Hypnotherapy for Abdominal Pain in Childhood.

No registrations found.

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

Summary

ID

NL-OMON27382

Source
Nationaal Trial Register

Health condition

Kinderen met chronische buikpijn als gevolg van prikkelbaar darm syndroom (IBS) of functionele buikpijn (FAP).
Children with chronic abdominal pain due to irritable bowel syndrome (IBS)or functional abdominal pain (FAP).

Sponsors and support

Primary sponsor: Universitair Medisch Centrum AMC Amsterdam and St. Antonius ziekenhuis Nieuwegein.
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The main goal in the treatment of IBS and FAP patients is reduction of abdominal pain and therefore pain is our primary outcome. Pain will be assesssed by means of a diary card on which patienst record daily intensity on a 10 point Likert scale and frequency of abdominal pain episodes during a period of 7 consecutive days. Recording of pain during 7 days is

elaborate, but has the benefit that the problem of individual variability in symptoms over time will be reduced. Because the intervention of this trail cannot be blinded, recording of symptoms by children (parents) themselves at home reduces the risk of detection bias in comparison with the situation where pain is recorded during a visit (single time point) by the health care professional.

Secondary outcome

Using the same diary, patient will also record associated symptoms including nausea, vomitting, loss of apetite and flatus. Additional outcomes include: Health related quality of life, child somatization scores, health utility index, depression and anxiety, absence of school, helath care resources and costs, reduction of stress hormons.

Study description

Background summary

Background:

Chronic abdominal pain due to irritable bowel syndrome (IBS) or functional abdominal pain (FAP) is common
in children, reduces their quality of life, and is associated with increased risk for depression and anxiety. Therapeutic options are limited, but several trials in children have shown that gut-directed hypnotherapy by a therapist or by self-hypnosis exercises on CD at home are effective treatments. No studies have been performed comparing these two treatments. If self-hypnosis exercises at home are comparable in effectiveness, it brings several potential advantages such as substantial savings in costs and reduction of waiting lists for hypnotherapists. A well designed cost-effectiveness study can discover whether self exercises of hypnotherapy could become the first line therapy of choice in the treatment of these patients.

Aim:

To compare the cost-effectiveness of hypnotherapy by therapist versus hypnotherapy by CD-recorded self exercises at home in children with IBS and FAP.

Methods:

260 children, aged between 8-18yrs, with IBS or FAP according to ROME III criteria will be randomized to one of

these treatments: 6 sessions of individual hypnotherapy given by a therapist during three month period or hypnotherapy through self exercises at home for 3 months.

The primary analysis will be the number of patients with > 50% reduction in abdominal pain intensity and frequency at the end of therapy (3 months) and after one year of follow-up. The expected percentage of success at three month in the therapist group is 75%. Based on the results of a study in children with IBS evaluating the effect of self exercises, we anticipate a success rate off 65%. Based on a non-inferiority limit of 50% and a drop-out of less than 10%, 130 patients per group are needed to test the hypothesis with a power of 80%.

Secondary outcomes will be changes in individual pain scores over time, other abdominal symptoms, anxiety and depression, health-related quality of life, health utility, costs, and school absence, measured at 1 year follow-up.

Time schedule:

The project will take 3 years: In the first two years children will be recruited in 6 hospitals and in the last year follow-up will take place and analysis of all results.

Participating centers in the Netherlands:

1. St. Antonius ziekenhuis Nieuwegein;

2. Medisch Centrum Alkmaar;

3. Leids Universitair Centrum;

4. Academisch Ziekenhuis Maastricht;

5. Amphia Ziekenhuis Breda;

6. Academisch Medisch Centrum Amsterdam;

7. Maxima Medisch Centrum Veldhoven;

8. Flevoziekenhuis Almere.

Study objective

This study may result in optimization of health care for children with irritable bowel syndrome. If this study shows that home-based therapy is comparable in effectiveness with hypnotherapy by a therapist, it could become therapy of choice in the treatment of these patients.

Study design

Such a 7-day diary recording will be done before start of therapy, in the fourth week of treatment, the eight week of treatment, the twelfth (last) week of treatment, six months after treatment and twelve months after treatment.

Intervention

Patients will be randomly allocated using a computerized random-number generato for concealment to individualized hypnotherapy given by a therapist or home-based therapy with hypnosis exercises on CS's.

Individual hypnotherapy will be carried out by one of six participating hypnotherapists and will consist of 6 sessions of 50 minutes over a 3 month period.

Children assigned to self-hypnosis by CD will be visited by a specially trained research nurse. She will explain the exercises on CD and hand them together with an instruction leaflet. The children are asked to do the first exercises on the CD during this visit to check if all instructions are understood. The children will be asked to listen to the exercises at least 5 times per week during 3 months. The research nurse will make phone calls with the children at week 4 and 8 to stimulate treatment compliance.

Contacts

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Eligibility criteria

Inclusion criteria

Children between 8 and 18 years diagnosed with bowel syndrome/functional abdominal pain according to the Rome III criteria.

Exclusion criteria

Children < 8 years are too young for formal hypnotherapy and therefore excluded from the study. Other exclusion criteria are a concomitant organic gastrointestinal disease, treatment by another health care professional for abdominal symptoms, mental retardation, insufficient knowledge of the Dutch lanuage and previous hypnose treatment.

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):	01-04-2011
Enrollment:	260
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-02-2011
Application type:	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	ID
NTR-new	NL2597
NTR-old	NTR2725
Other	ZonMw / METC AMC Amsterdam : 80823109711078 / NL3371401810 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A