'The effect of hypnotherapy on asthma control in children.'

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21081

Source NTR

Brief title EHAC

Health condition

asthma

exercise induced bronchoconstriction

Sponsors and support

Primary sponsor: Stichting Pediatrisch Onderzoek Enschede **Source(s) of monetary or material Support:** Stichting Pediatrisch Onderzoek Enschede

Intervention

Outcome measures

Primary outcome

• To assess the protective effect of hypnotherapy training on asthma control (measured with the fall in FEV1 after an ECT) in asthmatic children with EIB between 8-18 years.

Secondary outcome

• To assess the protective effect of hypnotherapy on EIB as assessed with Forced Oscillation Therapy (FOT).

• To assess the effect of hypnotherapy training on subjective asthmatic symptoms in asthmatic children between 8-18 years, using the C-ACT and the PAQLQ.

Study description

Background summary

Background of the study:

Asthma is the most common chronic condition in childhood, characterized by episodic airflow limitation, which can be relieved by different types of inhaled bronchodilator therapy. No asthma treatment currently available provides protection to all patients and a substantial number of asthmatic children will experience symptoms in spite of their therapy. It is therefore clinically important that new venues of therapy will be explored. Hypnotherapy has been reported as a promising therapy within pediatric respiratory medicine. More randomized controlled studies are needed to fully explore the possible benefits of hypnotherapy for asthmatic children. In this study, we want to analyse the protective effect of hypnotherapy on asthma control in children with exercise induced bronchoconstriction (EIB).

Objective of the study:

Primary Objective: • To assess the protective effect of hypnotherapy training on asthma control (measured with the fall in FEV1 after an ECT) in children with EIB between 8-18 years. Secondary Objectives: • To assess the protective effect of hypnotherapy on EIB as assessed with Forced Oscillation Therapy (FOT). • To assess the effect of hypnotherapy training on subjective daily asthmatic symptoms, using the C-ACT and the PAQLQ.

Study design:

This study is a multicenter randomized controlled trial. The patients will be recruited from two hospitals: MST and St. Antoniuis hospital. The patients from MST will undergo their ECT at the OCON in Hengelo. The patients from the St. Antonius Hospital will undergo their ECT at the Center of Excellence in Amersfoort. The ECT will be performed by a researcher who is blinded (single-blind). The hypnotherapy sessions and the visit to the nurse practitioner will take place in hospital where the patients were recruited.

Study population:

Asthmatic children between 8-18 years with mild to moderate EIB (fall of FEV1 < 40%) as only sign of uncontrolled asthma.

Intervention (if applicable):

The intervention group will receive 2 hypnotherapy sessions and are instructed to perform daily hypnotherapy exercises at home during 4 weeks. In the control group maintenance medication will not be changed.

Primary study parameters/outcome of the study:

The effect of hypnotherapy on asthma control compared to standard care, as measured with the fall in FEV1 during an exercise challenge test (ECT).

Secundary study parameters/outcome of the study (if applicable):

The effect of hypnotherapy on asthma control compared to standard care, as measured with FOT. The effect of hypnotherapy on subjective asthmatic symptoms as measured with the questionnaires C-ACT and PAQLQ.

Study objective

We expect treatment with hypnotherapy will diminish fall in FEV1 after exercise and improve quality of life.

Study design

During their first visit, children will fill out the C-ACT and PAQLQ and demographic data on age, sex and body mass index (BMI) will be noted. Lung function will be assessed with spirometry during a standard ECT (jumping castle or treadmill, depending upon the preference of the child with regard to age) and with FOT. In the next 4 weeks, group 1 will receive standard care as previously described, while group 2 will receive standard care complemented with hypnotherapy.

After 4 weeks, the participants will again fill out the C-ACT, PAQLQ and perform an ECT again.

Intervention

Contacts

Public

Afdeling kindergeneeskunde

N. Lammers Postbus 50.000

Enschede 7500 KA The Netherlands 053 4872310 **Scientific** Afdeling kindergeneeskunde

N. Lammers Postbus 50.000

Enschede 7500 KA The Netherlands 053 4872310

Eligibility criteria

Inclusion criteria

- Age between 8-18 years
- Paediatrician diagnosed as thma with mild to moderate EIB (13%-40% fall in FEV1) as measured with an ECT
- Ability to perform spirometry and ECT's and to receive hypnotherapy training

Exclusion criteria

- Other pulmonary or cardiac illnesses
- Severe EIB i.e. a fall of \geq 40% FEV1 in the first ECT, requiring an acute change in maintenance medication (standard care)
 - 4 'The effect of hypnotherapy on asthma control in children.' 10-05-2025

- Other symptoms of uncontrolled asthma such as nocturnal asthmatic symptoms, exacerbations in the 4 preceding weeks and during the study.

- Use of long acting bronchodilator agents 24 hours before testing
- Use of short acting bronchodilator agents 8 hours before testing
- Hospitalization or systemic prednisolone due to asthma exacerbation in last 6 weeks
- Other changes in asthma medication during treatment period
- Upper or lower respiratory tract infections during treatment period

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	60
Туре:	Anticipated

Ethics review

Positive opinion
Date:
Application type:

27-03-2017 First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register NTR-new NTR-old Other **ID** NL6356 NTR6540 METC Twente : P17-14

Study results

Summary results not applicable