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

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29940

Source
ToetsingOnline

Brief title
FAP

Condition

- Other condition
- Gastrointestinal ulceration and perforation

Synonym
abdominal pain, functional abdominal pain

Health condition

co morbide angst en depressie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,maag;lever en darmstichting

Intervention

Keyword: cognitive-behavioural family intervention, Functional abdominal pain (FAP), RCT, recurrent abdominal pain (RAP)

Outcome measures

Primary outcome

The primary outcome variable is reduction in abdominal pain measured by the Abdominal Pain Index (API)*. Standard medical therapy (SMC) yields a mean outcome API score of around 20 (Robins et all., 2005). A clinically significant result of CBT is conceived as an extra improvement of 4 points or more in the API.

Secondary outcome

Secondary study endpoints are anxiety and depression measured with The Anxiety Disorders Interview Schedule (ADIS-C/P; Silverman 1988, Siebelink 1995) and for symptoms using the Revised Child Anxiety and Depression Scale (RCADS; Chorpita 2000, Muris 2002). Other somatic symptoms measured by the Children*s Somatization Inventory (CSI; Walker 1992, Ghys 1993)

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.

Study objective

We hypothesize that cognitive behavioural family intervention will be more effective compared to standard treatment in regard to the perception of FAP and resolution of co morbid internalizing psychopathology.

Study design

To study this we will enrol 100 patients (2x50/30 months) with moderate to severe FAP, including children with co morbid anxiety and/or depression that have significant non-attendance at school and examine the effect on the severity of FAP and changes in disability, anxiety and depressive symptoms. The duration of the study will be 48 months: 6 months preparation and pre-testing, 30 month enrolment followed by analysis and writing of papers

Intervention

Every patient, control and investigational treatment, receives standard medical care (SMC). On top of SMC 50% of the patients are randomized to receive cognitive behavorial therapy.

SMC:
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. Dietray advice will be offered (f.i. fiber intake). If necessary pharmacological agents can be prescribed (laxative medication, spasmolytic drugs, H2 blockers or PP-inhibitors)

CBT:
Six treatment sessions with the patient and at least one with the parents that will contain:
• information about the treatment model (influence of cognitions and behaviour on the pain experience)
• learning pain management techniques (relaxation, breathing, imagery, physical exercises)
• discussing dysfunctional cognitions (learning helping thoughts in stead of catastrophizing thoughts)
• changing parent*s dysfunctional behaviour.

The content of the modules are described in detail in a protocol *CBT for FAP*.

Study burden and risks

Despite the fact that FAP shows a lot of resemblance to functional disorders in adults, such as IBS and dyspepsia, FAP is a diagnosis specific for children. At present no standard therapy is recommended for children with FAP. The current practice of pediatricians in treating children with FAP varies but show some aspects in common: supportive physician-patient relationship, empathy for the family with reassurance that no serious disease is present, dietray advices, and if necessary pharmacological agents such as laxative medication, spasmolytic drugs, H2 blockers or PP-inhibitors.
A recent systematic review of RCT*s of FAP treatment modalities found only ten articles that fulfilled preset criteria (Weydert 2003). Only CBT seemed to have general positive effect on children with FAP independent of their Rome II classification (Sanders 1989, Sanders 1994). However, in both (Australian) studies a very limited number of patients was enrolled. Recently, a third (American) RCT was published showing that CBT on top off standard medical treatment (SMT) was more effective in the reduction of AP and school absence compared to SMT only (Robins 2005). This study suffers a lot of methodological limitations (inadequate randomization procedure, significant differences at baseline, small sample size, loss of participants). Interestingly, a survey of practicing pediatricians found that pediatricians rarely consulted mental health professionals in the management of FAP (Edwards 1994). The primary reasons cited for the lack of referrals were concerns about cost, family resistance, and personal beliefs about the natural course of the disorder. Another reason might be that the CBT studies were published in psychological journals and likely were not read by practicing pediatricians as a means to expand their repertoire of treatments for FAP. There is evidence in the adult literature that management of functional disorders by the physician in collaboration with a mental health professional may reduce health care costs (Smith 1986).
Since three years a multidisciplinary Psy-Med Unit is functioning in our centre incorporating mental health evaluations and treatment in the management of children with severe FAP. The aim of our integrated approach is to facilitate symptom resolution by integrating the coping and self-management skills with other interventions, such as dietary and pharmaceutical (laxatives, spasmolytics etc.) therapies within the context of the family. In a pilot study children (7-18 yrs) with severe FAP (2nd or 3rd opinion, > 50% school absenteeism, high level of self reported AP) showed dramatic improvement in pain perception, school absenteeism and medical consumption following CBT. The burden of CBT is minimal, in fact all children were happy with the CBT treatment, and risks of CBT have not been described in the literature.
We hypothesize that cognitive behavioural family intervention is considered especially promising in the reduction of AP, disability, resolution of co morbid internalizing psychopathology and is economically feasible.

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
1105 az
Nederland
Scientific
Academisch Medisch Centrum

meibergdreef 9
1105 az
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

The enrolment criteria are in line with the Rome II criteria.
• Abdominal pain that waxes and wanes
• Occurs for three or more periodes over a 3-months period or longer
• No red-flag signals
• No abnormalities in the standard work-up
• Severe enough to affect daily activities
• Non-attendance at school 10% or more

Exclusion criteria

Exclusion criteria:
• Organic cause abdominal pain
• Major surgery
• Previous major medical illness

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL11658.018.06