

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 81 3838 0319

Email address

faezeh.saeediii96@gmail.com

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

Street address

Shahid Beheshti Hospital, Shahid Fahmideh St.,
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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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Info.research@umsha.ac.ir

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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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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