size is 92 participants.

Settings and conduct

The study was conducted at Fatemeh Zahra Hospital in Khomain and Amir Kabir Hospital in Arak. Patients with acute coronary syndrome were purposively selected and randomly assigned to intervention (Buteyko) and control (diaphragmatic) groups. The study was triple-blinded, meaning participants, assessors, and intervention providers were unaware of group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria include diagnosis of acute coronary syndrome by a cardiologist, age 30 years or older, and oxygen saturation (SpO2) above 90%. Exclusion criteria include a history of respiratory diseases or heart surgery within the past two months and the presence of cardiac dysrhythmia.

Intervention groups

Buteyko Breathing Technique (BBT): Controlled, shallow nasal breathing with breath-holding after exhalation to reduce over-breathing and increase carbon dioxide tolerance. Patients in the intervention group perform this technique twice daily for 20 minutes each session over six weeks. Diaphragmatic Breathing: Deep breathing using the diaphragm muscle to improve oxygenation , taught to the control group and practiced during hospitalization.

Main outcome variables

The primary outcomes of the study include sleep quality, fatigue severity, and peripheral oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250607066101N1**
Registration date: **2025-06-15, 1404/03/25**
Registration timing: **prospective**

Last update: **2025-06-15, 1404/03/25**
Update count: **0**

Registration date

2025-06-15, 1404/03/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Buteyko breathing technique on sleep quality, fatigue, and Peripheral blood oxygen saturation in patients with acute coronary syndrome(ACS)

Public title

Investigation of the effect of Buteyko breathing technique on sleep quality, fatigue, and Peripheral blood oxygen saturation in patients with acute coronary syndrome(ACS)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of acute coronary syndrome by a cardiologist Age ≥ 30 of the participants BMI < 35 SPO2>90%

Exclusion criteria:

No diagnosis of heart failure in the study subject No history of specific diseases: individuals with a history of respiratory diseases such as asthma, COPD, bronchitis, etc., or heart surgery within the past two months. Absence of cardiac dysrhythmia in the study subject No history of mental illness, because psychological problems can affect the patient's ability to participate in the intervention. No cognitive impairments affecting the ability to learn and perform breathing techniques No history of myocardial infarction in the past two weeks No use of any other breathing or relaxation techniques in the intervention and control groups to prevent cross-effects of other interventions. Non-smoking No diagnosis of rheumatoid arthritis Participants who develop serious complications, such as uncontrolled cardiac disorders, requiring exclusion from the study to prevent harm to them. Participants' unwillingness to continue the study for any reason Feeling discomfort while performing the Buteyko breathing technique

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization and allocation of participants will be performed by an independent researcher using a list of patients and selection via artificial intelligence (Chatbot).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The blinding procedure in this study is implemented as a triple-blind design. Participants are completely unaware of their allocation to either the intervention or control group. The interventionists, who are responsible for teaching and administering the breathing techniques, have no knowledge of the patients' group assignments. Randomization is carried out by an independent researcher using artificial intelligence software, ensuring that the interventionists deliver the assigned interventions without any information about group allocation. Data assessors, who collect questionnaires and perform physiological measurements such as peripheral oxygen saturation (SpO2), are also blinded to the type of intervention each patient receives and operate independently from the intervention team. The statistical analyst responsible for data analysis is likewise blinded to the group assignments to prevent any bias during interpretation of the results. Random allocation is performed by an independent supervisor, and coded labels are assigned to each group; these codes remain concealed until the completion of the study and all data analyses. The breathing technique trainings are provided to both groups in a standardized and visually identical manner, preventing participants and hospital staff from discerning any differences between groups. This rigorous blinding approach minimizes biases arising from the awareness of participants, interventionists, and assessors, thereby enhancing the internal validity and reliability of the study findings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Khomein University of Medical Sciences

Street address

Zeynab-e-Kobra Hospital, next to Health Network, Ghods Boulevard, after 9th Dey Square, Arak-Khomein Road

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Province

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3881858573

Approval date

2025-06-11, 1404/03/21

Ethics committee reference number

IR.KHOMEIN.REC.1404.008

Health conditions studied

1

Description of health condition studied

Acute Coronary Syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Pittsburgh Sleep Quality Index Score

Timepoint

At the beginning of the study, 7, 14, 21, 28, 35, 42

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Fatigue Score of the Multidimensional Fatigue Inventory

Timepoint

At the beginning of the study, 7, 14, 21, 28, 35, 42

Method of measurement

Multidimensional Fatigue Inventory

3

Description

Peripheral Oxygen Saturation

Timepoint

1 day after the first implementation of the intervention

Method of measurement

Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the first day, for patients with acute coronary syndrome in the hospital, once their physical and mental conditions stabilize, education is provided by the intervention team regarding the nature of acute coronary syndrome and its symptoms and complications. Then, on the same day, the intervention group is taught the Buteyko breathing technique by the intervention team. Patients are then asked to perform the breathing technique in the presence of the intervention team so that the researcher can correct any errors. Additionally, pamphlets related to the Buteyko breathing technique and an educational audio file of BBT narrated by the primary researcher are given to the intervention group. Group A also receives their usual therapeutic and care treatments.The method of performing the Buteyko breathing technique is described as follows:Step 1: Controlled Pause PhaseThe patient sits upright and breathes normally through the nose with the mouth closed for 30 seconds.Then, a small inhalation and exhalation are performed.After exhalation, the patient pinches the nose to prevent air from entering (lungs are almost empty).The patient counts the time until the first urge to breathe in (this time is called the "controlled pause").Then the nose is released, and the patient breathes in, but the next breath should not be deeper than before.The goal of this phase is to reduce hyperventilation and increase tolerance to carbon dioxide.Step 2: Shallow BreathingThe patient sits upright and feels the airflow from the nostrils with a finger placed under them.Breathing should be calm and shallow, without pressure or deep breaths.Repetition of StepsThese two steps are alternated and performed for about 20 minutes.Then, patients in Group A (intervention) are asked to practice the designed Buteyko breathing technique (BBT) for 6 weeks at times when they are at the hospital and at home. Each patient should practice intensively for 20 minutes, 5 days a week. The session time should be at least two hours after breakfast in the morning. Each patient is asked to perform this technique at home twice a day (morning and evening, at least 2 hours after eating) during the study period. However, on the first day of hospitalization, due to patient fatigue from admission, they are asked to perform the breathing technique only once, and the intervention duration on the first day is reduced to 10 minutes.

Category

Rehabilitation

2

Description

Control group: Group B (control group) learns the diaphragmatic breathing technique from the intervention team and also receives their usual therapeutic and care treatments from the medical staff. They are asked to perform this technique as long as they are hospitalized. Patients in both groups are followed up weekly by phone during the intervention period by the intervention team, who are blinded to the group assignments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Al-Zahra Hospital, Shahid Bahram Sheikhi St., Khomein, Markazi Province

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Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Khomein School 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
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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