

# The effect of yoga on chronic abdominal pain and quality of life.

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Children with chronic abdominal pain that received yoga treatment additional to standard care will show less abdominal pain compared to children that received only standard care.

<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-OMON21105

### Bron

Nationaal Trial Register

### Verkorte titel

YOGA study

### Aandoening

chronic abdominal pain

## Ondersteuning

**Primaire sponsor:** Jeroen Bosch hospital, Den Bosch

**Overige ondersteuning:** Nuts Ohra, medical financial support

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The reduction of abdominale pain is our primary outcome. Abdominale pain is measured by an abdominal pain diary. Patients will be instructed to score pain intensity and pain frequency during 1 month at baseline

period, after finishing the treatment and at 6 and 12 months follow up. Clinical remission is defined as a decrease of the pain intensity score and pain frequency score of  $> 80\%$ ; significant improvement is defined as a decrease of pain intensity score and pain frequency score between 30% and 80% and treatment is considered unsuccessful if the scores improved  $< 30\%$  or got worse.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Background: Chronic abdominal pain is a common problem of school-going children and is one of the most frequent reasons to visit a pediatrician. Abdominal pain is often associated with other somatic complaints such as headache, back and limb pain. These pain symptoms lead to low quality of life and frequent school absence. The benefits of standard treatment (reassurance, dietary manipulation) and of pharmacological therapy are limited. Several studies have shown that psychological distress is strongly associated with abdominal pain in children, not just as a consequence of the pain, but probably also as a predictor of symptoms. Research has shown that yoga decreases stress, including psychological and physical symptoms.

Aim: The aim of this study is to compare the effect of yoga exercises and standard care on pain frequency, intensity and quality of life in children with functional abdominal pain.

Methods: 65 children, aged 8-18 years with chronic abdominal pain will be randomized to one of these treatments: yoga therapy additional to standard care or standard care alone. Primary outcomes are the percentages of patients with complete remission of chronic abdominal pain after the treatment phase and at six and twelve months follow up. Secondary outcome are changes in quality of life.

### Doel van het onderzoek

Children with chronic abdominal pain that received yoga treatment additional to standard care will show less abdominal pain compared to children that received only standard care.

### Onderzoeksopzet

Outcomes are assessed at:

t=0 baseline; before randomisation;

t=1 directly after finishing the treatment;

t=2 six months follow up;

t=3 twelve months follow up.

### **Onderzoeksproduct en/of interventie**

Yoga therapy will be given in groups of 7- 8 children per group, in which patients will receive one treatment session each week for 3 months. These hatha yoga sessions of 1.5 h each will be provided by a children's yoga teacher. The sessions are based on classic Hatha yoga principles in combination with specialized yoga exercises for children.

The control group will receive treatment as usual (information about the disorder and dietary advice).

## **Contactpersonen**

### **Publiek**

Postbus 90153  
J.J. Korterink  
Henri Dunantstraat 1  
5223 GZ 's-Hertogenbosch  
Den Bosch 5200 ME  
The Netherlands  
+31 (0)73 5337932

### **Wetenschappelijk**

Postbus 90153  
J.J. Korterink  
Henri Dunantstraat 1  
5223 GZ 's-Hertogenbosch  
Den Bosch 5200 ME  
The Netherlands  
+31 (0)73 5337932

## **Deelname eisen**

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

Children aged 8-18 years are included if they meet the criteria for functional dyspepsia, IBS, functional abdominal pain (FAP) or abdominal migraine, based on the Rome III Criteria for Functional Bowel Disorders Associated with Abdominal Pain or Discomfort in Children.

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

Children with abdominal pain as result of inflammatory, anatomic, metabolic or neoplastic disease. Children who already participated in yoga therapy, hypnotherapy, psychotherapy or any form of relaxation therapy for functional abdominal pain in the past. Children with mental retardation.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	65
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies

Datum: 14-02-2012  
Soort: Eerste indiening

## Registraties

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

ID: 37663  
Bron: ToetsingOnline  
Titel:

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

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL3142
NTR-old	NTR3286
CCMO	NL38810.028.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37663

## Resultaten

### Samenvatting resultaten

N/A