Cognitive Behavior Therapy for Pediatric Functional Abdominal Pain: A Randomized Controlled Trial

**WHAT'S KNOWN ON THIS SUBJECT:** Pediatric functional abdominal pain is common and costly. Cognitive behavior therapy (CBT) is a promising treatment for these complaints, but solid evidence for its effectiveness is lacking.

**WHAT THIS STUDY ADDS:** This randomized controlled trial shows that CBT reduces abdominal pain in 60% of children 1 year after treatment. Six sessions of CBT delivered by trained master's students in psychology were equally effective as 6 visits to an experienced pediatrician.

**OBJECTIVE:** This randomized controlled trial investigated the effectiveness of a 6-session protocolized cognitive behavior therapy (CBT) compared with 6 visits to a pediatrician (intensive medical care; IMC) for the treatment of pediatric functional abdominal pain (FAP).

**METHODS:** One hundred four children aged 7 to 18 were randomized to CBT or IMC. CBT was delivered primarily by trained master's degree students in psychology; IMC was delivered by pediatricians or pediatric gastroenterologists. Assessments were performed pretreatment, posttreatment, and at 6- and 12-month follow-up. Primary outcomes were level of abdominal pain (AP) as reported on questionnaires and diaries. Secondary outcomes were other gastrointestinal complaints, functional disability, other somatic complaints, anxiety, depression, and quality of life.

**RESULTS:** Both CBT and IMC resulted in a significant decrease in AP ($P < .001$), but no significant difference was found between the treatments in their effectiveness ($P > .05$ for all end points). According to the questionnaire-derived data, 1 year after treatment, 60% of children that received CBT had significantly improved or recovered, versus 56.4% of children receiving IMC, which did not significantly differ ($P = .47$). These percentages were 65.8% versus 62.8% according to the diary-derived data, which also did not significantly differ ($P = .14$). Additionally, nearly all secondary outcomes improved after treatment.

**CONCLUSIONS:** CBT was equally effective as IMC in reducing AP in children with FAP. More research into the specific working mechanisms of CBT for pediatric FAP is needed.

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**KEY WORDS**
functional abdominal pain, cognitive behavior therapy, randomized controlled trial

**ABBREVIATIONS**
AP—abdominal pain
API—Abdominal Pain Index
CBT—cognitive behavior therapy
FAP—functional abdominal pain
IMC—intensive medical care
PDS—Pain Duration Score
PIS—Pain Intensity Score
RCT—randomized controlled trial

Dr van der Veek conducted the study, collected, analyzed, and interpreted the data, and drafted the initial manuscript; Drs Derkx and Benninga conceptualized and designed the study, treated children included in the study, and reviewed and revised the manuscript, Dr Boer conceptualized and designed the study and reviewed and revised the manuscript; Dr De Haan conceptualized and designed the study, treated children included in the study, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

This trial has been registered with the Netherlands National Trial Register (http://www.trialregister.nl/trialreg/index.asp) (identifier NTR1613).

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Abdominal pain (AP) is a common complaint in children and adolescents. Most children experience occasional episodes of AP, which often resolve spontaneously. However, in ~10% of children in Western countries, the pain does not disappear and becomes chronic, affecting daily life significantly. An explanatory organic disease is rarely found. Without an organic cause, chronic AP is called “functional” (FAP). If left untreated, there is a considerable chance that FAP will persist into adulthood or change into other (psycho)pathology.

The effectiveness of psychological therapies for pediatric FAP has been studied in several randomized controlled trials (RCTs). Although a recent Cochrane review described cognitive behavior therapy (CBT) as a promising psychological treatment, this review also underscored that many RCTs have considerable methodological drawbacks such as small sample sizes and high dropout rates. Moreover, a well-designed RCT published after the Cochrane review did not provide unequivocal evidence for the benefit of CBT because it showed CBT to be superior to a control condition but only according to parent report of the child’s pain, not according to child-reported pain. Thus, considering the current state of the literature, it is difficult to draw conclusions on the actual effectiveness of CBT for the treatment of pediatric FAP.

Therefore, we performed a large RCT, investigating the effectiveness of a 6-session CBT protocol compared with 6 visits to a pediatric gastroenterologist. The effects of CBT were compared with this intensified medical care (IMC) control condition and not to (less frequent) care as usual because we aimed to control for the therapeutic effect of receiving attention from a health care professional. In accordance with recent recommendations for treatment trials in pediatric chronic pain, we investigated the impact of the interventions on pain as well as on nonpain outcomes such as other gastrointestinal complaints (eg, nausea), functional disability, anxiety, depression, and quality of life. We expected CBT to be superior to IMC on all outcomes.

**METHODS**

**Design and Procedure**

The study was a prospective RCT. The study protocol was approved by the ethical committee of the Academic Medical Center Amsterdam. The trial was registered at the Netherlands National Trial Register; trial number NTR1613.

Children were screened for inclusion by pediatricians of the general pediatric and pediatric gastroenterology outpatient clinics at the Emma Children’s Hospital Academic Medical Center Amsterdam in the Netherlands. Children who consented to participate received 2 intake sessions (T1) at De Bascule, an academic center for child and adolescent psychiatry in Amsterdam, during which baseline assessments of outcomes took place. At the end of the second intake session, the first author randomized the children using a computerized randomization program, stratifying by age (2 age groups: 8–12 and 13–17 years) and gender. Children and parents were notified immediately of the results of the randomization. Assessments took place 2 weeks after treatment (T2) and 6 months and 12 months after treatment (T3 and T4).

**Inclusion Criteria**

Children were eligible if they were 7 to 18 years of age and fulfilled the Rome III criteria for pediatric AP-related functional gastrointestinal disorders: (1) AP is main complaint; (2) AP present at least once per week for at least 2 months before diagnosis; (3) no evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the patient’s symptoms. Presence of an explanatory organic disease was investigated by conducting a physical examination; mapping the medical history of the child; performing laboratory tests on stool, urine, and blood; and performing an ultrasound. Additional criteria were (4) absence of a psychiatric disorder that required treatment before treatment of FAP (eg, psychotic symptoms); (5) Dutch speaking; and (6) AP had to be present during the 2 weeks before inclusion.

**Calculation of Sample Size**

On the basis of an earlier study, we expected a 31.8% difference in effectiveness between CBT and IMC. To be able to detect that difference with an 80% power and a 2-sided 5% significance level, a sample size of 45 participants per group was necessary. Therefore, our goal was to include 50 participants per group, given an anticipated dropout rate of 10%.

**Interventions**

Both treatments comprised 6 weekly sessions. CBT was delivered by master’s students in psychology or by psychologists with a master’s degree. All received training and biweekly supervision by an experienced children’s psychotherapist (fifth author). IMC was delivered by pediatricians or pediatric gastroenterologists. During both treatments, children were requested to keep a standardized pain diary to enable the therapist/pediatrician to discuss the progress of the complaints. To increase participants’ compliance, at the beginning of every session/consult, children and their parents were asked to report on the results of the exercises they had done the previous week (CBT) or on the effects of the advice they had done the previous week (IMC).
given or medication prescribed (IMC). Subsequently, the results, as described in the pain diary, were discussed with the child and the family.

CBT

The CBT protocol, consisting of 6 sessions of 45 minutes, was based on the protocols used in previous RCTs. The protocol had 1 standard and 3 optional modules that the therapist could select depending on the needs and problems of the child (see Table 1), allowing tailoring of the protocol to the individual child. This approach reflects normal practice and is suggested to be more effective than applying a standard protocol to every patient. In children 7 to 12 years of age, a parent was present during every session. In children >12 years, parents were present during the first, middle, and last session and at the end of every session to reflect on what was discussed with the child. If the module on parental behavior was used (see Table 1), a parent was present during every session. If parents or children felt the need to visit their referring pediatrician during CBT, they were allowed to do so; however, none of the participants did.

IMC

Pediatricians educated children and their parents about the complaints, gave dietary advice, gave advice about continuing school and daily activities, and, if indicated, prescribed medication such as laxatives, loperamide, proton pump inhibitors, or pain medication. Contacts lasted ~20 to 30 minutes. Usually, parents were present during every consult; children >12 years of age were sometimes seen without their parents.

<table>
<thead>
<tr>
<th>Module/Intervention</th>
<th>Description of Intervention</th>
<th>n (%) of Children Who Received Module/Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1. Relaxation training</td>
<td>Made use of following successive breathing and relaxation exercises: 1. Breathing calmly through abdomen instead of breathing through chest. 2. Jacobson’s progressive muscle relaxation: teaches children difference between tensing and relaxing muscles. 3. General relaxation: teaches children to relax without tensing muscles first. 4. Cue relaxation: teaches children to relax whole body at once on cue (eg, say “relax” in your mind and then relax the whole body). 5. Hypnotic suggestion: teaches children to visualize their AP and change that image to decrease AP (eg, pain is visualized as red, spiky ball, during exercise child needs to imagine the ball getting less and less spiky, getting smaller, translucent, until it disappears).</td>
<td>51 (100)</td>
</tr>
<tr>
<td>Module 2. Cognitive therapy</td>
<td>Focus: change negative thoughts about pain or negative thoughts about other things that aggravate pain (eg, worry about school or friends). Children were taught how the way they think about pain can affect the experience of pain and received exercises to try to change negative thoughts (eg, identify negative thoughts and think of alternative, more positive thoughts).</td>
<td>30 (58.8)</td>
</tr>
<tr>
<td>Module 3. Behavior therapy directed at behavior child</td>
<td>Focus: change maladaptive pain-related coping behavior of child. Children were educated about the benefits of continuing daily activities as a distraction from pain. In addition, children indicated what they could not do anymore because of the AP and what they would like to be able to do at the end of treatment. A hierarchy consisting of small consecutive steps was made to help guide the child to reach those activity goals (eg, goal: playing soccer again; step 1 = take a 15-min walk each day; step 2 = in addition to these walks, do two 10-min runs each week; step 3 = join soccer practice once a week; etc). A reward system was used to motivate children.</td>
<td>31 (60.8)</td>
</tr>
<tr>
<td>Module 4. Behavior therapy directed at behavior of parent</td>
<td>Focus: change maladaptive pain-related coping behavior of parent. Parents were educated about the maladaptive effects of refraining children from activities and asking children frequently about their AP. Instead, parents were asked to stimulate their child to practice relaxation skills when the child complained of AP and to encourage their child to keep active. Additionally, they were taught how their own reactions to their physical complaints may serve as a model for how children respond to physical complaints.</td>
<td>24 (47.1)</td>
</tr>
<tr>
<td>IMC</td>
<td>Focus: pediatricians and pediatric gastroenterologists were allowed to do what they would normally do when treating children with FAP. Topics discussed: pain diary, education on brain-gut axis, dietary advice, advice to continue school and daily activities (without making detailed plans to achieve those goals). Types of medication prescribed: laxatives, loperamide, proton pump inhibitors, or pain medication.</td>
<td>50 (100)</td>
</tr>
</tbody>
</table>

* These numbers are based on the children who actually received the intervention not on intention to treat (eg, 1 child was allocated to IMC but received CBT instead at his request; this child is added to n for CBT in this Table).
parents for a maximum of half of the contacts.

Measures

Questionnaires were filled out by both children and parents. AP was assessed with the Abdominal Pain Index (API), which consists of 5 questions that focus on the frequency, duration, and intensity of the AP the child experienced in the past 2 weeks. Scores range from 0 to 50. The API has been shown to have good internal consistency. Gastrointestinal symptoms and other physical symptoms were assessed using the validated Dutch version of the Children’s Somatization Inventory. Six items (nausea/upset stomach, constipation, loose bowel movements or diarrhea, vomiting, feeling bloated or gassy, food making the patient sick) were summed to measure gastrointestinal symptoms; 28 items were summed to measure other physical symptoms. Functional disability was measured with the Functional Disability Inventory, a validated and reliable instrument. Anxious and depressive symptoms were measured with the Revised Child Anxiety and Depression Scale—short version. Two separate scores for anxious and depressive symptoms were calculated. Quality of life was assessed using the KIDSCREEN-27, an internationally developed and validated instrument. Five aspects of quality of life were measured: physical well-being, psychological well-being, parent relations and autonomy, social support and peers, and school environment. Satisfaction with treatment and therapist/doctor was assessed on a scale ranging from 0 (bad) to 10 (excellent).

In addition, children filled out a 1-week pain diary at all assessments, which measured frequency, duration, and intensity of AP on a daily basis. Intensity of AP was scored using a Facial Affective Scale ranging from 1 (smiling face, no pain) to 9 (crying face, most intense pain possible). Diary data were entered in SPSS (IBM SPSS Statistics, IBM Corporation) by students who were blinded to treatment. Using the same coding procedure as Vlieger and colleagues, daily intensity scores were recoded as follows: 0 = no pain, 1 = faces 1 to 3, 2 = faces 4 to 6, and 3 = faces 7 to 9. Daily duration scores were recoded as follows: 0 = no pain, 1 = 1 to 30 minutes of pain, 2 = 31 to 120 minutes of pain, and 3 = >120 minutes per day. The recoded daily scores were added for all 7 days of the diary, resulting in a total Pain Intensity and Pain Duration Score (PIS and PDS) with a range of 0 to 21.

To assess whether any psychiatric diagnoses were present, we used the validated Anxiety Disorders Interview Schedule for Children, a semistructured interview assessing the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, anxiety disorders and depression. The interview was separately administered to parents and children. Children received a diagnosis when either the parent- or the child-interview showed a psychiatric disorder.

Finally, to assess health care use after treatment, children and parents were asked during follow-up assessments if they had sought any health care after completion of CBT or IMC.

FIGURE 1
Flow diagram of the progress of children through the phases of the trial.
Statistical Analyses

The intention-to-treat principle was used for all analyses. To investigate whether both treatments led to a significant decrease of pain and secondary measures over time, and whether there was a significant difference in effectiveness between both treatments, linear mixed-model analyses were performed in SPSS 18.0, which make use of every observation for every participant, irrespective of missing data. In addition to these analyses, we calculated which percentage of children showed a clinically significant improvement after treatment. To calculate these percentages for the questionnaire-derived data, we used the frequently recommended reliable change index. This index calculates a critical change score for reliable improvement, based on the baseline SD and Cronbach’s alpha reliability of the instrument used. For the current study, children were considered improved if they decreased ≥9.90 points on the self-reported API (range 0–50); if in addition to this, their level of AP after treatment was closer to the mean of a healthy population than to the mean of the clinical population, they were considered recovered (Jacobson and Truax’s criterion). If the AP increased ≥9.90 points after treatment, children were considered deteriorated. To compare our results to those of an earlier study performed in our institution, we additionally calculated an index of treatment success based on the pain diaries. Children were considered recovered if both their PIS and PDS decreased >80%; if both PIS and PDS decreased between 30% and 80%, children were considered improved, and if children’s PIS or PDS decreased <30%, they were considered not improved.

RESULTS

Participant Flow

Between April 2007 and April 2010, 201 children were screened for participation in the study. Ninety-four children did not fulfill inclusion and exclusion criteria (Fig 1). One hundred four children were included and randomized, 52 in each condition. At baseline, no significant differences were found in any of the demographic and clinical characteristics between the 2 groups, except for the presence of comorbid anxiety disorders, which were more prevalent in the IMC group (Table 2). Forty-six children completed CBT, and 48 completed IMC. Data of all 104 included children were used for analyses. Last follow-up data were gathered in August 2011.

Differences Between Treatment Effectiveness

Figure 2 displays the progression of child-reported AP throughout the study. The results of the linear mixed models investigating differences between the 2 treatments, correcting for the effects of age and gender, are displayed in Table 3. Compared with the scores before treatment, children improved on all measures at all time points, except for some of the quality-of-life subscales (parent relations and autonomy and school environment). No significant differences were found between the 2 treatments on any of the time points concerning child- or parent-reported AP, functional disability, gastrointestinal complaints, other somatic complaints, and 4 of 5 quality-of-life domains. For child-reported anxiety and depression directly after treatment (T2) and at 6-month follow-up (T3), a significant interaction effect between time and treatment indicated that children’s levels of anxiety and depression decreased more after CBT than after IMC. At 12-month follow-up (T4), levels of anxiety and depression in

<table>
<thead>
<tr>
<th>TABLE 2 Baseline Characteristics of Sample as a Function of Treatment Condition</th>
<th>CBT, Mean (SD) or %</th>
<th>IMC, Mean (SD) or %</th>
<th>P (t, μ², or Fisher’s exact)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>11.94 (2.61)</td>
<td>11.87 (2.93)</td>
<td>.888</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>71.2</td>
<td>73.1</td>
<td>.827</td>
</tr>
<tr>
<td>Nationality (% Dutch)</td>
<td>90.4</td>
<td>78.8</td>
<td>.103</td>
</tr>
<tr>
<td>No. of mo since onset of complaints</td>
<td>34.79 (36.77)</td>
<td>33.23 (38.31)</td>
<td>.833</td>
</tr>
<tr>
<td>No. of wk of AP in past year</td>
<td>42.61 (14.14)</td>
<td>42.71 (14.97)</td>
<td>.971</td>
</tr>
<tr>
<td>Average number of schooldays missed per wk</td>
<td>0.96 (1.38)</td>
<td>0.70 (1.06)</td>
<td>2.65</td>
</tr>
<tr>
<td>Rome III diagnosis</td>
<td></td>
<td></td>
<td>.180</td>
</tr>
<tr>
<td>FGID/FAP syndrome</td>
<td>65.4</td>
<td>59.6</td>
<td></td>
</tr>
<tr>
<td>Irritable bowel syndrome</td>
<td>21.2</td>
<td>54.6</td>
<td></td>
</tr>
<tr>
<td>Other/combination</td>
<td>13.5</td>
<td>5.8</td>
<td></td>
</tr>
<tr>
<td>Functional complaints among family members</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FGID in mother/father</td>
<td>24.5</td>
<td>38.0</td>
<td></td>
</tr>
<tr>
<td>FGID in other family member</td>
<td>18.4</td>
<td>18.0</td>
<td></td>
</tr>
<tr>
<td>Other functional complaint in family</td>
<td>12.2</td>
<td>16.0</td>
<td></td>
</tr>
</tbody>
</table>
### TABLE 3  Mean Scores of Outcome Measures at All Time Points, Tested With Linear Mixed Models

<table>
<thead>
<tr>
<th></th>
<th>Before Treatment</th>
<th>Directly After Treatment</th>
<th>6 Mo Post-Treatment</th>
<th>12 Mo Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CBT  IMC</td>
<td>P of Test for Time Effect</td>
<td>P of Test for Time × Treatment Interaction Effect</td>
<td>CBT  IMC</td>
</tr>
<tr>
<td>Child-reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain (API)</td>
<td>32.18 35.56</td>
<td>23.10 26.51 &lt;.001*</td>
<td>51</td>
<td>18.67 24.66 &lt;.001*</td>
</tr>
<tr>
<td>Pain intensity</td>
<td>15.43 14.76</td>
<td>6.82 8.80 &lt;.001*</td>
<td>.08b</td>
<td>5.61 7.45 &lt;.001*</td>
</tr>
<tr>
<td>(diary)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain duration (diary)</td>
<td>14.55 15.56</td>
<td>6.84 8.67 &lt;.001*</td>
<td>.96</td>
<td>5.32 8.58 &lt;.001*</td>
</tr>
<tr>
<td>Functional disability</td>
<td>10.06 12.29</td>
<td>7.17 7.79 .008*</td>
<td>.95</td>
<td>4.70 9.17 &lt;.001*</td>
</tr>
<tr>
<td>GI complaints</td>
<td>6.55 5.94</td>
<td>3.65 4.20 &lt;.001*</td>
<td>.34</td>
<td>3.44 3.80 &lt;.001*</td>
</tr>
<tr>
<td>Other physical</td>
<td>11.89 13.74</td>
<td>9.08 10.74 .005*</td>
<td>.94</td>
<td>7.53 1.24 .003*</td>
</tr>
<tr>
<td>complaints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>10.61 8.54</td>
<td>6.83 7.76 &lt;.001*</td>
<td>.05</td>
<td>5.38 7.72 &lt;.001*</td>
</tr>
<tr>
<td>Depression</td>
<td>3.92 3.72</td>
<td>2.17 2.33 &lt;.001*</td>
<td>.03</td>
<td>1.88 3.06 &lt;.001*</td>
</tr>
<tr>
<td>Physical QoL</td>
<td>45.41 45.30</td>
<td>48.26 47.61 .10</td>
<td>.81</td>
<td>49.74 46.95 .05*</td>
</tr>
<tr>
<td>Psychological QoL</td>
<td>50.60 50.08</td>
<td>53.77 52.16 .05</td>
<td>.50</td>
<td>54.17 50.08 .07*</td>
</tr>
<tr>
<td>QoL support</td>
<td>50.26 51.98</td>
<td>52.91 51.85 .09</td>
<td>.19</td>
<td>54.94 51.53 .002*</td>
</tr>
<tr>
<td>and peers</td>
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<tr>
<td>Parent-reported</td>
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<tr>
<td>variables</td>
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</tr>
<tr>
<td>Abdominal pain (API)</td>
<td>34.46 32.38</td>
<td>21.78 24.03 &lt;.001*</td>
<td>.20</td>
<td>18.88 2.28 &lt;.001*</td>
</tr>
<tr>
<td>Functional disability</td>
<td>15.86 15.13</td>
<td>8.02 8.45 &lt;.001*</td>
<td>.09b</td>
<td>5.12 7.29 &lt;.001*</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>6.71 6.06</td>
<td>4.38 3.90 &lt;.001*</td>
<td>.87</td>
<td>3.47 3.45 &lt;.001*</td>
</tr>
<tr>
<td>complaints</td>
<td>10.48 9.23</td>
<td>8.17 7.79 .01</td>
<td>.33</td>
<td>5.74 7.72 .001*</td>
</tr>
<tr>
<td>Anxiety</td>
<td>9.62 9.05</td>
<td>6.42 6.87 .001</td>
<td>.64</td>
<td>5.32 7.33 &lt;.001*</td>
</tr>
<tr>
<td>Depression</td>
<td>3.30 3.41</td>
<td>1.82 1.96 &lt;.001*</td>
<td>.35</td>
<td>1.56 1.82 &lt;.001*</td>
</tr>
<tr>
<td>Physical QoL</td>
<td>40.68 41.22</td>
<td>45.71 47.80 &lt;.001*</td>
<td>.76</td>
<td>46.43 48.01 .02*</td>
</tr>
<tr>
<td>Psychological QoL</td>
<td>48.67 49.53</td>
<td>54.54 54.21 .004*</td>
<td>.87</td>
<td>53.18 49.94 .08b</td>
</tr>
<tr>
<td>QoL support</td>
<td>54.27 53.38</td>
<td>55.98 54.10 .04</td>
<td>.48</td>
<td>54.08 53.18 .02</td>
</tr>
<tr>
<td>and peers</td>
<td></td>
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</tbody>
</table>

Groups did not differ on any of the outcome measures before treatment. For the QoL scales, higher scores reflect better well-being. For all other measures, lower scores reflect better well-being. Analyses were corrected for the effects of age and gender. Tests of significance of time and time × treatment interaction use the score before treatment as reference point. QoL, quality of life.

* *P* < .05.

+ *P* < .10.
the IMC-group had dropped to similar levels as those in the CBT-group. For quality of life related to social support and peers, children receiving CBT had improved more at T3 than children receiving IMC. This significant effect decreased to a nonsignificant trend at T4.

Treatment effectiveness was not influenced by which therapist/doctor or by which specialty (pediatric gastroenterologist versus pediatrician) delivered treatment (all Ps of time × therapist/doctor interaction >.05). Receiving ≥1 optional modules did not influence effectiveness of CBT (P of all time × module interaction effects >.05; P of all Bonferroni corrected post hoc t tests >.05).

**Treatment Success**

According to the questionnaire data, 31.8% of children in CBT and 29.8% of the children in IMC were recovered or improved at T2 (Table 4). These percentages increased at T3 and T4 to 51.2% and 60.0% for CBT and to 41.5% and 56.4% for IMC. There were no significant differences between the conditions (P of all Fisher’s exact tests >.05). The improvement/recovery percentages of the diary data were much higher: 66.6%, 65.0%, and 65.8% for CBT conditions (P of all Fisher’s exact tests >.05). The improvement/recovery percentages signifi
cantly differed between treatment groups (P of all χ² tests >.05).

Two children in the CBT condition deteriorated at T2, none at T3, and 4 at T4 (questionnaire data). In the IMC condition, 2 children deteriorated at T2 and 2 at T3. Most of these children had a low child-reported API score at baseline (Fig 2). These scores were significantly lower than their parent-reported baseline API scores (mean children = 19.88, mean parents = 30.00, t₆ = −2.530; P = .05).

**Adverse Events**

No serious adverse events were reported.

**Satisfaction With Treatment and Therapist/Doctor**

On a scale from 0 (bad) to 10 (excellent), CBT was rated a 7.61 by children and a 7.52 by parents, and the therapist was rated an 8.45 by children and an 8.28 by parents. For IMC, these ratings were 7.74 and 8.57, respectively, as rated by children, and 7.57 and 8.54 as rated by parents. The ratings did not differ between treatments or between therapists/doctors (P of all t tests >.05).

**Health Care Use After Completion of Treatment**

During the 6 months to the first follow-up, 69.4% and 64% of children receiving CBT or IMC, respectively, reported no health care use for FAP. At 12-month follow-up, this was 60.4% (CBT) and 75.5% (IMC), respectively. None of these percentages significantly differed between treatment groups (P of all χ² tests >.05).

**DISCUSSION**

This RCT shows that 6 weekly sessions of CBT resulted in a significant reduction of AP in >60% of children with FAP up to 1 year after treatment. However, 6 weekly visits to a pediatric gastroenterologist were equally effective, with 56% of children being improved or recovered 1 year after treatment. CBT and IMC were also equally effective in increasing other gastrointestinal complaints, functional disability, other somatic complaints, and physical and psychological quality of life. CBT, however, was more effective than IMC directly after treatment and at 6-month follow-up in decreasing symptoms of anxiety and depression. This advantage of CBT over IMC disappeared at 12-month follow-up. The interventions did not differ with respect to health care consumption after treatment and satisfaction with treatment.

In contrast to our hypothesis, CBT was not superior to IMC on most outcomes. However, CBT resulted in similar decreases in complaints as in earlier studies that did find a difference between CBT and control. In the study by Levy et al, parents reported a similar decrease in disability, whereas the trial by Robins et al showed an equivalent child-reported reduction of disability directly after treatment and at 6- and 12-month follow-up. Moreover, the 60% success rate suggests that the CBT protocol investigated in this study is indeed an effective treatment of pediatric FAP. The most likely explanation for the equal effectiveness of CBT and IMC in the current study lies in the more active nature of the IMC control condition used for this study as opposed to control conditions used in...
We purposefully designed the control condition to be this active to ensure children in both interventions received equal amounts of attention from their therapist/doctor and would have equal opportunities to build a supportive relationship with their therapist/doctor. After all, it is well known in both the medical and psychological literatures that nonspecific treatment factors may account for a considerable part of treatment effectiveness. For instance, a study in adult irritable bowel syndrome patients showed that the effect of a placebo treatment was much stronger if it was accompanied by supportive interaction with a practitioner. Therefore, when considering the equal effectiveness of CBT and IMC, we may conclude that part of this equal effectiveness may indeed be attributable to these nonspecific treatment factors of receiving attention from and building a supportive relationship with a health care professional. However, IMC cannot be seen as a pure “attention-control condition” because specific treatment techniques were also used during IMC that probably contributed to its effectiveness. As such, it remains difficult for this trial to discern how large the effect of these nonspecific treatment factors actually was. It is therefore advised that future trials include a control condition that corrects for attention effects without adding specific treatment elements such as receiving psychoeducation on health behaviors. Additionally, if having a supportive relationship with a therapist partly explains the effectiveness of CBT, the question remains what percentage of the effect is attributable to specific techniques used in CBT. No previous RCTs of CBT for pediatric FAP have tried to unravel the exact mechanisms through which CBT reaches its effect. Future researchers are encouraged to investigate these working mechanisms of CBT because this may enable us to improve and tailor the intervention.

It should be noted that the full-blown IMC provided in this study might not be feasible as a treatment of pediatric FAP in daily practice because outside the experimental setting of an RCT, it is questionable whether pediatricians have time to see children with FAP for 6 months. Therefore, it remains difficult for this trial to discern how large the effect of these nonspecific treatment factors actually was. It is therefore advised that future trials include a control condition that corrects for attention effects without adding specific treatment elements such as receiving psychoeducation on health behaviors. Additionally, if having a supportive relationship with a therapist partly explains the effectiveness of CBT, the question remains what percentage of the effect is attributable to specific techniques used in CBT. No previous RCTs of CBT for pediatric FAP have tried to unravel the exact mechanisms through which CBT reaches its effect. Future researchers are encouraged to investigate these working mechanisms of CBT because this may enable us to improve and tailor the intervention.

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consecutive weeks. In that regard, CBT seems a more feasible treatment and has the potential advantage of being less costly, with, to mention 1 source of expense, salary costs being approximately twice as high for pediatricians compared with psychologists.

Finally, because of the modular nature of the CBT protocol, not every child received the exact same treatment, and therefore, one may question whether the protocol tested can be viewed as 1 comprehensive treatment. However, the use of optional modules was based on empirical findings and theory, supporting that a multitude of biopsychosocial factors are related to the etiology of pediatric FAP and that substantial variation exists in which specific factors contribute to a single patient’s disease progression.17 The advantage of this modular approach is that it is more sensitive to an individual’s needs and may have an advantage over blindly applying the same techniques to every patient, which may not be applicable for every patient’s unique combination of complaints. Because the flexibility of the protocol was explicitly part of the treatment approach and every therapist was trained in applying the protocol in this way, we feel that the protocol can indeed be viewed as 1 comprehensive treatment.

There are several limitations to this study. First, there was a notable difference in clinical experience between the doctors delivering IMC and the therapists delivering CBT. However, it has been found that inexperienced therapists, when trained in an intervention and receiving supervision, are equally effective as experienced therapists.38 Second, even though this study is the second largest RCT performed for CBT in pediatric FAP, generalizability might be compromised because sample size was small. Third, effectiveness of CBT might increase if the number of sessions were increased. Future studies are needed to investigate what number of sessions is optimal for treatment outcome. Fourth, the diary-derived data showed larger success percentages than the questionnaire data. Future researchers are therefore warned not to rely on just one of both outcomes. Finally, because the current study did not include “no treatment” or a waiting list as control group, it is uncertain to what extent the treatment effects differ from the natural course of FAP within a 1-year time frame. In fact, little is known about the natural course of FAP because only a few longitudinal epidemiologic studies exist with a follow-up period of ≥ 1 year. Importantly, Walker and colleagues found persistence of complaints in 44.7% of tertiary care outpatients at 5-year follow-up39 and 35.6% at 10-year follow-up.40 In the present patient sample, before study entry, children had experienced pain for ~3 years, whereas 11.5% experienced AP for more than half of their lives. These numbers suggest that the success rate of 60% found in the current study surpasses spontaneous remission.

CONCLUSIONS

CBT appears effective in the treatment of children with FAP but is equally effective as an intensified form of medical care delivered by pediatricians or pediatric gastroenterologists experienced in treating children with functional gastrointestinal disorders. Future studies should focus on unraveling the working mechanisms of CBT to improve and tailor the treatment of children with FAP.

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