Cognitive-Behavioral Therapy for Adolescents With Inflammatory Bowel Disease and Subsyndromal Depression

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ABSTRACT

Objective: To examine the feasibility and efficacy of a manual-based cognitive-behavioral therapy (CBT) in reducing depressive symptomatology in adolescents with inflammatory bowel disease (IBD). Primary and Secondary Control Enhancement Therapy-Physical Illness (PASCET-PI) modified for youths with IBD was compared to treatment as usual (TAU), plus an information sheet about depression, without therapist contact using assessable patient analysis. Method: Following assessment, participants 11 to 17 years old with IBD and mild to moderate subsyndromal depression were randomly assigned to PASCET-PI (n = 22) or comparison treatment (n = 19). Primary outcome measures at baseline (T1) and 12 to 14 weeks posttreatment (T2) were Children's Depression Inventory (child/parent report), Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS), Children's Global Assessment Scale, and Perceived Control Scale for Children. Results: The PASCET-PI group showed significantly greater improvement in Children's Depression Inventory (child/parent report), Children's Global Assessment Scale, and Perceived Control Scale for Children posttreatment than the comparison group. Conclusions: Screening and treatment of depressive symptoms in pediatric settings is feasible. PASCET-PI may be an efficacious intervention for subsyndromal depression in adolescents with IBD, although comparison with a more active treatment is necessary to attribute the improvement to PASCET-PI. J. Am. Acad. Child Adolesc. Psychiatry, 2007;46(10):1290-1298. Key Words: depression, physical illness, inflammatory bowel disease, cognitive-behavioral therapy. Clinical trial registration information: URL: http://clinicaltrials.gov. Unique identifier NCT00446238

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Pediatric inflammatory bowel disease (IBD), which includes Crohn disease (CD) and ulcerative colitis (UC), is a chronic debilitating illness characterized by recurrent episodes of abdominal pain and bloody diarrhea as well as weight loss, growth retardation, and pubertal delay (Murch et al., 2004). Although autoimmune and infectious etiologies may induce disease activity, psychological factors have adversely affected the course of IBD (Engstrom, 1999; King, 2003), suggesting an interaction between gastrointestinal, brain, and behavioral functioning.

The chronic physical problems associated with IBD can co-occur with psychological problems and impaired functioning (Akobeng et al., 1999; Mackner et al., 2006; Moody et al., 1999). In addition, youngsters with IBD have high rates of depressive symptoms (Burke

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et al., 1990; Helzer et al., 1982; Szigethy et al., 2004a) compared with both youths without a chronic illness (Ferry, 1999; Steinhausen and Kies, 1982) and youths with cystic fibrosis or diabetes (Burke et al., 1989; Engstrom, 1992). Depression severity has been associated with IBD severity and exogenous steroids, suggesting a physiological contribution to the depressive symptoms (Szigethy et al., 2004a). Cognitive processing factors (e.g., believing events are out of one's control rather than affected by one's efforts) have been linked to depression in youth with IBD (Engstrom, 1999). In physically ill youngsters, depression is associated with greater health care use, less optimal medical outcomes, heightened functional impairment, decreased quality of life, and increased mortality (Lernmark et al., 1999; Strunk, 1987).

Cognitive-behavioral therapy (CBT) has considerable empirical support in treating depression in otherwise healthy adolescents (Brent et al., 1997; Weersing et al., 2006; Weisz et al., 1997). In an open CBT trial with 11 youths with IBD and depression, participants were found to experience significant improvements in depression, global adjustment, and physical functioning (Szigethy et al., 2004b). The CBT protocol was based on the Primary and Secondary Control Enhancement Training (PASCET) protocol (Weisz et al., 1997) that draws on behavioral activation, cognitive restructuring, and problem-solving skills to change maladaptive behaviors, cognitions, and coping strategies. The PASCET-Physical Illness (PASCET-PI) is a modification of the original PASCET with the additional components of a physical illness narrative, social skills training, and parent sessions to address physical illness concerns (Szigethy et al., 2004b). PASCET-PI is the first study to demonstrate the feasibility of screening for depression and integrating psychiatric treatment into the IBD medical care setting (Szigethy et al., 2004b, 2006).

The present study used a randomized controlled trial design to assess the efficacy of the PASCET-PI for adolescents with IBD and mild to moderate subsyndromal depression. The comparison group received treatment as usual (TAU) plus a written information sheet about the signs, symptoms, and treatment of clinical depression. Outcomes assessed were changes in depressive symptoms, cognitive processing, and global functioning. It was hypothesized that relative to the comparison group, adolescents with IBD treated with PASCET-PI would show a significant improvement in self- and blinded clinician-rated depressive symptoms, self-reported perceived control, and clinician-rated global functioning.

METHOD

Participants

Data were collected using identical procedures at two sites: Children's Hospital Boston (n = 30) and Children's Hospital of Pittsburgh (n = 11). This study was conducted in each hospital's gastroenterology clinic and was approved by the respective institutional review boards. Informed assent and consent were obtained.

Participants were recruited through a two-step screening process (Fig. 1). Step 1 consisted of screening adolescents with IBD for depressive symptoms using the Children's Depression Inventory, child and parent report (CDI and CDI-P; Kovacs, 1992). Participants who scored ≥ 9 on the CDI and/or CDI-P and met inclusion/exclusion criteria (described below) were invited to participate in step 2, the standardized psychiatric assessment, using the Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL; Kaufman et al., 1997). A score of 9 on the CDI or CDI-P is consistent with an adjustment disorder (Kovacs, 1992).

Inclusion criteria for the intervention phase were CDI score ≥ 9 and/or CDI-P score ≥ 9 at step 2, age between 11 and 17 years old inclusive, biopsy-confirmed IBD, and English speaking. Exclusion criteria included current major depressive, dysthymic, bipolar, and/ or psychotic disorders by *DSM-IV* criteria; antidepressant medications within 2 weeks of assessment; substance abuse/dependence by history within 1 month of enrollment; suicide attempt within 1 month of enrollment; depression requiring psychiatric hospitalization; or failure of previous manual-based CBT of at least eight sessions. Major depression and dysthymic disorders were excluded for ethical reasons, given that the comparison group did not have therapist contact.

Assessments

Assessments were at baseline (T1) and within 2 weeks posttreatment (12–14 weeks; T2). They included self- and parentreport questionnaires plus clinician-rated measures. All of the assessments were administered to both groups by independent evaluators unaware of the participants' treatment condition. These evaluators had bachelor's degrees in psychology and were trained in the assessments (CGAS and K-SADS) before the study. Training consisted of observing four interviews and then administering four interviews under the supervision of a child and adolescent psychiatrist (E.S.). A second independent child and adolescent psychiatrist assessed 20% of the audiotaped K-SADS interviews for interrater reliability. Cohen's κ found acceptable interrater reliability for K-SADS depression diagnoses (1.00 at T1 and 0.79 at T2) and CGAS (0.90 at T1 and 0.94 at T2).

Measures

Psychiatric Diagnoses. The K-SADS-PL (parent and child version) was used to assess current and past psychiatric diagnoses based on the synthesis of information collected from interviewing the adolescent



Fig. 1 Recruitment flowchart for treating depression in children and adolescents with inflammatory bowel disease. CDI = Children's Depression Inventory; CDI-P = Children's Depression Inventory-parent report; PASCET-PI = Primary and Secondary Control Enhancement Therapy-Physical Illness.

and the parent, a method that has been shown to have good interrater reliability (Kaufman et al., 1997; Szigethy et al., 2004b).

Depressive Severity. The K-SADS-PL, CDI, and CDI-P were used to measure depressive severity. The CDI is a validated self-report measure of depressive severity (Kovacs, 1992). Parent and child responses were synthesized on both self-report and clinician-rated measures of depressive severity. The CDI and CDI-P scores were summed to yield a total CDI severity score (CDI-CP), which served as the primary measure of depressive severity (range 9–42). Also, the total number of syndromal depressive symptoms on the K-SADS-PL was recorded according to the synthesized child and parent report (number of K-SADS depressive symptoms). *Cognitive Processing.* The Perceived Control Scale for Children (PCSC), a 24-item self-report questionnaire, was used to assess children's beliefs in their ability to exert control over life events (Weisz et al., 1986, 1994). Scores on the PCSC have been found to show good internal consistency and test-retest reliability, to correlate with self-reported depressive symptoms, and to predict change in depressive symptoms (Weisz et al., 2001). The total score reflects perceived control over academic, social, and behavioral outcomes.

Global Functioning. The Children's Global Assessment Scale (CGAS) is a clinician-rated instrument of general adjustment and current level of impairment that was used as an indicator of global functioning (Shaffer et al., 1983).

IBD Severity. Two well-validated IBD severity scales were used: the Pediatric Crohn's Disease Activity Index (PCDAI; Hyams et al., 1991) for CD and the Clinical Score of Kozarek (Kozarek et al., 1989) for UC were used to measure illness severity. Both wellvalidated IBD scales are based on clinical information from the medical chart and provide continuous and ranked categorical disease severity ratings. Although both scales rate a combination of signs and symptoms (e.g., abdominal pain, diarrhea, well-being), the PCDAI also includes physical findings and laboratory values. Only the categorical rating system (inactive, mild, and moderate/ severe) was used because this allowed for pooling the CD and UC data. Categorical disease severity was scored by two independent physician raters who were blinded to treatment status for all of the participants. Interrater reliability scores were 0.87 at T1 and 0.97 at T2. Exogenous steroid use and dose at the time of the assessments were obtained from the medical record.

Randomization

Because the effect of treatment may differ for mild versus moderate subsyndromal depressive severity, randomization was stratified according to severity. Mild severity was indicated by fewer than two syndromal depressive symptoms on the K-SADS, whereas moderate severity was defined as two to four syndromal depressive symptoms (consistent with a *DSM-IV* research diagnosis of minor depression). At least one of the depressive symptoms had to be depressed mood, irritability, or anhedonia.

Intervention Procedures

Comparison Group. This group received TAU, as well as a written sheet for parents about the warning signs of major depression and available treatment options (AACAP, 2002). If worsening depressive symptoms were noted, then parents were asked to contact the first author so that appropriate psychiatric care could be facilitated.

PASCET-PI. The PASCET-PI consisted of nine modules (Table 1) delivered over 9 to 11 sixty-minute sessions. Each participant completed the same nine PASCET-PI skills training using a manual-based workbook. Some sessions were delivered by telephone, but no more than three sessions per participant. Face-to-face sessions were coordinated with medical visits and hospitalizations whenever possible. Individual sessions were supplemented by three independent parent sessions (beginning, middle, and end of treatment), designed to educate parents about IBD and depression as well as to teach them to become CBT coaches.

Besides targeting depression, PASCET-PI focused on teaching skills to improve cognitions and behaviors related to IBD. Therapists used the physical illness narrative to address cognitive distortions, taught relaxation and guided imagery for pain, worked to find behavioral motivators to improve medication adherence, and helped youths remain active and socially connected during IBD flares when medically feasible. These elements are integrated throughout the individual and parent sessions.

Six trained therapists delivered the PASCET-PI (child and adolescent psychiatrists, n = 2; child and adolescent psychologists, n = 2; clinical social workers, n = 2). Training of therapists included reading the PASCET-PI manual, participating in three half-days of didactic training, and being supervised weekly by the first author. (The treatment manual and PASCET-PI workbook are available from the first author.) Independent evaluators

PASCET-PI Training Modules Covered Over 9–11 Weekly Sessions

Module No.	Session Content
1	Education about CBT, IBD, and depression and
	eliciting child's physical illness narrative.
	Problem-solving skills applied to depression and
	IBD-related factors, including medication adherence.
2	Relaxation skills and self-hypnosis for abdominal pain.
3	Show positive self, especially when depressed or feeling
	physically ill.
4	Plan activities, including exercise, both alone and with others.
5	Practice existing talents or plan new ones.
6	Identify and modify negative cognitions about life and about IBD.
7	Alternative methods to identify and modify negative cognitions, including eliciting help from others and distraction with activities.
8	Plan a set of the above coping skills to address problems.
9	Predict problems in the future and reinforce plan to use coping skills and reassess physical illness narrative using new skills learned.

Note: PASCET-PI = Primary and Secondary Control Enhancement Therapy-Physical Illness; CBT = cognitive-behavioral therapy; IBD = inflammatory bowel disease.

consisting of undergraduate psychology students trained by the first author used the PASCET-PI Protocol Adherence Checklist (Szigethy et al., 2004b) to measure therapist fidelity to the CBT manual.

Statistical Analysis

t Tests and Fisher exact test were used to examine participant differences across hospital sites and groups. There were no differences between hospital sites on baseline depressive severity, IBD type, demographic characteristics (sex, age, percentage of minority), nonstarters (14/176 in Boston; 7/57 in Pittsburgh), or treatment dropouts (one participant in Pittsburgh; two participants in Boston). The results from the two hospitals were pooled because the randomization procedures and treatments were identical.

When participants had incomplete T2 assessments (missing child report, n = 1; missing CDI-CP and PCSC, n = 1), only available data were used. Analyses were conducted using independent-sample *t* tests to assess intergroup differences in pre- to posttreatment change for four primary outcome variables of this trial: CDI-CP (combined CDI and CDI-P scores), K-SADS depressive symptoms, PCSC, and CGAS. For the two cases in which attrition occurred, posttreatment data were collected at attrition and carried forward to be analyzed with the 14-week assessments. Cohen's *d* was calculated as an estimate of effect size. An overall *F* test of the pre- to posttreatment differences in the four measures was performed to control for type 1 error. With sample sizes of 22 and 19 in the two treatment groups, the power to detect moderate (0.5) or large (0.8) effects was 0.34 and 0.70, respectively, for a two-sided *t* test ($\alpha = .05$).

RESULTS

Sample Characteristics

Of the 168 participants eligible to participate in the step 1 screening, 156 (93%) agreed to be screened (mean age 14.29 years, SD 1.97). Sixty-five participants (51%) met criteria for step 2; 56 of these participants (84.1%) completed the step 2 assessment. Forty-one participants were randomized to either modified CBT (n = 22) or the comparison treatment (n = 19). Seven of 56 participants (12.5%) were excluded for major depression, and the remainder declined due to time or distance factors (n = 8). Of the 41 participants randomized, 10 qualified by CDI score alone (24.4%), 13 by CDI-P score alone (31.7%), and 18 by both (43.9%).

For the 41 participants randomized, mean age was 14.99 years (SD 2.01), with 51% female. Ethnic distribution was 78.1% white, 14.6% African American, 2.4% Hispanic, and 4.9% unspecified. The median annual family income was \$75,000 to \$90,000 with an income range of under \$15,000 (level 1) through >\$90,000 (level 6). Parents' level of education included some high school (7.5%), high school diploma (17.5%), some college education (15%), and 4 or more years of college (60%). There was no significant difference in gross income or parent education between the two sites.

At baseline, there was no difference between the two treatment groups in terms of age, sex, IBD type, IBD severity, or mean steroid dose (Table 2). At T2, 15.4% of the CBT group and 25% of the comparison group still had moderate/severe disease activity (N = 25). The change score of IBD severity between groups was not significant.

Treatment. The full content of the PASCET-PI was received by 19 (86.4%) of the adolescents. One participant (six sessions) dropped out due to loss of interest; one participant (four sessions) discontinued due to relocation and returned for the T2 assessment; and one participant (one session) stopped because she felt significantly better. There were no significant differences between these three PASCET-PI noncompleters and the 19 completers in terms of demographic variables or depressive severity.

Cohen's κ for therapist fidelity to the manual was .72. Excluding the participant who dropped out after one session, the therapists completed 80% of the

 TABLE 2

 Demographic and Sample Characteristics at Baseline

PAS	SCET-PI	Comparison	
(7.	ı = 22)	(n = 19)	p ^a
Age, y (SD) 14.9	5 (2.33)	15.02 (1.83)	91
Female, %	54.5	47.5	.44
African American, %	9.1	21.1	.26
Crohn disease, %	68.2	73.7	.49
Moderate/severe IBD 28.69	% (<i>n</i> = 21)	29.4% (<i>n</i> = 17)	.62
On steroids, %	50.0	42.9	.70
Mean dose, mg 9.8	9 (16.66)	11.18 (4.75)	.35
Comorbid diagnoses			
Specific phobia	3	1	N/A^b
Separation anxiety	0	1	
Generalized anxiety disorder	2	0	
Oppositional defiant disorder	3	0	
ADHD, inattentive type	0	3	

Note: PASCET-PI = Primary and Secondary Control Enhancement Therapy-Physical Illness; IBD = inflammatory bowel disease; ADHD = attention-deficit/hyperactivity disorder.

^{*a*} Fisher exact test for categorical variables and independentsample *t* tests for continuous variables.

^b Statistics were not completed due to small sample size.

mandatory therapy items. Of the total PASCET-PI sessions delivered, 38% were conducted by telephone. Mean time between T1 and T2 was 14.6 weeks (SD 5.4). There was no significant difference between treatment groups in time between T1 and T2.

PASCET-PI Efficacy. There were no significant differences between groups on baseline CDI-CP, number of K-SADS depressive symptoms, CGAS score, or PCSC score. The overall test of treatment effect as measured by the pre- to posttreatment changes in all four measures was significant ($F_{4,40} = 4.48$, p = .004). The PASCET-PI group showed a significant reduction in pre- to posttreatment CDI-CP, CGAS, and PCSC scores compared with the comparison group (Table 3). Only the PASCET-PI group had a significant positive change in overall PCSC score from T1 to T2. There were no significant differences between groups for number of K-SADS depressive symptoms.

Psychiatric Diagnoses. At T1 12 participants in PASCET-PI group and 10 participants in the comparison group had depressive symptom counts consistent with minor depression. At T2 in the PASCET-PI group, two participants had minor depression, whereas in the comparison group, two participants had minor depression and three had major depression.

Means for Primary Outcome Measures by Group									
	(CBT Group	Comparison Group						
Measure	n	Mean (SD)	n	Mean (SD)	t	р	Effect Size		
CDI-CP									
T1	22	25.7 (10.8)	19	21.8 (8.1)	1.30	.200			
T2	21	10.7 (8.0)	19	16.7 (11.1)	1.97	.056	0.62		
T2-T1	21	-15.0 (7.9)	19	-5.1 (11.6)	3.18	.003	1.01		
No. of K-SA	DS sym	ptoms							
T1	22	2.3 (1.8)	19	2.3 (1.2)	0.09	.929			
T2	21	1.0 (1.2)	19	2.4 (2.3)	2.41	.021	0.76		
T2-T1	21	-1.4 (2.0)	19	-0.1 (2.6)	1.98	.055	0.63		
CGAS									
T1	22	61.8 (5.0)	19	62.4 (4.4)	0.44	.663			
T2	21	69.9 (6.7)	19	62.8 (8.9)	2.84	.007	0.90		
T2-T1	21	7.8 (7.2)	19	0.9 (8.8)	2.72	.010	0.86		
PCSC									
T1	20	58.4 (10.00)	19	59.1 (8.9)	0.25	.805			
T2	20	63.3 (6.5)	18	54.7 (14.6)	2.30	.031	0.77		
T2-T1	20	4.8 (9.4)	18	-4.4 (15.8)	2.13	.042	0.71		

 TABLE 3

 Means for Primary Ourcome Measures by Gr

Note: CBT = cognitive-behavioral therapy; CDI-CP = Children's Depression Inventory-child/ parent report; T1 = baseline; T2 = 12–14 weeks posttreatment; K-SADS = Schedule for Affective Disorders and Schizophrenia for School-Age Children; CGAS = Children's Global Assessment Scale; PCSC = Perceived Control Scale for Children.

At T1 comorbid DSM-IV psychiatric diagnoses included specific phobia (n = 4), generalized anxiety disorder (n = 2), oppositional defiant disorder (n = 3), attention deficit-hyperactivity disorder, inattentive type (n = 3), and separation anxiety (n = 1). At T2 comorbid psychiatric diagnoses included specific phobia (n = 2; one per group); ADHD (n = 3; all in the comparison group); and obsessive-compulsive disorder (n = 1 incomparison group). In the PASCET-PI group 30% of youths with pretreatment specific phobia and 100% with generalized anxiety disorder and oppositional defiant disorder no longer met diagnostic criteria for these disorders at T2. In the comparison group one participant with specific phobia no longer met criteria at T2, and one participant manifested obsessivecompulsive disorder at T2.

DISCUSSION

These findings demonstrate the feasibility and preliminary efficacy of a manual-based CBT intervention in reducing depressive symptoms and improving functioning in adolescents with IBD. These results are consistent with earlier findings in an open trial of PASCET-PI with clinically depressed adolescents with IBD (Szigethy et al., 2004b). This study furthers these results by showing that PASCET-PI effects could not be attributed alone to the passage of time.

Participants in the PASCET-PI group showed statistical and clinically significant improvement relative to the comparison group. Depressive severity was reduced by 40%, and global functioning improved from moderate to mild levels of impairment. The effect sizes obtained were similar to those achieved in other studies of CBT for depressed, physically healthy adolescents that used inactive comparison arms (Weisz et al., 2006). The effects of PASCET-PI may have been even greater if youths with major depression had been included.

The comparison group in this study controlled for the passage of time as well as the time and attention involved in the pre- and posttreatment assessments. A pure TAU condition (without giving parents written information about depression) would have been preferable as a comparison group, given that this was the first randomized trial assessing the PASCET-PI efficacy. However, the institutional review boards did not find it ethical to screen for and identify depression in a previously undiagnosed cohort without offering an intervention, even with participants with major depression being excluded. Thus, a minimally interactive intervention involving a written sheet was determined to be the least active compromise because it did not involve any therapist interactions.

Our findings suggest the feasibility of screening for depressive symptoms in a tertiary pediatric clinic for youths with physical illnesses. This was accomplished at two sites with modest refusal rates initially and low attrition over the course of the intervention. The study focused on adolescents with subsyndromal depression, not only because of the documented functional impairment found with depressive symptoms but also because youths with depressive symptoms are at risk for developing major depression (Gonzalez-Tejera et al., 2005). The present study also demonstrated the viability of providing psychosocial treatments in this setting by a diverse group of behavioral health providers. It should be noted that more than one third of the CBT sessions were offered by telephone as part of the comprehensive PASCET-PI treatment of depression in this physically ill population. Regardless, our intervention showed promising efficacy, suggesting the need for advocacy for coverage of telephone sessions with managed care and/or Medicaid entities, if these types of treatments are to be available in clinical settings.

The PASCET-PI group showed significant improvement in self-reported perceived control over the comparison group. This is a cognitive process that is hypothesized to mediate depressive severity in nonphysically ill youths (Hammen and Goodman-Brown, 1990; Weisz et al., 1986, 2001). It is reasonable to hypothesize that perceived lack of control may contribute to feelings of depression and teaching reappraisal, as the PASCET-PI model does, can reduce depression and possibly induce feelings of optimism and hope (Folkman, 1984; Rothbaum et al., 1982). Future studies with adequate sample sizes are needed to address whether changes in cognitive processes lead to fewer symptoms of depression.

One important application of the CBT skills in this study is helping adolescents accept the uncontrollable elements of having a chronic physical illness and being more active in the controllable elements (e.g., adhering to medication, staying active). This was achieved by inviting CBT participants to share their physical illness narratives (e.g., What do you think caused your illness? How has it affected your life?). PASCET-PI coping skills were used to help youths reconstruct unrealistic, negative, and/or helpless narratives and formulate more accepting, realistic narratives. Previous studies have shown that sharing illness narratives resulted in decreasing social isolation and fostering positive reactions in youths with other pediatric illnesses (DeMaso et al., 2000). Similarly, adults with physical illness who wrote about their distressing experiences reaped multiple health benefits (Pennebaker, 1990; Smyth et al., 1999). These data suggest that including an emphasis on individual physical illness narratives may enhance the applicability of CBT by providing a framework to organize the skills taught. Future work is needed to ascertain whether inclusion of the physical illness narratives within the PASCET-PI program mediates changes in depression, functioning, and quality of life.

The PASCET-PI protocol included three parent sessions. It is not clear how much these parent sessions contributed to the efficacy of the intervention, although previous studies have shown that family-based therapy can improve family climate and depressive symptoms in children and adolescents (Beardslee et al., 1993; Diamond and Josephson, 2002). Parental psychoeducation has also been shown to be important in treating depressed adolescents by helping families identify affect and deal with stigmatization. It also helps to decrease noncompliance, psychosocial deficits, and resistance to the concept of illness (Beardslee et al., 1997; Brent et al., 1993). It will be important to examine in future studies how much these family sessions contribute to the success of the individual therapy part of the intervention.

Approximately 17% of the sample randomized had a comorbid anxiety disorder. Many studies also report high rates of anxiety disorders in youths with IBD, although the rates vary considerably from 11% to 73% due to methodological differences and small samples of children and adolescents (Burke et al., 1989; Engstrom, 1999; Steinhausen and Kies, 1982; Szajnberg et al., 1993). Although the study design in the current research did not stratify randomization in terms of anxiety diagnoses or severity, the reduction of anxiety disorders in the PASCET-PI group warrants further study, particularly given the high comorbidity of anxiety disorders with depression. To date, there are no studies simultaneously assessing the effects of CBT on both depression and anxiety in physically ill

pediatric samples, but it is reasonable to speculate that teaching more realistic perceived control and new coping skills would also improve anxiety.

The modest sample size, in conjunction with heterogeneity in IBD type, disease severity, and steroid status, made it difficult to assess the effects of treatment on disease factors and the contribution of disease factors to behavioral improvement, if any. Carefully designed studies assessing the effects of depression and its treatment on IBD-related factors (e.g., disease course, medical adherence, quality of life) would be an important next step to understand these interactions; however, such studies would need to carefully control for medical and surgical treatment of IBD.

Limitations

This study had several additional limitations. First, the comparison group was not an adequate time and attention control for PASCET-PI; thus, conclusions are limited regarding whether the improvements seen can be attributed to PASCET-PI. Because the comparison group did not participate in a therapeutic relationship, it cannot be ruled out that nonspecific therapy factors (e.g., therapeutic alliance, time spent with the therapist, therapist attention) and not the proposed active ingredients of CBT, may have been responsible for treatment effects in the PASCET-PI group. Also, the present study design does not allow for determination of specific variables or therapy components that may have invoked therapeutic effects in the PASCET-PI group. Second, this modest randomized trial was underpowered, particularly to detect interaction effects (time x treatment) and mediation. Multisite longitudinal studies capable of providing adequate sample size will be necessary to answer these types of questions. Because this study used a small sample size and focused on a priori hypothesis-driven tests using four primary outcome measures, no corrections to control type I error were used. The decision was made to err on the side of detecting versus not detecting a difference in treatment effect in this exploratory study. Third, differences in expectancies between participants in the two treatment groups could also account for differences in self-reported outcomes. In addition, even though evaluators were blinded, their expectancies were not measured and could also lead to bias. Fourth, the K-SADS was administered by bachelor's degree-level interviewers without standardized training in clinical

child psychopathology. They did, however, undergo extensive study training and were carefully supervised by child and adolescent psychiatrists. Finally, because our sample was a nonreferred clinical sample with mild to moderate subsyndromal depression, our results cannot be generalized for treatment of more severe depression.

Clinical Implications

These findings suggest the feasibility of screening for depressive symptoms in a tertiary pediatric clinic for youths with physical illnesses and the viability of providing psychosocial treatments in this setting. The study also indicates the importance for child and adolescent psychiatrists and other mental health professionals to develop relationships with pediatric providers to effectively integrate physical health and psychiatric care. This study demonstrated that this modified CBT intervention was more effective than no treatment and also showed flexibility in delivery across a broad range of therapists. The results may have implications for other populations of youths who have physical illnesses with characteristics similar to those of IBD, such as chronic pain, disease-related impairments, unpredictable disease course, and complicated medical treatments (e.g., juvenile rheumatoid arthritis, sickle cell disease). Larger scale studies will be needed to determine the efficacy of PASCET-PI longitudinally, how it compares to other active treatments in this pediatric population, and the impact of behavioral treatments on the physical health of children with chronic illness.

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