Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of multimodal rehabilitation exercises on dyspnea and quality of life among asthmatic patients.

Protocol summary

Study aim
Evaluate multimodal rehabilitation effects on dyspnea and quality of life.

Design
This single-blind randomized controlled trial includes two groups: the Integrated Rehabilitation Group and the Exercise and Pulmonary Rehabilitation Group. Participants are randomly assigned. Outcome assessors are blinded.

Settings and conduct
The study will be conducted at Imran Idrees Hospital, Sialkot, using non-probability convenience sampling. Interventions will be supervised by physiotherapists and dietitians. Ethical approval and informed consent will be obtained. Patient safety and confidentiality will be maintained.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Participants will be male and female, aged 20–40 years, diagnosed with asthma by a physician. They must have mild to moderate asthma with a Peak Expiratory Flow Rate (PEFR) ≥40%, oxygen saturation ≥90%, and occasional accessory muscle use. Participants should also present with respiratory symptoms such as wheezing or shortness of breath Exclusion Criteria: Participants will be excluded if they have cognitive impairment, severe co-morbidities greater than asthma, other pulmonary diseases, locomotor impairments, irregular medication use, significant cardiovascular conditions, pregnancy or lactation, or inability/unwillingness to attend rehabilitation sessions regularly.

Intervention groups
Integrated Rehabilitation Group (IRG): 8-week program combining exercise, muscle relaxation, and nutrition to improve lung function, reduce stress, and enhance quality of life. Exercise-Based Pulmonary Rehabilitation Group (EPRG): 8-week standard exercise program focusing on aerobic and resistance training, without additional psychological or nutritional support.

Main outcome variables
Pulmonary Function – assessed via Peak Expiratory Flow Rate (PEFR) using a peak flow meter.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250428065499N1**
Registration date: **2025-05-15, 1404/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-15, 1404/02/25**
Update count: **0**

Registration date
2025-05-15, 1404/02/25

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-30, 1403/05/09

Expected recruitment end date
2025-05-30, 1404/03/09

Actual recruitment start date
2024-07-30, 1403/05/09

Actual recruitment end date
2025-06-05, 1404/03/15
Trial completion date
2025-07-30, 1404/05/08

Scientific title
Effects of multimodal rehabilitation exercises on dyspnea and quality of life among asthmatic patients.

Public title
Rehabilitation exercises to improve breathing and quality of life in asthma patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-40 years Diagnosed with asthma Asthma patients eligible for pulmonary rehabilitation should have mild to moderate asthma with PEFR ≥ 40%, oxygen saturation ≥ 90%, and occasional use of accessory muscles Presence of respiratory symptoms such as wheezing, shortness of breath, or asthma Willingness to participate in the study Ability to perform and complete the 6-Minute Walk Test (6MWT)
Exclusion criteria:
Cognitive impairment Severe co-morbidities indicating greater illness morbidity than asthma alone Complications from any other pulmonary diseases in addition to asthma Locomotor system problems that interfere with the evaluation/intervention protocol Irregular use of medication prescribed by a physician Significant cardiovascular diseases, pregnancy, or lactation Inability to perform physical exercise or engage in rehabilitation activities Patients unable or unwilling to attend training sessions regularly
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **64**
More than 1 sample in each individual
Number of samples in each individual: **3**
pre-intervention, mid-intervention, and post-intervention measurements
Actual sample size reached: **50**
More than 1 sample in each individual
Actual sample size in each individual: **3**
Each individual provided three sets of data: baseline, mid-point, and post-intervention evaluations, including dyspnea levels, and quality of life scores.
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to the intervention or control group using a computer-generated random number sequence. Allocation concealment will be ensured using sealed, opaque, and sequentially numbered envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor will be blinded to the group allocation of participants. Due to the nature of the intervention, participants and the therapist will not be blinded.
Placebo
Not used
Assignment
Parallel
Other design features
This study will use single blinding, where participants will be unaware of their group allocation (intervention or control). The researchers conducting the interventions and assessments will not be blinded to the group allocation. This blinding method aims to reduce participant bias in reporting outcomes and responses, while recognizing that the researchers involved in the study cannot be blinded due to the nature of the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and ethics committee
Street address
26-M GULBERG 3,LAHORE
City
Sialkot
Postal code
51310
Approval date
2025-06-05, 1404/03/15
Ethics committee reference number
REC/RCR and AHS/24/0334

Health conditions studied

1

Description of health condition studied
Asthma is a chronic inflammatory disease of the airways characterized by symptoms such as wheezing, shortness of breath, chest tightness, and coughing. This study focuses on individuals with mild to moderate asthma eligible for pulmonary rehabilitation, aiming to improve respiratory function, exercise tolerance, and quality of life."
ICD-10 code
J45. 9
ICD-10 code description
Asthma

Primary outcomes

1

Description
Dyspnea Severity :Measures the intensity of breathlessness during activities.
Timepoint
Baseline, post-intervention (8 weeks), and 3-month follow-up.
Method of measurement
Modified Borg Dyspnea Scale.

Secondary outcomes

1

Description
Anxiety and Depression Levels:Evaluates psychological symptoms related to asthma.
Timepoint
Baseline, post-intervention (8 weeks), and 3-month follow-up.
Method of measurement
Hospital Anxiety and Depression Scale (HADS).

2

Description
Quality of Life:Assesses the impact of asthma on daily life and well-being.
Timepoint
Baseline, post-intervention (8 weeks), and 3-month follow-up.
Method of measurement
Asthma Quality of Life Questionnaire (AQLQ).

3

Description
Functional Capacity:Measures physical endurance and capacity to perform exercise.
Timepoint
Baseline and post-intervention (8 weeks).
Method of measurement
6-Minute Walk Test (6MWT).

Intervention groups

1

Description
Intervention group:Description: An 8-week multidisciplinary program including:Supervised exercise-based pulmonary rehabilitationProgressive muscle relaxation sessionsNutritional counselingGoals: Improve pulmonary function, dyspnea, psychological well-being, and quality of lifeFrequency & Duration: 3 sessions per week at the rehab center, for 8 weeksAssessment Points: Baseline, post-8 weeks, and 3-month follow-up.
Category
Rehabilitation

2

Description
Control group: Description: Patients receive standard asthma care as per current clinical guidelines without additional rehabilitation sessionsGoals: Serve as comparison for evaluating the IRG programFrequency & Duration: As determined by standard clinical practiceAssessment Points: Same as intervention group (baseline, post-8 weeks, and 3-month follow-up)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imran Idrees Teaching Hospital, Sialkot, Pakistan
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
Riphah international university of Lahore
Proportion provided by this source
100
Public or private sector
Private
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
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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 dataset will include all collected deidentified individual participant data (IPD) related to the study. This will include baseline demographic data, clinical data, and outcome measures such as pulmonary function, dyspnea severity, anxiety and depression scores, and quality of life questionnaires.
When the data will become available and for how long
The deidentified IPD will become available 6 months after the publication of the study results. It will remain accessible for a period of 5 years after the publication

To whom data/document is available

The deidentified IPD will be available to researchers working in academic institutions, non-profit organizations, and other research-focused entities. Business professionals may also apply if their research is in a related field and aligned with the study's objectives.

Under which criteria data/document could be used

The data will be available for academic research, focusing on analysis related to asthma management, rehabilitation, and respiratory function. Requests for data use will be reviewed by the research committee to ensure they meet ethical standards and the scope of the study.

From where data/document is obtainable

The data will be available upon request through the hospital's research office.

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

Interested researchers will need to submit a formal request through email, including the purpose of the analysis, the methodology, and a plan for data handling. Requests will be reviewed by the study's research committee, which will take 4–6 weeks to process.

Comments

The data will be made available in a secure, accessible format, and requests will be handled in compliance with data privacy regulations.