Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

An Investigation into the Combined Effects of Diaphragmatic and Pursed-Lip Breathing Exercises on the Quality of Life of Patients with Asthma

Protocol summary

Study aim
The aim of this study is to investigate the simultaneous effects of pursed-lip and diaphragmatic breathing exercises on the quality of life of patients with asthma.

Design
Randomized clinical trial with control group, with two parallel groups

Settings and conduct
The present study will be conducted as a two-group clinical trial with the participation of 60 patients with asthma admitted to Shahid Beheshti Hospital in Hamadan in 2026. Patients will be divided into two groups of control and intervention by simple random assignment method.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Definitive diagnosis of asthma by a specialist, age 18 to 65 years, ability to perform breathing exercises, willingness to participate in the study and signing informed consent. Exclusion criteria: Severe heart or lung disease, pregnancy

Intervention groups
Intervention group: Before the intervention, in a 90-minute session, the method of pursed-lip and diaphragmatic breathing exercises will be taught to the patients (each group including 5 people). Also, a CD containing the training of breathing techniques will be provided to the samples. Then, they will perform breathing exercises for 20 minutes every day for a month, once a day each time. To ensure that the breathing exercises are performed by the samples, follow-up will be conducted via text message. Control group: In the control group, no special action will be taken other than the routine training.

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260104068543N1**
Registration date: **2026-01-30, 1404/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-30, 1404/11/10**
Update count: **0**

Registration date
2026-01-30, 1404/11/10

Registrant information
Name
Faezeh Saeedian
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-03-06, 1404/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
An Investigation into the Combined Effects of Diaphragmatic and Pursed-Lip Breathing Exercises on the Quality of Life of Patients with Asthma

Public title
Effect of Breathing Exercises on Quality of Life in Patients with Asthma
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of asthma by a physician Age between 18 and 65 years Ability to perform breathing exercises Willingness to participate and signed informed consent
Exclusion criteria:
Severe concurrent cardiac or pulmonary diseases Pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
To generate the random allocation sequence, restricted randomization with variable block sizes (2, 4, and 6) and a 1:1 allocation ratio was utilized to ensure the unpredictability of the assignments. The random sequence was generated by an independent statistician (who played no role in recruitment, intervention, or data analysis) using computer-generated random numbers in SPSS software version 26. The unit of randomization was individual, and eligible patients were assigned to two groups: intervention (A) and control (B). To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) were used. The treatment group name was placed on a card inside each envelope. The envelopes were opened only after definitive patient registration and completion of baseline assessments by an independent administrative staff member (not involved in conducting the study), after which the contents were verified by the investigator. This rigorous protocol ensured that both investigators and patients remained completely blinded to the intervention type until the moment of envelope opening, eliminating any possibility of predicting or manipulating the group assignments.
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 Hamedan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh St., Hamedan
City
Hamedan
Province
Hamadan
Postal code
386 986 5178
Approval date
2025-12-13, 1404/09/22
Ethics committee reference number
IR.UMSHA.REC.1404.760

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Quality of life .
Timepoint
Measurement of quality of life at baseline (before starting the intervention), and at 4 and 8 weeks after beginning the breathing exercises.
Method of measurement
Using the standard SF-36 questionnaire to assess quality of life.

Secondary outcomes

1

Description
Quality of life related to respiratory health.
Timepoint
Measurement of respiratory-related quality of life at baseline (before starting the intervention), and at 4 and 8 weeks after beginning the breathing exercises.
Method of measurement
Using the standard Saint George’s Respiratory Questionnaire (SGRQ) to assess respiratory-related quality of life.

Intervention groups

1

Description

Intervention group: The intervention involves performing breathing exercises, including diaphragmatic breathing and pursed-lip breathing. These exercises do not require special equipment, and patients perform them in a semi-sitting (relaxed) position. Initially, participants receive training in a single 90-minute session led by the researcher. In this session, the precise method of diaphragmatic breathing (inhaling through the nose with abdominal protrusion and exhaling gently through pursed lips) and pursed-lip breathing (inhaling through the nose and exhaling slowly and prolonged through the mouth with compressed lips) is taught. Following the training, patients perform the exercises once daily for a total duration of 20 minutes over a period of one month (4 weeks). The structure of each session consists of 5 minutes of diaphragmatic breathing followed by 15 minutes of pursed-lip breathing. All exercises are conducted under the direct supervision of the researcher to ensure correct execution.

Category

Behavior

2

Description

Control group: Participants receive standard usual care without any additional breathing exercises.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital, Hamedan

Full name of responsible person
Faezeh Saeedian

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Shahid Beheshti Hospital, Shahid Fahmideh St., Hamedan

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6516783451

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Alireza soltanian

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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
Faezeh Saeedian

Position
Nursing student.msc

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No plan to share individual participant data is currently in place due to confidentiality concerns and the absence of a formal data sharing policy. No further information is available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available