

# Comparison of the effect of yoga and standard care on functional abdominal pain: pain reduction and improvement of quality of life? A randomized controlled trial

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The aim of this study is to find a succesful treatment for functional abdominal pain in children and at the same time improve the quality of life of these children. A second aim is to reduce the hospital visits and with that the costs.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal signs and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37663

### Source

ToetsingOnline

### Brief title

Yoga study

### Condition

- Gastrointestinal signs and symptoms
- Somatic symptom and related disorders

### Synonym

functional abdominal pain, irritable bowel syndrome

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Jeroen Bosch Ziekenhuis

**Source(s) of monetary or material Support:** Nuts Fonds Ohra (subsidie aangevraagd)

## Intervention

**Keyword:** children, functional abdominal pain, yoga therapy

## Outcome measures

### Primary outcome

Primary outcome measures are the percentages of patients with complete remission of functional abdominal pain after the treatment phase (t = 1) and at six months follow up (t = 2). 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.

### Secondary outcome

Secondary outcome measures are pain intensity score, pain frequency scores and the results of the Kidscreen questionnaire.

## Study description

### Background summary

Recurrent abdominal pain is present in 0.3-19% of school-going children in the US and Europe and in 1.8-4.6% in Dutch school-going children. This is one of the most frequent reasons to visit a pediatrician<sup>1</sup>. This type of abdominal pain is often functional, i.e. no organic cause is found to explain the symptoms. In

almost 30% of patients with chronic or recurrent abdominal pain, pain persists for more than 5 years, despite frequent medical attention. 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 and adult as well as pediatric patients are often referred for additional psychological or behavioural therapy. The relaxation-based therapy, hypnotherapy, has shown to be more effective than standard medical therapy in children with Functional Abdominal Pain (FAP) or Irritable Bowel Syndrome (IBS). One other type of complementary therapy that has been receiving more attention recently is yoga therapy. Research has shown that yoga decreases stress, including psychological and physical symptoms. In 2008 we performed a pilot study, in which 20 children, aged 8-18 years, with Irritable Bowel Syndrome (IBS) or Functional Abdominal Pain (FAP) were enrolled and received 10 yoga lessons. We showed that yoga exercises are effective for children aged 8-18 years with FAP, resulting in significant reduction of pain intensity and frequency, especially in children of 8-11 years old. Although the result of the pilot study are promising, there is a need to further investigate and confirm the effects of yoga on children with abdominal pain with a randomized controlled study. The lack of effective therapies for FAP, the lower quality of life and frequent school absence as result of FAP are strong arguments in favor of this study. Yoga is simple, can be easily applied at home, and has lower costs than hypnotherapy.

## **Study objective**

The aim of this study is to find a successful treatment for functional abdominal pain in children and at the same time improve the quality of life of these children. A second aim is to reduce the hospital visits and with that the costs.

## **Study design**

65 children in two different age groups (8-11 years and 12-18 years) will be randomized and receive yoga therapy or standard therapy.

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 will be given by a yoga teacher and the yoga exercises are created especially for children with abdominal pain.

Standard care will include education about functional abdominal pain by a paediatrician, advice about fibres and fluid.

Outcomes are assessed at several time points: a t=0 (at baseline; before randomisation), at t=1 (directly after finishing the treatment period) at t=2 (three months after finishing the treatment period) and at t=3 (9 months after finishing the treatment period).

We will use the following instruments:

- Abdominal pain diary (APD): Patients will be instructed to score pain intensity and pain frequency in an abdominal pain diary during the baseline period (a month prior to t=0), for a month after t = 1, for a month prior to t = 2 and for a month prior to t= 3. Pain intensity will be scored using the validated six-face Faces Pain Scale-Revised 12: ranging from 1 (=no pain) to 6 (very much pain) (Fig. 1). Pain frequency will be scored as 0 = no pain, 1 = 0\* 20 min of pain, 2 = 20 40 min of pain, 3 = 40\*90 min of pain and 4 = more than 90 min of daily pain.

The daily scores will be added up to obtain a pain intensity score (minimum score of 31 and a maximum score of 186) and a pain frequency score (with a minimal score of 0 and a maximum score of 124) for these different time points.

- Kidscreen-27: The Kidscreen-27 Quality of Life questionnaire will be administered to the patients and their parents at t = 0, t = 1, t = 2 and t = 3 with permission of the authors<sup>13</sup>. The Kidscreen questionnaire is a validated 27-item quality of life screening instrument for children of 8 years and above and their parents that encompasses physical wellbeing (5 items), psychological well being (7 items), autonomy and parents (7 items), social support and peers and school (4 items) functioning. A 5-point response scale is used (low and high scores indicate low and high health related QoL respectively).

## **Intervention**

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 sessions are a mixture of classical yoga poses and relaxation exercises in which children learn to relax with yoga breathing techniques. During and after the treatment period, patients will be allowed to perform the yoga exercises at home. Patients will be taught to relax the abdomen and to focus their thoughts on a single topic or good experience instead of random wandering of thoughts or thinking about negative experiences. The overall goals of the yoga lessons will be to achieve balance, flexibility, concentration and relaxation.

## **Study burden and risks**

In our opinion there are no extra risks involving this study. The only extra burden for the children in the intervention group is the yoga therapy. This will take 1,5 hours a week and a total of 18 hours in 3 months.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

### Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	65
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-02-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	02-07-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	21-08-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21105

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
CCMO	NL38810.028.11
OMON	NL-OMON21105