

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

Gepubliceerd: 27-03-2017 Laatste bijgewerkt: 13-12-2022

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21081

### Bron

NTR

### Verkorte titel

EHAC

### Aandoening

asthma

exercise induced bronchoconstriction

### Ondersteuning

**Primaire sponsor:** Stichting Pediatrisch Onderzoek Enschede

**Overige ondersteuning:** Stichting Pediatrisch Onderzoek Enschede

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

- 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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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. Antonius 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).

Secondary 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.

## **Doel van het onderzoek**

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

## **Onderzoeksopzet**

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.

## **Onderzoeksproduct en/of interventie**

Hypnotherapie

## Contactpersonen

### Publiek

Afdeling kindergeneeskunde

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### Wetenschappelijk

Afdeling kindergeneeskunde

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Postbus 50.000

Enschede 7500 KA  
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053 4872310

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age between 8-18 years
- Paediatrician diagnosed asthma 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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)
- 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

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	27-03-2017

Soort:

Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL6356
NTR-old	NTR6540
Ander register	METC Twente : P17-14

## Resultaten

### Samenvatting resultaten

not applicable