ISRCTN33794377 https://doi.org/10.1186/ISRCTN33794377

Inspiratory muscle training in patients with asthma

Submission date
14/04/2016

Recruitment status
No longer recruiting

Registration date
15/04/2016

Overall study status
Completed

Last Edited
02/03/2021

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma is a common long-term health condition caused by inflammation of the small tubes (bronchi) that carry air in and out of the lungs. Symptoms vary in severity and include coughing, wheezing, a tightness in the chest and feeling breathless. It occurs when the sufferer comes in contact with something that irritates their lungs – a trigger - causing their airways to narrow and an increase in the production of phlegm in their airways. Common triggers include house dust mites, animal fur, pollen, cigarette smoke, exercise and viral infections (such as a cold). Sometimes, as it can be more difficult for asthma sufferers to take a breath, the respiratory muscles (the muscles that help a person to breathe) can become overworked, or overloaded. This can be alleviated though physiotherapy treatments (interventions) that reduce the demand on the muscles or strengthen them. There is some scientific literature demonstrating that strengthening the muscles that help a person to breathe in (the inspiratory muscles) does help to reduce symptoms. However, more scientific evidence is needed. This study looks at the effects of inspiratory muscle training (IMT) on the strength, endurance and function of these muscles, as well as a person's quality of life, the number of hospital admissions, and any worsening of a patient's condition.

Who can participate?
Asthma sufferers aged between 20-70.

What does the study involve?
Participants are randomly allocated to one of two groups, a IMT group or a control group. All participants attend two educational sessions on asthma care and information about the respiratory system, the symptoms of asthma and what can influence it, how to prevent a worsening of symptoms, training on good breathing techniques and information regarding regular physical activity. Those in the IMT group also receive IMT training twice a day, over 5 days for a period of 8 weeks. All participants are assessed before the study begins, after the 8 week study period and then again 3 months later.

What are the possible benefits and risks of participating?
The participant receives a report with the results of lung function tests and inspiratory muscle strength for his/her knowledge and medical care and the results of this study can be used in

future studies contributing to the advancement of science. Potential risks include a shortness of breath and faster heart rate during the test.

Where is the study run from?
Federal University of Minas Gerais (Brazil)

When is the study starting and how long is it expected to run for?
March 2014 to February 2018

Who is funding the study?
National Council for Scientific and Technological Development (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of a high intensity inspiratory muscle training program versus an education program on inspiratory muscle strengh and endurance, functional capacity and quality of life in patients with asthma: a randomised controlled trial.

Study objectives

Inspiratory muscle training (IMT) associated to an educational program improves inspiratory muscle strength and endurance, functional capacity and quality of life in patients with asthma more than only an educational program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Universidade Federal de Minas Gerais Ethics Committee, 23/10/2014, ref: CAAE: 35493714.1.0000.5149

Study design
Randomised controlled trial - single centre

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
Description of intervention:
1. IMT Group (IMT plus educational program)
2. Control Group (educational program)

Inspiratory muscle training (IMT): six sets of 30 breaths per day, divided in twice per day, five days a week, during eight weeks, with PowerBreathe K3. Minimum load of 50% of maximal inspiratory pressure, weekly adjusted.

Educational program: two individual (or with family) sessions on asthma care, including: knowledge about respiratory system, symptoms of asthma and factors that influence it, preventive strategies to avoid exacerbations, training about correct inhalation technique, encouragement for regular physical activity.

Intervention Type
Other

Primary outcome(s)
1. Inspiratory muscle strength - maximal inspiratory pressure assessed by a digital manovacuometer
2. Inspiratory muscle endurance – time, volume, flow, work and power assessed by an electronic tapered flow resistive loading device
3. Functional capacity – maximal distance covered during shuttle walking test
4. Quality of life - Brazilian version of the Asthma Quality of Life Questionnaire

Assessed at baseline, 8 weeks and 3 months.

Key secondary outcome(s))
1. Lung function: Forced expiratory volume in the first second-FEV1, forced vital capacity-FVC and peak expiratory flow-PEF
2. Hospital admissions
3. Number of exacerbations

Assessed at baseline, 8 weeks and 3 months.

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Patients with asthma according to GINA - an increase in FEV1 of > 12% and 200mL after administration of a bronchodilator indicates reversible airflow limitation consistent with asthma
2. Age between 20 and 70 years old
3. No smokers
4. Asthma control test above 18 points; 5.- Auto report of absence of cardiac and neurological diseases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Fever
2. Flu symptoms or respiratory infection in the seven days prior to evaluation
3. Orthopedic and neurological problems
4. Inability to understand or carry out any study procedures

Date of first enrolment
20/05/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Minas Gerais
Brazil
31.270-901

Sponsor information

Organisation
Federal University of Minas Gerais

ROR
https://ror.org/0176yjw32

Funder(s)

Funder type
Government

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Alternative Name(s)
Brazilian National Council for Research and Development, National Council for Scientific and Technological Development, CNPq - Conselho Nacional de Desenvolvimento Científico e Tecnológico, National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CNPq

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2021	02/03/2021	Yes	No