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

No registrations found.

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

Summary

ID

NL-OMON21105

Source
Nationaal Trial Register

Brief title
YOGA study

Health condition

chronic abdominal pain

Sponsors and support

Primary sponsor: Jeroen Bosch hospital, Den Bosch
Source(s) of monetary or material Support: Nuts Ohra, medical financial support

Intervention

Outcome measures

Primary outcome

The reduction of abdominale pain is our primairy 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.

Secondary outcome

Secondary outcome measure is the quality of life, which will be measured by the The Kidscreen-27 Quality of Life questionnaire. This questionnaire will be administered to the patients and their parents at baseline, after finishing the treatment and at 6 and 12 months follow up.

Study description

Background summary

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.

Study objective

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.

Study design

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.

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

Contacts

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Eligibility criteria

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	65
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37663
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A