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Evaluating the effects of exercise on asthma control and quality of life among asthmatic children

Submission date
09/11/2015

Recruitment status
No longer recruiting

Registration date
13/11/2015

Overall study status
Completed

Last Edited
12/11/2015

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Asthma is a long-term condition which affects the airways. It can affect people of any age, however in most cases it starts in childhood. When a person is suffering from asthma, the bronchi (tubes which carry air in and out of the lungs) can become narrowed or swollen (inflammation). The airways are extremely sensitive (hyperresponsive) to both natural chemicals the body produces and irritants outside the body, such as dust or pollen. This causes the sufferer to feel tightness in the chest as the airways become inflamed, causing coughing and difficulty breathing. In many children suffering from asthma these problems are worse at night, causing problems with sleep. Regular exercise is thought to play an important part of controlling asthma. Many studies have shown that moderate intensity exercise can help to expand the airways and increase lung capacity (the amount of air that can be breathed into the lungs). There is also evidence that exercise can help to lower the amount of inflammatory biomarkers (chemical indicators of inflammation) in the body. Currently, there is not enough evidence that regular exercise has an effect on the level of inflammatory biomarkers in asthma. The aim of this study is to find out whether regular exercise can help to lower the amount of inflammatory biomarkers, and improve lung function and sleep quality in children suffering from asthma.

Who can participate?
Children aged between 6 and 12 years old who have well-controlled asthma.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a two hour educational session. The session provides information about asthma, how important it is to monitor your own condition and the importance of getting regular medical checks from the doctor. These participants then carry on as normal for the next 12 weeks. Those in the second group also receive the educational session, but also take part in physical training. Participants have physical training sessions three times a week for 12 weeks. Each session involves a warm up, 30-40 minutes of moderate intensity exercise and a cool down. Enjoyable children's games such as rope jumping and dodge-ball are used in order to keep up the children's motivation. At the start of the study and then again after 12 weeks, participants in both groups are tested to

find out how well their lungs and hearts are working, as well as having a blood test to find out if there is any different to the markers in their blood related to inflammation.

What are the possible benefits and risks of participating?
Participants who take part in the physical training may benefit from an improvement to their breathing and may sleep better. There are no notable risks of taking part in this study, although participants may experience pain and bruising from blood testing.

Where is the study run from?
Chung-Shan Medical University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2010 to January 2013

Who is funding the study?
China Medical University (Taiwan)

Who is the main contact?
Dr Yu-Kuei Teng

Contact information

Type(s)
Scientific

Contact name
Dr Yu-Kuei Teng

ORCID ID
http://orcid.org/0000-0003-4041-6783

Contact details
No. 91, Hsueh-Shih Road
Taichung
Taiwan
404

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of Physical Training on pulmonary function, inflammatory biomarkers, and sleep quality in non-obese CHildren with ASthma: A randomized control trial

Acronym
EPTCHAS

Study objectives
Children in the physical training group would have better lung function, a lower level of biomarkers, and better sleep quality than those children in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Broad China Medicial University Hospital, 22/05/2009, ref: DMR98-IRB-095-4

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet

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

Interventions
Each child is randomly assigned to either the training group (asthma self-management education and physical activity training program) or the control group (asthma self-management education).

The self-management education program includes a two hour session providing information about asthma, self-monitoring (the importance of self-monitoring of peak expiratory flow rate), regular medical checks, and asthma management plan.

The physical training involves three sessions a week for a period of twelve weeks. Each session starts with a 10-15 minute warm-up period, followed by 30-40 minutes of moderate intensity physical training and a 10-15 minute cool-down period. Participants are encouraged to perform moderate intensity physical training at 60-75% of maximal heart rate (HRmax) for 30-40 minutes, aiming to improve their endurance. In order to arouse children’s motivation, enjoyable

recreational games were included, such as jogging, walking, basketball, dodge-ball, and rope jumping.

All children received an evaluation of lung function, pulmonary function, sleep quality and inflammatory biomarkers at baseline and the end of twelve weeks of physical training.

Intervention Type
Other

Primary outcome measure
Effects of physical training measured using the lung function test, methacholine test, biochemical analysis (Cytokine assays and Lipoxin A4) and polysomnography at baseline and 12 weeks.

Secondary outcome measures
1. Anthropometric measures (weight, height, waist circumference and BMI Z-score) and demographic data (gender ratio, percentage of allergic rhinitis, duration of asthma history, age) are measured at baseline and 12 weeks
2. Pulmonary function is measured using spirometry and methacholine test at baseline and 12 weeks
3. Inflammatory biomarkers are measured using Bio-Plex Pro human Cytokine/Chemokine Panel kits (Bio-Rad) and the enzyme-linked immunosorbent assay (ELISA) at baseline and 12 weeks
4. Sleep quality is measured using polysomnography at baseline and 12 weeks

Overall study start date
20/05/2009

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Children aged between 6 and 12 years
2. Diagnosis of mild asthma by a physician based on the criteria of asthma symptoms and medical history
3. Having a methacholine test dose (PD20) of 8 mg/ml or less
4. Able to read and write
5. Having a score on the Asthma Control Test ≥ 20 indicated ‘‘well-controlled’’ asthma

Participant type(s)
Other

Age group
Child

Lower age limit
6 Years

Upper age limit

12 Years

Sex
Both

Target number of participants
62

Key exclusion criteria
1. Any chronic disease, e.g. epilepsy, congenital heart disease, serious physical/psychiatric disorders, severe asthma, acute asthma exacerbations, obesity (body mass index above 95th percentile)
2. Children who had a regular exercise habit (who perform physical activity 3 or more sessions per week at moderate to vigorous intensity for 30 min or above)
3. Participating in any other clinical trials

Date of first enrolment
01/04/2010

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
Taiwan

Study participating centre
Chung-Shan Medical University Hospital
Department of Pediatrics and Center of Sleep Medicine
110 Chien-Kuo N Road
Sec. 1
Taichung
Taiwan
40402

Sponsor information

Organisation
China Medical University

Sponsor details

No. 91, Hsueh-Shih Road
Taichung
Taiwan
404

Sponsor type
University/education

ROR
https://ror.org/0368s4g32

Funder(s)

Funder type
University/education

Funder Name
China Medical University

Alternative Name(s)
, CMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in PLOS ONE journal.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request