Functional abdominal pain (FAP) within the context of internalizing disorders in childhood; A randomized controlled cognitive-behavioural family intervention.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24858

Source
NTR

Brief title
Buikpijn de Baas

Health condition

Functional abdominal pain (FAP) in children aged 8-18 [functionele buikpijn bij kinderen van 8-18].
FAP can also be described as:
- recurrent abdominal pain [terugkerende buikpijn]
- Irritable Bowel Syndrome (IBS) [prikkelbaar darmsyndroom (PDS)]
- Fuctional dyspepsia [functionele dyspepsie]
- Abdominal migraine (abdominale migraine)

Sponsors and support

Primary sponsor: - Emma Children's Hospital AMC (Amsterdam)
- De Bascule, Academic Center for Child and Adolescent Psychiatry (Amsterdam)
Source(s) of monetary or material Support: - Maag Lever Darm Stichting

- De Bascule, Academic Center for Child and Adolescent Psychiatry
- Academic Medical Center Amsterdam

Intervention

Outcome measures

Primary outcome

1. Abdominal pain, as measured by the Abdominal Pain Index (API; Walker et al., 1997).

2. Abdominal pain, as measured by 1 week diary cards, making use of the Facial Affect Scale (FAS; McGrath et al., 1996).

Secondary outcome

1. Anxiety and depression, measured by a structured interview (ADIS-C/P; Silverman et al., 1988);

2. Anxious and depressive symptoms, measured by the Revised Child Anxiety and Depression Scale - short version (RCADS; Muris et al., 2002);

3. Other somatic complaints, measured by the Children's Somatization Inventory (CSI; Walker & Garber, 1992, Ghys & Meesters, 1993);

4. Functional impairments due to the abdominal pain, as measured by the Functional Disability Inventory (FDI; Walker & Greene, 1991);

5. Quality of life, as measured by the Kidscreen-27 (The KIDSCREEN Group, 2004);

6. School absence;

7. Health care use.

Study description

Background summary

Abdominal pain (AP) in children is ranked in the top five of visits to the general practitioner and cross-sectional functional AP (FAP) is reported to occur in 7-25% of the school age population. In these children significantly higher scores for internalizing emotional symptoms (depression and anxiety) are observed and studies suggest that ‘little bellyachers’ grow up to suffer from psychiatric ailments as adults.

We hypothesize that cognitive behavioural family treatment (CBT) will be more effective compared to medical care (MC) in regard to the perception of FAP and resolution of co morbid internalizing psychopathology.
To study this we will enrol 100 patients (2x50/30 months) with moderate to severe FAP, including children with comorbid anxiety and/or depression and examine the effect on the severity of FAP and changes in disability, anxiety and depressive symptoms. Also, a number of mediators and moderators of the treatment effect will be studied.

Study objective

1. Cognitive behavioural family treatment (CBT) will be more effective compared to medical care (MC) in decreasing the abdominal pain and improving secondary outcomes (less comorbid internalizing psychopathology, less other somatic complaints, less functional disability, higher quality of life, less school absenteeism, less health care use).

2. The following factors will mediate the treatment effects: negative thoughts about pain, coping with pain, experienced control over pain, selective attention to pain, parental reactions to pain.

3. The following moderators will influence the treatment effects: emotion awareness, negative life-events, general coping skills, control over anxious feelings, anxiety sensitivity and selective attention to anxiety, modeling.

Study design

1. Prior to treatment

2. 2-3 weeks after treatment

3. 6 months after treatment

4. 12 months after treatment

Intervention

MC:

In line with the current practice of pediatricians in treating children with FAP: supportive physician-patient relationship and empathy for the family with reassurance that no serious disease is present. Dietary advice will be offered (f.i. fiber intake). If necessary pharmacological agents can be prescribed (laxative medication, spasmolytic drugs, H2 blockers or PP-inhibitors). No referrals to psychotherapist and/or hypnotherapist will take place and no ‘alternative’ medical therapy (such as acupuncture, homeopathy) will be prescribed.

MC will be offered in the same frequency as the CBT will take place.

CBT:

Six treatment sessions with the patient and at least one with the parents that will contain:

1. information about the treatment model (influence of cognitions and behaviour on the pain experience);

2. learning pain management techniques (relaxation, breathing, imagery, physical exercises);

3. discussing dysfunctional cognitions (learning helping thoughts in stead of catastrophizing thoughts) if applicable;

4. changing parent’s dysfunctional behaviour, if applicable;

5. changing children's dysfunctional behaviour, if applicable (f.i., school absence).
The content of the modules are described in detail in a protocol ‘CBT for FAP’.

During this period no outpatient visit to the pediatrician will take place. Also no other referrals (such as hypnotherapy or ‘alternative’ medical therapy (such as acupuncture, homeopathy) will be initiated.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 8-18;

2. Abdominal pain is main complaint;

3. Abdominal pain is present at least three times a week, 15 minutes a day. On the Facial Affect Scale (McGrath, 1996) ranging from 1-9, it hurts at least a '5';

4. At least 8 weeks of abdominal pain in the last twelve months;

5. Has to understand the Dutch language sufficiently to receive treatment and fill out questionnaires in Dutch;

6. Informed consent from both parent and child.

Exclusion criteria

1. Red flag signals in physical examination (localized tenderness in right upper or lower quadrant, spine or costovertebral angle tenderness, hepatomegaly or splenomegaly, oral ulcers, perianal fissures or fistula);

2. Alarm signals in history (involuntary weightloss, decelerated growth, late puberty, significant vomiting or diarrhea, loss of blood at defecation, unexplained fever, rash, arthritis, IBD in family);

3. Abnormalities in laboratory tests in blood, urine or feces;

4. Abnormalities shown on ultrasound;

5. Patient has undergone a significant surgery that might explain the abdominal pain;

6. Patient has been treated for the abdominal pain by a psychologist, psychiatrist or hypnotherapist in the last six months;

7. Psychosis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	05-01-2009
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	NL1542
NTR-old	NTR1613
Other	CCA/SWO : 13010/05-09
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results