A psychosocial perspective on pediatric functional abdominal pain: risk factors and treatment

van der Veek, S.M.C.

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Exploring moderating and mediating factors of cognitive behavior therapy for the treatment of pediatric functional abdominal pain

S. M.C. van der Veek, H. H. F. Derkx, M. A. Benninga, F. Boer, & E. de Haan, submitted for publication
Abstract

Objectives: Cognitive behavior therapy (CBT) is a promising treatment for pediatric functional abdominal pain (FAP). However, a considerable percentage of children does not respond to CBT. To be able to improve and tailor CBT for pediatric FAP, we explored which factors moderate and mediate treatment effectiveness of CBT.

Method: A total of 104 children aged 7-18 were included and randomized between 6 sessions of CBT and 6 sessions of MC. Measures for outcome, moderation and mediation were derived from child and parent self report (diaries and questionnaires). Investigated moderators were age, gender, Rome III diagnosis, time since start of complaints, anxiety, depression, emotion awareness, coping with everyday problems, parental functional gastrointestinal disorder, and parental stress, anxiety, depression and somatization. Investigated mediators were parental and children's negative cognitions about AP and positive thoughts about coping potential, children's coping with AP, parental solicitous responses to AP, and vigilance for pain. Assessments were performed pre- and post-treatment, and at 6 and 12 months follow-up.

Results: Children that were more likely to show their emotions and to seek social support for everyday problems prior to treatment, benefitted significantly more from CBT (about 80% effectiveness) than children scoring low on these variables (44%). Decreases in children's negative thoughts about their condition were related to better treatment outcome for both CBT and MC. Increases in children's positive thoughts about coping potential and decreases in parental solicitous behavior were related to better treatment outcome in CBT only.

Discussion: The present study shows that CBT is more effective for children who are more likely to show their emotions and to seek social support prior to treatment. Changes in children's positive and negative cognitions and changes in parental solicitous behavior may be mechanisms through which CBT exerts its influence.
Introduction

Pediatric functional abdominal pain is a common and disabling condition, affecting about 10% of children in Western countries (Chitkara et al., 2005; Youssef et al., 2006). Cognitive behavior therapy (CBT) has been found to be a promising treatment for children with FAP (Huertas-Ceballos et al., 2009c; Sprenger et al., 2011). However, a considerable percentage of children and adults with FAP do not respond to CBT (20-40%; Lackner et al., 2004; Van der Veek, Derks, Benninga, Boer, & De Haan, submitted b). Moreover, a recent randomized controlled trial by our research group showed that, although CBT reduced abdominal pain (AP) significantly in over 60% of children, CBT was not more effective than an intensified form of medical care in decreasing levels of AP, co-morbid physical complaints and quality of life (Van der Veek et al., submitted b). As two different treatments resulted in similar outcomes, this raises the question through what processes or mechanisms CBT might work. Additionally, we found considerable variance in how children responded to treatment, suggesting that CBT might be most effective for certain subgroups of patients. Therefore, the aim of the present study was to explore for which children CBT works best (i.e., to find moderators of treatment effectiveness), and through what processes or mechanisms CBT works (i.e., which factors mediate treatment effectiveness) (Kraemer et al., 2002). Learning more about mediators and moderators of CBT may enable us to improve and tailor the intervention (Kraemer et al., 2002; Nock, 2007; Weersing & Weisz, 2002).

Which factors moderate the effectiveness of CBT has not yet been investigated for pediatric FAP, and only to a limited extent for adult functional gastrointestinal disorders (FGID). Studies in adults have mostly focused on the moderating influence of demographic and clinical characteristics like gender, symptom severity or distress. These variables seem to exert some influence on outcome, but the size of this influence is only modest, which led researchers to conclude that other factors are likely to be responsible for treatment effectiveness (Blanchard et al., 2006; Lackner et al., 2010). Therefore, the present study focused, in addition to baseline clinical and demographic characteristics, on the moderating influence of the psychological variables emotion awareness and coping with everyday problems. Previous studies suggest that a psychological intervention is less effective if patients are more alexithymic/less aware of their emotions, or are less inclined to talk about or show their emotions to others (Lumley, Neely, & Burger, 2007). Indeed, alexithymia has been shown to be related to a decreased effectiveness of medical and psychological treatment in adult patients with FGIDs (Porcelli et al., 2003). The way children cope with everyday problems is another possible psychological moderator of effectiveness of CBT in pediatric FAP. Specifically, it has been suggested that CBT is more effective for those children using maladaptive strategies to cope with general problems, as CBT may teach them to use more effective coping strategies in other areas of life as well, resulting in a greater treatment response (Oxman, Hull, & Dietrich, 2008). Finally, in addition
to these child-related variables, the moderating influence of parental stress, parental anxious, depressive and somatization symptoms and presence of an FGID in one of the parents was investigated. Previous studies suggest that, although the influence seems modest, parents may maintain the AP of their children if they experience a lot of somatic or psychological complaints themselves (Levy, 2011; Van der Veek et al., 2012). Therefore, we expected that if parents reported more physical or psychological complaints, this would be related to lower treatment effectiveness.

Concerning mediating factors of treatment effects, the study by Sanders and colleagues (1994) was the first study explicitly focusing on such factors for a CBT protocol designed for pediatric FAP. They found that children's and parent's ways of coping with AP after treatment, were related to post-treatment levels of AP. However, to establish that a factor mediates the effect of treatment on outcome, that factor should not only be related to treatment outcome, but treatment should also lead to a change in that factor (the mediator) (Baron & Kenny, 1986; MacKinnon et al., 2002), which was not studied by Sanders et al.. Levy and colleagues (Levy et al., 2010) and Gross and Warschburger (Gross & Warschburger, 2012) did investigate whether CBT led to a change in variables targeted by the CBT (i.e., cognitions, parental solicitous behavior, coping with the AP), but did not relate these changes to changes in outcome, again making it impossible to conclude whether the investigated factors were actually mediators of treatment effects. Therefore, we decided to investigate which factors mediate the effectiveness of CBT in treating pediatric FAP by studying a) whether treatment resulted in changes in possible mediating variables directly after treatment and at 6 months follow-up, and whether such changes were larger for the children receiving CBT than for children in the control condition receiving an intensified form of medical care (MC); and b) whether these changes in mediators related to changes in outcome. The mediating variables that were selected for this study focused on the variables that CBT intends to change: a) negative cognitions about AP of children and parents; b) parental and children's positive cognitions about the coping potential of the child; c) children's coping with the AP; d) parental solicitous responses to the AP; and e) children's vigilance towards their AP. Note that to properly establish whether a mediator is an actual mechanism of change of the therapy, it should be shown that a change in mediator precedes a change in outcome in time, necessitating measures of the mediators during treatment (Kraemer et al., 2002; Maric, Wiers, & Prins, 2012; Weersing & Weisz, 2002). Because our CBT only lasted six sessions and we focused on many different possible mediators, we decided against incorporating an assessment during treatment and to first explore which mediators might be candidate mechanisms of change. It was expected that the mediators would change more strongly following CBT than following MC, and that a change in each mediator would be related to a change in treatment outcome.
Methods

Design and procedure
The study was part of a prospective randomized controlled trial. The study protocol was approved by the medical ethical committee of the Academic Medical Center Amsterdam. The trial was registered at the Netherlands National Trial Register, trial number NTR1613. The study protocol is described in more detail elsewhere (Van der Veek et al., submitted b) and can be requested from the first author.

Children were included at the general pediatric and pediatric gastroenterology outpatient clinics at the Emma Children's Hospital AMC in the Netherlands. They were randomized between 6 sessions of CBT and 6 sessions of medical care (MC). CBT took place at De Bascule, academic center for child and adolescent psychiatry, Amsterdam, and MC was provided at the Emma Children's Hospital AMC. Prior to treatment, two to three weeks after treatment, 6 months and 12 months after treatment, assessments took place. The assessments consisted of filling out a diary for one week, filling out questionnaires and undergoing a face-to-face or phone interview during which the functioning of the child and the effects of the treatment were evaluated.

In- and exclusion criteria
Children were eligible if they were between 7 and 18 years of age and fulfilled the following criteria, in accordance with the Rome III criteria for pediatric abdominal pain-related functional gastrointestinal disorders (Rasquin et al., 2006): 1) AP is main complaint; 2) AP lasted at least 8 weeks in past 12 months; 3) no evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject’s symptoms. Additional criteria were: 4) absence of a psychiatric disorder which required treatment prior to treatment for FAP (e.g., psychotic symptoms, presence of an anxiety disorder that was clearly causing the AP); 5) Dutch speaking; 6) AP had to be present in two weeks prior to inclusion. Presence of an explanatory organic disease was investigated by performing laboratory tests on stool, urine and blood, and by performing an ultrasound, in addition to taking a physical examination and mapping the medical history of the child.

Sample
Over two hundred children were screened for eligibility, 97 of which were excluded for various reasons (for more detail on participant flow throughout the study, see Van der Veek et al., submitted b). A total of 104 children were randomized to either CBT (N=52) or MC (N=52). Children were predominantly female (72.1%) and of Dutch nationality (84.6%). Mean age was 11.9 years (range 7-18, sd=2.76). On average, children had experienced AP for nearly three years when they entered treatment (mean=34.01 months, sd=37.37) and most of them had experienced AP for the largest part of the preceding year (mean=42.66
weeks, sd=14.49). Because of the AP, the children missed approximately one day of school per week at inclusion (mean= .83 days, sd=1.23). Ninety-two children (88.5%) participated at follow-up directly after treatment, 87 (83.7%) at 6 months follow-up and 88 (84.6%) at 12 months follow-up.

Interventions
Both treatments comprised of 6 sessions, scheduled approximately one week apart. Most children (N=33) received CBT from master students in psychology, who received training and supervision by the developer of the intervention, an experienced children's psychotherapist (fifth author). In the other cases (N=13), CBT was delivered by a therapist with a master's degree or higher. MC was delivered by experienced pediatricians or pediatric gastroenterologists.

Detailed descriptions of the content of both treatments are provided elsewhere (Van der Veek et al., submitted b). In essence, the CBT-protocol (Thiadens & De Haan, 2007) made use of 4 distinct modules, three of which were only used when the therapist deemed them appropriate for the child, allowing some tailoring of the protocol to the individual child. The module that was used for every child, consisted of a series of relaxation exercises, teaching children to relax when they experienced AP and in doing so, teaching them a way to cope with their AP. The three optional modules consisted of 1) cognitive therapy directed at changing negative cognitions about the pain, or negative cognitions about other things (e.g. worrying about school) that aggravated the pain; 2) behavior therapy directed at changing maladaptive coping behavior of the child (e.g., avoiding school and social activities because of the pain); and 3) behavior therapy directed at changing maladaptive parental coping behavior (e.g., allowing the child to stay home from school). To establish which modules the therapist should use, children and their parents were interviewed by the therapist about how they were doing in these three areas during the two intake sessions preceding the treatment, and during the first two therapy sessions. Applying additional modules or not was found to be unrelated to treatment effectiveness, suggesting that although the treatment is tailored to the individual child, it can be regarded as one protocol and analyzed as such (Van der Veek et al., submitted b).

The pediatricians providing the MC educated children and their parents about the complaints, prescribed medication, gave dietary advice, or gave advice about continuing school and daily activities, as they saw fit.

Measures

Pain diary
At all four assessments, children filled out a diary, in which they had to report about the frequency, duration and intensity of their AP on a daily basis for one week. The intensity of
their AP was scored making use of a Facial Affective Scale (McGrath et al., 1996; Vlieger et al., 2007), with intensity scores ranging from 1 (smiling face, no pain) to 9 (crying face, most intense pain possible). The diary data were entered in SPSS by a medical and a psychology student who were blinded for randomization. From these diaries, we calculated two scales indicating pain intensity (pain intensity scores; PIS) and pain frequency (pain frequency scores; PFS) (Vlieger et al., 2007). For the PIS, daily scores were transposed to the following range: 0=no pain, 1=faces 1 through 3, 2=faces 4 through 6, and 3=faces 7 through 9. For the PFS, daily scores were transposed as follows: 0=no pain, 1=1 to 30 minutes of pain, 2=31 to 120 minutes of pain, and 3=more than 120 minutes per day. For both PIS and PFS, the daily scores were added for all 7 days of the diary, resulting in a total score with a possible range of 0-21.

**Semi-structured interview for psychiatric diagnoses**

To assess whether any psychiatric diagnoses were present, the Anxiety Disorders Interview Schedule for Children was used (ADIS-C; Silverman & Albano, 2001). The ADIS-C is a semi-structured interview assessing DSM-IV diagnoses for all anxiety disorders and depression. Additionally, it screens whether any other psychiatric diagnoses like developmental disorders or AD(H)D may be present. The ADIS-C takes between 30 to 90 minutes to administer. It was separately administered to parents and children. The primary investigator and the masters students in psychology who also delivered the CBT were trained in administering the ADIS-C and interviewed all parents and children. If any doubts rose about diagnoses resulting from the ADIS-C, these were discussed with an experienced children’s psychotherapist (fifth author). The ADIS-C has been found to be a valid and reliable instrument to diagnose DSM-IV psychiatric disorders in children and adolescents (Silverman, Saavedra, & Pina, 2001).

**Questionnaires**

The following questionnaires were filled out by both children and parents. Children reported about their own complaints, and parents reported about the complaints of their child. Moderating variables were measured prior to treatment, and mediating variables were measured prior to treatment, directly after treatment and at 6 months follow-up.

**Abdominal pain.** The Abdominal Pain Index (API) was used to measure level of AP (Walker et al., 1997). The API consists of five questions, and taps on the frequency, duration and intensity of the AP the child experienced in the past two weeks. Two questions make use of a 6-point scale, one of a 9-point scale and another two of an 11-point scale. A total score for the API was computed by recoding each item to reflect a scale ranging from 0 to 10, and summing all items (Van der Veek et al., 2010). The API has been shown to be a reliable instrument, with a Cronbach’s alpha ranging from .80 to .93 (Walker et al., 1997).

**Anxious and depressive symptoms.** The Revised Anxiety and Depression Scale – short version (RCADS-25; Muris et al., 2002) was used to measure symptoms of anxiety and depression. The shortened version of the RCADS has been shown to be a valid and reliable
instrument to measure symptoms of generalized anxiety disorder, separation anxiety disorder, social phobia, panic disorder, and major depressive disorder (Muris et al., 2002). Each of the five scales consists of five items that have to be scored on a 4-point scale, ranging from (0) never to (3) always. Cronbach’s alphas of the five scales ranged from .65 to .83 in previous research (Muris et al., 2002). The four scales of the different anxiety disorders were summed to compute one score for anxious symptoms. A separate score was calculated for depressive symptoms.

**Emotion awareness.** Emotion awareness was measured by the self-report Emotion Awareness Questionnaire – revised version (EAQ; Rieffe et al., 2008), which has specifically been designed for children and adolescents and was partly based on the Toronto Alexithymia Scale (TAS-20; Bagby et al., 1994). The EAQ measures six aspects of emotion awareness: (1) Differentiating Emotions, (2) Verbal Sharing of Emotions, (3) Not Hiding Emotions, (4) Bodily Awareness of Emotions, (5) Attending to Others’ Emotions, and (6) Analyses of Emotions. The respondents are asked to rate the degree to which each item is true about them on a three-point scale (1 = never, 2 = sometimes, 3 = often). A higher score on each subscale reflects a higher ability at the measured concept. All scales have been shown to have acceptable psychometric properties, with Cronbach’s alphas ranging from .64 to .77 (Rieffe et al., 2008).

**Coping with everyday problems.** Coping strategies were measured by a Dutch translation of the Children’s Coping Strategies Checklist - Revision 1 (CCSC-R1; Ayers & Sandler, 2000; De Boo & Wicherts, 2009). The CCSC-R1 consists of 54 items, all starting with the words “If I have a problem…”. The 54 items can be divided in five higher-order scales, which measure problem focused coping, positive cognitive reframing, distraction strategies, avoidance strategies, and support seeking strategies. Answers are given on a four-point Likert scale, ranging from 1 (never) to 4 (always). The CCSC-R1 has been found to have sound psychometric properties, with Cronbach’s alphas ranging from .72 to .88 (De Boo & Wicherts, 2009).

**Parental FGID, anxiety, depression, somatization, and stress.** Whether parents suffered from any FGIDs was enquired after by the pediatrician during a consult prior to inclusion. Depressive, anxious and somatization symptoms of the parents were measured by three subscales of the Symptom Check List (SCL-90; Derogatis, 1977, Dutch translation and adaptation by Arrindell & Ettema, 2003). The depression subscale consists of 16 items, the anxiety subscale of 10 and the somatization subscale of 12 items. The items are measured using a 5-point Likert scale, ranging from (1) not at all to (5) very much. Individual scale scores were obtained by summing the items belonging to the subscale; higher scores reflect more depressive, anxious and somatization symptoms. Test-retest reliability has been found to be good for this instrument and strong convergent validity was found with other conceptually related scales (Arrindell & Ettema, 2003). Finally, to measure parental stress, the NOSI-K (De Brock, Vermulst, Gerris, & Abadin, 1992) a Dutch version of the
Parenting Stress Index (PSI; Abidin, 1983) was filled out by parents. This scale asks parents to rate 25 statements about their child, for example, “I notice I am not as capable in taking care of my child as I thought I would be” and “Parenting this child is harder than I thought it would be.” The NOSI-K is a short version of a more comprehensive measure—the NOSI. This shorter version was constructed by factor analysis on the original items. A selection of 25 items was made, which all loaded high on one common factor, ‘parental stress’. Within these 25 items, 10 of the original 13 scales of the NOSI are represented (De Brock et al., 1992). The 25 items are totaled to form one new scale, with high scores reflecting a high level of parental stress. Participants were asked to rate on a six-point Likert scale ranging from ‘totally disagree’ (1) to ‘totally agree’ (6) whether or not they agreed with the 25 statements. The NOSI-K has been found to have good psychometric properties (De Brock et al., 1992).

**Negative and positive cognitions about FAP.** Children in both groups and their parents filled out the Pain Beliefs Questionnaire (PBQ) to measure both negative and positive beliefs about the child’s AP (Van Slyke, 2001; Walker et al., 2005). The PBQ was translated into Dutch by the present research group (Van der Veek et al., submitted a). The PBQ is a 32-item questionnaire, with 20 items assessing beliefs about condition frequency, duration and seriousness, and episode specific intensity and duration. The other 12 items make up the problem focused and emotion focused coping potential scales (PFCP and EFCP), which measure whether children and parents believe that the child can cope with the pain. Responses are given on a 5-point Likert scale; higher scores reflect that the child or parent has such thoughts more often. The negative beliefs scale was calculated by averaging all 20 items pertaining to that subject. The PFCP and EFCP scales were calculated by averaging the 6 items of each scale.

**Coping with FAP.** To measure the way children coped with their AP, children filled out the Pain Response Inventory (PRI; Walker et al., 1997). The PRI is a 60 item questionnaire measuring several types of coping strategies. Answers can be given on a 5-point Likert scale, with higher scores reflecting a greater usage of these coping strategies. The PRI was also translated into Dutch by the present research group (Van der Veek et al., submitted a). The PRI consists of 3 higher order scales, measuring active coping (e.g., “try to do something to make it go away”), passive coping (e.g., “not even try to do anything about it because it will not help”) and accommodative coping (e.g., “try to learn to live with it”). Scale scores are calculated by averaging the items pertaining to that scale. The PRI has been shown to be a valid instrument, with Cronbach’s alpha’s ranging from .71 to .78 (Walker et al., 1997).

**Parental solicitous behavior.** Parents filled out the Illness Behavior Encouragement Scale (IBES; Walker & Zeman, 1992) to measure parental solicitous behavior. The IBES consists of 12 items which are answered on a 5-point scale. Higher scores reflect more parental solicitous behavior. The IBES has been shown to be a reliable instrument, with Cronbach’s alphas of .75 to .85 (Walker & Zeman, 1992).
Vigilance to pain. To measure self-reported vigilance to pain, the Pain Vigilance and Awareness Questionnaire was used (PVAQ; Roelofs et al., 2002, 2003). The PVAQ consists of 16 items which can be answered on a 6-point Likert scale, ranging from (0) never to (5) always. Exemplary items are “I focus on sensations of pain” and “I know immediately when pain starts or increases”. It has been validated in a Dutch sample of adult healthy participants and fibromyalgia patients (Roelofs et al., 2002, 2003). For the present study, the items were adapted slightly to accommodate the reading level of the children participating in our study. Two subscales were calculated, measuring attention to pain and attention to changes in pain. Subscale scores were calculated by summing the items pertaining to each scale.

Statistical analyses
To investigate whether age, gender, Rome III diagnosis, time since start of complaints, anxiety, depression, emotion awareness, coping with everyday problems, parental FGID diagnosis, and parental stress, anxiety, depression and somatization moderated treatment effects, a series of linear mixed models was run in SPSS 18.0 with the moderating variable and all its interactions with time and treatment as independent factors, and child and parent API scores and PIS and PFS scores as dependent variables. Age and gender were entered as covariates. Our objective was to ascertain whether the time x treatment x moderator interaction effect reached significance, as this indicates that for different levels of the moderator, the interventions lead to a significantly different effect over time.

To investigate whether the hypothesized mediator variables parental and children’s negative cognitions about the AP and positive thoughts about coping potential, children’s coping with AP, parental solicitous responses to AP, and children’s vigilance towards their AP changed during each treatment, another series of linear mixed models was performed. Time, treatment, and time x treatment were entered as independent variables, and age and gender as covariates. Second, to investigate whether a change in mediator was related to a change in AP, we calculated Pearson correlations between changes on the mediators and changes on self and parent reported API scores, and PIS and PFS diary scores. This was only done for those mediators showing significant changes over time in the mixed models analyses. Two change scores were calculated per mediator, one indicating change from pre- to post-treatment, and one from pre-treatment to 6 months follow-up. For the four outcome measures, these two change scores were also calculated, and a third change score was added to indicate the change from pre-treatment to 12 months follow-up. As such, six possible correlations between change in mediator and change in outcome could be calculated. With twelve mediator variables and four outcome measures, this resulted in 288 correlations. Because of the large number of correlations calculated and the exploratory nature of this part of the study, we decided to only interpret the influence of those mediators who showed significant correlations.
on at least three of the six possible correlations between change in mediator and change in outcome, and these three correlations had to be significant for at least two of the four possible outcomes. Correlations were calculated separately for the two treatments, which resulted in rather small sample sizes, showing some outliers. Therefore, Spearman instead of Pearson correlations were calculated (Field, 2005).

Results

Data inspection

For 20 children (17.9%), no parental PBQ data were available because this questionnaire was added to the instrument battery at a later time. The reason for the missings in these cases was thus observed, and as such it can be described as “missing at random” (MAR) (Rubin, 1976). It has been shown that in the case of MAR it is better to impute data than do a complete-case analysis (Schafer & Graham, 2002). Therefore, we imputed the PBQ data making use of the multiple imputations subroutine available in SPSS 18.0. All variables used in this study were used to impute the missing data five times.

Moderators of treatment effect

None of the demographic (age, gender) or clinical (time since start of complaints, Rome III diagnosis, anxiety, depression) characteristics had any moderating effects on treatment effectiveness ($p$'s of all time x treatment x moderator effects >.05 in linear mixed models). Also, none of the parent related variables had a moderating effect on treatment effectiveness ($p$'s for time x treatment x moderator effects >.05 for presence of FGID in parents and parental stress, anxiety, depression and somatization). The only two variables for which we found a moderating effect on two, respectively one of the four outcome measures, were ‘not hiding emotions’ (aspect of emotion awareness; PIS: $F(3,90.76) = 2.947; p = .037$. PFS: $F(3,86.66) = 3.093; p = .031$), and ‘seeking social support’ (coping strategy; parent reported API: $F(3,85.52) = 2.970; p = .036$). The moderating effects of these variables are displayed in figure 1 and 2. For children who reported to hide their emotions from others less often prior to treatment, CBT was more effective than MC at decreasing PIS and PFS diary scores at 6 months follow-up (PIS: $t(81.71) = 2.949; p = .004$. PFS: $t(85.13) = 2.710; p = .008$). For children who reported to seek social support in the face of everyday problems more often prior to treatment, CBT was more effective than MC at decreasing parent reported API scores at 12 months follow-up ($t(86.49) = 2.874; p = .005$).

To see how large these significant effects were on the treatment success of CBT, we calculated the percentage of treatment success on the respective outcome measures in the group of children scoring below and above the mean scores of not hiding emotions and seeking social support (see Van der Veek et al., submitted b, for more detail on how
scores on treatment success were calculated. This analysis showed that in the group of children scoring above the mean of not hiding emotions, 79.2% of children who received CBT had improved or recovered at 6 months follow-up according to their diaries, versus 43.75% of children in the group scoring below the mean of not hiding, which was a significant difference ($\chi^2(2) = 9.995; p = .007$). For MC, no significant relationship was found between levels of not hiding emotions and treatment effectiveness (50.0% vs. 45.5% success, $\chi^2(2) = 1.261; p = .532$). Concerning social support, we found that 81.0% of the children scoring above the mean of seeking social support prior to treatment had reliably improved at 12 months follow-up according to parent reported API scores, whereas 43.5% of the children scoring below the mean of seeking social support had reliably improved. This difference was also significant ($\chi^2(1) = 6.502; p = .011$). Again, for MC, there was no relationship between levels of seeking social support and treatment success (64.7% vs. 56.5% success, $\chi^2(1) = .273; p = .601$).

*Figure 1.* Moderating effect of not hiding emotions on pain intensity (PIS) and pain frequency (PFS) scores at 6 months follow-up.
Figure 2. Moderating effect of seeking social support on parental abdominal pain index score at 12 months follow-up.
Mediators of treatment effect

The linear mixed models showed that for all investigated mediator variables, a significant time effect was found, except for active coping ($F(2, 138.273) = .018; p =.982$) and for attention to changes in pain ($F(2, 108.91) = .084; p =.919$). This significant time effect indicated that all children changed on those mediators over time, irrespective of the treatment they received. For two variables, there was a significant difference between treatments. First, a significant time x treatment interaction effect was found for parental thoughts about the problem focused coping potential of their children directly after treatment (pooled $t$-test on imputed datasets $t = -2.278; N=104; p=.027$) and a trend was found at 6 months follow-up (pooled $t$-test on imputed datasets $t = -1.769; N=104; p =.086$). Post-hoc one sample $t$-tests showed that both treatments led to a significant increase in positive parental thoughts, but this effect was stronger for CBT (post-treatment: pooled mean difference=1.05, $p <.001$. 6 months follow-up: pooled mean difference = 1.22, $p <.001$) than for MC (post-treatment: pooled mean difference=.43, $p <.05$. Six months follow-up: pooled mean difference=.73, $p <.01$). The effect is shown in figure 3a.

A second significant interaction effect displayed in figure 3b, was for attention to changes in pain (post-treatment: $t(124.81) = 2.391; p =.018$. Six months follow-up: $t(154.67) = 2.501; p =.013$). While children receiving MC did not change in how much attention they paid to changes in their AP after treatment (post-treatment: mean difference = 1.79, $p =.216$. Six months follow-up: mean difference = 1.98, $p =.109$), this attention decreased in children receiving CBT at 6 months follow-up (mean difference = -2.91, $p =.021$).

Figure 3. Change in mediating variables over time for both treatments.

a. Parental beliefs about problem focused coping potential of child

Note: scores increased significantly for both treatments at post-treatment and 6 months follow-up. Difference between treatments at post-treatment: $p <.05$; difference between treatments at 6 months follow-up: $p <.10$. 
Second, to investigate whether changes in mediators were related to changes in outcomes, we calculated correlations between changes on the mediator variables and changes on self and parent reported API scores, and PIS and PFS diary scores. The results are displayed in table 1. The mediators most strongly related to change in CBT were children’s negative cognitions about condition seriousness, children’s positive cognitions about coping potential, and parental solicitous behavior. Improvements in these variables were significantly related to decreases in AP, both at the same time point and prospectively (e.g., decrease in negative cognitions from pre- to post-treatment correlated significantly (r = -.377) with a better outcome on API score from pre-treatment to 6 months follow-up). Changes in children’s negative cognitions were also related to change in AP in children receiving MC.

**Discussion**

The present exploratory study showed that the psychological factors emotion awareness and coping moderated treatment effectiveness of CBT for pediatric FAP. None of the demographic, clinical or parental characteristics were found to moderate treatment effectiveness. In addition, the results showed that three factors may be candidate working mechanisms of CBT: children’s negative cognitions about their AP, children’s positive cognitions about their potential to cope with their AP, and parental solicitous behavior.

Looking at the results for the moderation analyses in more detail, we see that children that were more likely to show their emotions to others and to seek social support prior to treatment, benefitted more from CBT than from MC. This effect was profound: about...
80% of children receiving CBT and scoring high on not hiding emotions or seeking social support were recovered or improved at 6 or 12 months follow-up, while only 44% of the children scoring low on these variables recovered or improved. A possible reason why the current protocol was less effective for children that weren’t likely to seek social support or to show their emotions, is because it may be more difficult for them to go to a therapist and talk about their complaints, making the current protocol less suitable for them. As such, incorporating a screening on these variables prior to treatment may be useful in deciding which children should receive the CBT protocol as it is, and for which children efforts should be undertaken to adapt the CBT protocol, by for example delivering the intervention through the internet or through audiotapes (van Tilburg et al., 2009), or by paying more attention to their difficulties with showing their emotions. However, because of the exploratory nature of the present study, future studies into the influence of these moderators on treatment effectiveness of CBT are needed.

Concerning mediators, decreases in children’s negative thoughts about their condition, increases in children’s positive thoughts about their coping potential, and decreases in parental solicitous behavior were all related to better treatment outcomes. Note, however, that, in contrast to other studies (Levy et al., 2010; Litt, Shafer, Ibanez, Kreutzer, & Tawfik-Yonkers, 2009), changes in the way children coped with their AP, were unrelated to treatment effectiveness. Thus, it seems that for the present population, whether a child believes he/she can cope with the AP is more important than the actual coping mechanism employed, suggesting that feeling you are in control of your AP might be the factor of essence. Also, although parental negative and positive thoughts changed following CBT, and positive thoughts increased significantly more following CBT than following MC, these changes were mostly unrelated to treatment outcome, making it unlikely that changing parental thoughts was a working mechanism for CBT. Instead, changes in parental solicitous behavior were related to treatment outcome, suggesting that the overt behavior displayed by the parent is more important than the covert thoughts parents have about the AP of their child.

Surprisingly, decreases in children’s negative cognitions about their condition were related to decreases in AP in children receiving CBT as well as MC. Indeed, a study in adult patients with IBS showed that medical consultations can change negative cognitions about complaints, and these changes were related to better outcome of IBS (Van Dulmen, Fennis, Mokkink, Van der Velden, & Bleijenberg, 1997). Thus, it can be questioned whether the specific techniques used in CBT exclusively effect changes in negative cognitions. Moreover, for all of the mediators it can be questioned what the direction is of the relationships between the mediators and treatment outcome. As shown in table 1, changes in the mediators were related to changes in outcome concurrently and prospectively, but also prospectively in the opposite direction, meaning that a change in outcome from pre- to post-treatment was related to a change in mediator at 6 months follow-up. This makes...
### Table 1. Spearman correlations between change in mediators and change in outcome.

**a. CBT**

<table>
<thead>
<tr>
<th></th>
<th>Abdominal pain index</th>
<th>Abdominal pain index-parent</th>
<th>Pain intensity score</th>
<th>Pain frequency score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1-T2</td>
<td>T1-T3</td>
<td>T1-T4</td>
<td>T1-T2</td>
</tr>
<tr>
<td>Child-reported variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative cognitions T1-T2</td>
<td>-.463**</td>
<td>-.304</td>
<td>-.224</td>
<td>-.614***</td>
</tr>
<tr>
<td>Negative cognitions T1-T3</td>
<td>-.520**</td>
<td>-.645***</td>
<td>-.605***</td>
<td>-.463**</td>
</tr>
<tr>
<td>PFCP T1-T2</td>
<td>.512**</td>
<td>.353*</td>
<td>.174</td>
<td>.366*</td>
</tr>
<tr>
<td>PFCP T1-T3</td>
<td>.488**</td>
<td>.445**</td>
<td>.290</td>
<td>.370*</td>
</tr>
<tr>
<td>EFCP T1-T2</td>
<td>.210</td>
<td>.175</td>
<td>.169</td>
<td>.309*</td>
</tr>
<tr>
<td>EFCP T1-T3</td>
<td>.212</td>
<td>.408**</td>
<td>.307</td>
<td>.385*</td>
</tr>
</tbody>
</table>

| Parent-reported variables |          |          |        |        |          |          |        |          |        |        |          |          |        |
| Solicitous behavior T1-T2 | .130 | .062 | -.039 | -.026 | -.155 | -.189 | -.177 | -.283 | -.458* | -.014 | -.098 | -.204 |
| Solicitous behavior T1-T3 | -.289 | -.317* | -.273 | -.350* | -.420** | -.370* | -.446* | -.573*** | -.512** | -.344 | -.394* | -.347 |

**b. MC**

<table>
<thead>
<tr>
<th></th>
<th>Abdominal pain index</th>
<th>Abdominal pain index-parent</th>
<th>Pain intensity score</th>
<th>Pain frequency score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1-T2</td>
<td>T1-T3</td>
<td>T1-T4</td>
<td>T1-T2</td>
</tr>
<tr>
<td>Child-reported variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative cognitions T1-T2</td>
<td>-.471**</td>
<td>-.210</td>
<td>-.293</td>
<td>-.358*</td>
</tr>
<tr>
<td>Negative cognitions T1-T3</td>
<td>-.406**</td>
<td>-.736***</td>
<td>-.329*</td>
<td>-.088</td>
</tr>
</tbody>
</table>

Note. *p < .05; **p < .01; ***p < .001. T1 = pre-treatment, T2 = post-treatment, T3 = 6 months follow-up, T4 = 12 months follow-up. PFCP = problem-focused coping potential. EFCP = emotion-focused coping potential. Positive scores on change in outcome variables indicate decreases in abdominal pain. Positive scores on change in mediator variables indicate more solicitous behavior, more negative cognitions, and more positive thoughts about coping potential at follow-up.
sense intuitively: if the treatment is effective and the AP decreases, negative cognitions about AP will probably also diminish. It is clear that more research is needed to discern the directionality of these processes, before judgments can be made about whether a factor is a mediator or a consequence of CBT.

There are a number of limitations to this study that should be addressed. First, not every child received the same treatment because the CBT protocol consisted of optional modules, allowing tailoring of the protocol to the individual child. However, this limitation is mitigated because treatment effectiveness showed no relations with which module or which combination of modules was applied (Van der Veek et al., submitted b). Second, the present study did not measure change in mediators during treatment, precluding an investigation of whether the change in mediator precedes change in outcome and thus whether a mediator is an actual mechanism of change of the therapy (Kraemer et al., 2002; Maric et al., 2012; Weersing & Weisz, 2002). Because our CBT only lasted six sessions and we focused on many different possible mediators, we decided against incorporating an assessment during treatment and to perform an exploratory study on which mediators might be candidate mechanisms of change. To be able to study whether children’s negative and positive cognitions and parental solicitous behavior are actually mechanisms of change, however, future research should incorporate an assessment of mediators during treatment. Also, we did not assess whether the moderating variables emotion awareness and coping with everyday problems changed during treatment, which may have occurred. Finally, a lot of exploratory analyses were done, resulting in an increased chance on type I errors. More research is needed focusing on specific moderators and mediators of treatment effectiveness, to formally establish their influence.

Concluding, this study shows that CBT is more effective in decreasing AP in children with FAP who show their emotions to others and seek social support more often prior to treatment. Changing children’s positive and negative cognitions and changing parental solicitous behavior may be mechanisms through which CBT exerts its influence. The results of our study may be used as a basis for future studies, incorporating a more vigorous design to test for moderators and mechanisms of change of CBT for pediatric FAP.