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Precision exercise in obese children with bronchial asthma

Submission date
31/10/2025

Recruitment status
No longer recruiting

Registration date
08/11/2025

Overall study status
Completed

Last Edited
07/11/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Bronchial asthma (BA) is a chronic inflammatory airway disease that is increasingly prevalent in children. When combined with obesity, it creates a complex clinical phenotype characterized by heightened systemic inflammation, altered adipokine profiles, impaired respiratory mechanics, and reduced exercise tolerance. This study aimed to evaluate the dose-dependent effects of aerobic exercise training on adiposity-linked biomarkers (e.g., leptin, adiponectin, resistin, IL-6, hs-CRP), body composition (e.g., fat mass, fat-free mass), and respiratory efficiency (e.g., FEV_1, FVC) in obese children with moderate bronchial asthma.

Who can participate?
Children aged 8 to 18 years, of either sex, diagnosed with moderate bronchial asthma according to GINA guidelines and with a BMI between 30 and 35 kg/m^2 (classified as obese). All participants were medically stable, on consistent asthma medication for at least 3 months prior, and not engaged in regular structured exercise.

What does the study involve?
In this study participants were randomly allocated into three groups:
- Control group: Received only a standardized 30-minute respiratory retraining program, 3 times /week for 12 weeks.
- Low-dose aerobic exercise group: Received the same respiratory retraining plus 150 minutes /week of moderate-intensity treadmill-based aerobic exercise (50–70% HRmax).
- High-dose aerobic exercise group: Received respiratory retraining plus 300 minutes/week of the same aerobic exercise.

All exercise was supervised and progressed gradually over 12 weeks. Measurements taken before and after the intervention included:
- Serum levels of adipokines and inflammatory markers (leptin, adiponectin, resistin, IL-6, hs-CRP)
- Body composition via bioelectrical impedance analysis (BFP, FM, FFM, TBW, BMR)
- Pulmonary function tests (FEV_1, FVC, FEV_1/FVC ratio)

What are the possible benefits and risks of participating?
Benefits: Participants could experience improvements in asthma control, reduced systemic

inflammation, favorable changes in body composition, and enhanced respiratory and cardiovascular fitness. The study also provided supervised, safe exercise training and respiratory retraining at no cost.

Risks: Potential risks included exercise-induced bronchoconstriction or transient dyspnea during aerobic sessions. However, all sessions were medically supervised, and participants were under optimal asthma management throughout. No serious adverse events were reported in the study.

Where is the study run from?
The study was conducted at the Physical Rehabilitation Center and Cardiopulmonary Assessment Unit, College of Applied Medical Sciences, Prince Sattam bin Abdulaziz University (PSAU), in Al-Kharj, Kingdom of Saudi Arabia.

When is the study starting and how long is it expected to run for?
The study ran from September 2023 to September 2024 (a total duration of 12 months).

Who is funding the study?
The Deanship of Scientific Research at PSAU, Saudi Arabia

Who is the main contact?
Prof. Ragab K. Elnaggar, rke_pt2001@yahoo.com; r.elnaggar@psau.edu.sa

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Precision exercise prescription for obese children with bronchial asthma: a dose-dependent study on adiposity biomarkers, body composition, and respiratory efficiency

Study objectives
This study explored the dose-dependent effects of aerobic exercise on adiposity-linked biomarkers, body composition, and respiratory efficiency in obese children with bronchial asthma

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/09/2023, Physical Therapy Research Ethics Committee (College of Applied Medical Science, Prince Sattam Bin Abdulaziz University, Al-Kharj, 11942, Saudi Arabia; +96615886301 ; a.osailan@psau.edu.sa), ref: RHPT/0023/041

Study design
A prospective three-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Obesity and bronchial asthma

Interventions
This investigation recruited 72 obese children with a confirmed bronchial asthma diagnosis.

Randomization Method: The study employed permuted block randomization with blocks of varying sizes. Allocation was concealed using sequentially numbered, sealed, opaque envelopes. The randomisation process was conducted by an independent researcher not involved in participant recruitment or assessment.

Participants were randomized into three cohorts:
A control group undertaking less than 75 minutes of weekly aerobic activity
A low-dose group completing 150 minutes/week
A high-dose group performing 300 minutes/week

Exercise intensity was maintained between 50-70% of the age-predicted maximum heart rate across 3-4 supervised sessions per week for a 12-week intervention period.

All groups engaged in a concomitant structured respiratory retraining program delivered three times/week for 12 weeks in succession. The program included breathing exercises, inspiratory muscle training, diaphragmatic release, thoracic mobilization, breath-hold technique, pursed-lip breathing, and relaxation techniques.

Intervention Type
Behavioural

Primary outcome(s)
The following adiposity and inflammatory biomarkers were measured using commercially available enzyme-linked immunosorbent assay (ELISA) kits, pre- and post-training:
1. Serum leptin concentration
2. Serum total adiponectin
3. Serum high-molecular-weight adiponectin
4. Serum resistin concentration
5. Systemic interleukin-6
6. High-sensitivity C-reactive protein

The following body composition variables were measured using a bioelectrical impedance analysis device, except where stated, pre- and post-training:
7. Body fat percentage
8. Total body fat mass
9. Fat-free mass
10. Total body water
11. Basal metabolic rate

The following respiratory function variables were measured using a calibrated spirometer pre- and post-training:
12. Forced expiratory volume in one second (FEV#)
13. Forced vital capacity (FVC)
14. Forced Expiratory Volume in One Second (FEV1) / Forced Vital Capacity (FVC) Ratio

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
05/09/2024

Eligibility

Key inclusion criteria
1. Age of 8-18 years
2. Body mass index ranging from 30 to 35 kg/m2
3. Verified asthma diagnosis per the Global Initiative for Asthma (GINA)
4. criteria
5. Moderate Onset
6. Clinically Stable
7. Maintained medication dosages in the past three months
8. Free of lower limb or spinal deformities
9. Not engaging in regular exercise regimens in the past six months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
18 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Exacerbated asthma symptoms
2. Chronic lung comorbidities
3. Cardiovascular or musculoskeletal conditions expected to hinder the training

Date of first enrolment
17/09/2023

Date of final enrolment
12/04/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Physical Rehabilitation Center of Prince Sattam Bin Abdulaziz University
Abdullah Ibn Amer St., Postal Code: 11942
Al-Kharj
Saudi Arabia
11942

Sponsor information

Organisation
Prince Sattam Bin Abdulaziz University

ROR
https://ror.org/04jt46d36

Funder(s)

Funder type
University/education

Funder Name
Deanship of Scientific Research, Prince Sattam bin Abdulaziz University

Alternative Name(s)
Deanship of Scientific Research, Deanship of Scientific Research at Prince Sattam bin Abdulaziz University, , DSR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data (IPD) collected during this study, including demographic characteristics, clinical measurements, biomarker levels, body composition indices, and pulmonary function test results, will be made available upon reasonable request. Data sharing will be permitted for research purposes only, following approval by the Principal Investigator and the Physical Therapy Research Ethics Committee at Prince Sattam bin Abdulaziz University.

Requests for data access must be submitted in writing to the corresponding author, Prof. Ragab K. Elnaggar, rke_pt2001@yahoo.com; r.elnaggar@psau.edu.sa, outlining the proposed research objectives, methodology, and intended use of the data. Approved researchers will be required to sign a data use agreement that ensures participant confidentiality, prohibits re-identification, and restricts data use to the approved scope. Data will be shared in a secure, anonymized format no earlier than 6 months and no later than 24 months following publication of the primary study results. They will be retained for a minimum of 5 years after study completion in accordance with institutional and ethical guidelines.

IPD sharing plan summary
Available on request