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Effects of a cognitive behavioral therapy intervention trial to improve disease outcomes in children with Inflammatory Bowel Disease

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Abstract

Background—Studies testing the efficacy of behavioral interventions to modify psychosocial sequelae of IBD in children are limited. This report presents outcomes through a six month follow up from a large RCT testing the efficacy of a cognitive-behavioral intervention for children with IBD and their parents.

Methods—185 children age 8-17 years with a diagnosis of Crohn's (CD) or Ulcerative Colitis (UC) and their parents were randomized to one of two 3-session conditions: 1.) a social learning and cognitive-behavioral therapy condition (SLCBT) or 2.) an education support condition designed to control for time and attention.

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Conflicts of Interest
None declared

Results—There was a significant overall treatment effect for school absences due to CD or UC ($p<.05$) at 6 months post-treatment. There was also a significant overall effect post-treatment for child-reported quality of life ($p<.05$), parent- reported increases in adaptive child coping ($p<.001$) and reductions in parents' maladaptive responses to children's symptoms ($p<.05$). Finally, exploratory analyses indicated that for children with a higher level of flares (2 or more) pre-baseline, those in SLCBT experienced a greater reduction in flares post-treatment.

Conclusions—This trial suggests that a brief cognitive-behavioral intervention for children with IBD and their parents can result in improved child functioning and quality of life, and for some children may decrease disease activity.

Keywords

Inflammatory Bowel Disease; Crohn's Disease; Ulcerative Colitis; Pediatric Gastroenterology; Quality of Life

INTRODUCTION

Inflammatory Bowel Disease (IBD) is a serious medical condition that has broad adverse health implications and is being seen with increasing frequency among children.[1-3] IBD usually refers to two disorders: Crohn's disease (CD) and ulcerative colitis (UC). Both conditions are diagnosed after positive medical findings have determined chronic inflammation in the gastrointestinal tract. IBD can lead to increased rates of missed school or work, medical costs, hospitalizations, surgery, and even death.[4,5] Although IBD is not believed to have a psychosocial origin, a number of studies have identified psychosocial variables associated with the disease,[6-8] some of which clearly have the potential for significantly affecting the quality of life of IBD patients.[9-11] Comparing children with IBD to matched controls, researchers have found more anxiety, depression, social functioning (inter-personal interactions in social situations) problems and family dysfunction in those with IBD.[7] Many studies have found depression in particular is increased in youth with IBD compared to controls[7] and parents of children with IBD also show increased levels of depression.[12]

Considerable research has found an association between psychosocial factors, most notably anxiety and/or depression as well as maladaptive coping, and IBD symptoms and symptom severity in children with IBD.[7,13-17] Typical of these, recently Reigada et al.[18] found that anxiety symptoms were significantly associated with moderate/severe disease activity among children and adolescents with CD. Similarly, Srinath et al.[19] found that depression was a significant predictor of abdominal pain in children and adolescents with IBD, perhaps more so in UC than in CD. Reed-Knight et al[20] also found that higher ratings of disease severity were related to greater depressive symptoms in youth with IBD. Finally, how children cope with IBD has also been found to be associated with physical symptoms, quality of life and disability.[14] Catastrophizing (the tendency to describe an experience or the likely outcome of the experience in exaggerated negative terms) in particular has been found to be associated with negative outcomes such as disability and depression in youth with IBD.[21,22]

Studies testing the efficacy of interventions to modify these psychosocial factors have been limited. In one small trial (n=22), cognitive behavioral therapy (CBT) was shown to reduce depression in youth with IBD; the CBT group was compared to treatment as usual,[23] rather than a condition that controlled for time and attention. Content for this intervention was delivered on nine modules during 9 to 11 sixty-minute sessions. A 2014 study by the same group included 178 depressed youth age 9-17 with active IBD who received 3 months of either CBT (teaching coping skills) or supportive nondirective therapy (SNDT; empathic listening and reflecting by the therapist in response to content raised by the patient).[24] The intervention was a 12-session intervention spanning three months. Results showed significantly greater reduction in disease activity for the CBT group vs. the SNDT group. Although there were significant reductions in depressive symptoms overall, group differences were not significant. A secondary analysis of these data with a subsample of adolescents with CD found significantly greater reductions in both depressive symptoms and disease activity for the CBT group vs. the SNDT group after excluding those taking steroids.[25] However, there were some limitations of these studies, most notably the inclusion of only depressed participants and the absence of any follow-up period, as outcome data were only obtained immediately following treatment. Additionally, these interventions, while consistent with traditional CBT approaches for depression which are typically 8-15 sessions long, may not be practical in many clinical settings, or necessarily applicable to interventions aimed at coping with health problems such as IBD.

The present randomized controlled study tested the efficacy of a brief CBT intervention on reducing the negative impact of IBD on children's lives. The intervention was designed as an adaptation for IBD of a three session cognitive behavioral intervention that was previously shown to be effective in reducing symptoms and disability in children with unexplained abdominal pain.[26,27] This prior study targeted reductions in parent solicitousness and increases in children's adaptive pain coping efficacy beliefs and use of adaptive coping strategies. The current study focused on the same targets, but modified the intervention content to include coping with IBD as well as parent and child responses specifically to IBD symptoms, rather than idiopathic abdominal pain. Thus, in the present study we sought to demonstrate reductions in parent solicitousness and increases in children's adaptive pain coping efficacy beliefs and use of adaptive coping strategies for families receiving the CBT intervention, relative to a comparison condition. We also predicted that, as a result of training in children and parents in coping and adaptive responses to illness, children in the CBT group would be less likely to miss school or other activities due to illness-related concerns, thus showing greater improvements in quality of life, and reductions in disability, health care utilization and school absenteeism. Although our intervention was not specifically designed to reduce anxiety or depression, we included depression and anxiety as secondary outcome variables given the association between cognitive factors and anxiety/depression symptoms. Addressing the methodological limitations of prior CBT studies in IBD, the current intervention was aimed at children and their parents and included follow-up assessments through one year post intervention.

MATERIALS AND METHODS

Study Design

The study design was prospective, randomized, and longitudinal. The treatment and comparison conditions each included three sessions that were approximately one week apart (mean = 9.36 days, SD = 4.54). The study was approved by the institutional review boards at each site. The study was registered with ClinicalTrials.gov as study number NCT00679003.

Participants

Participants included 185 children, age 8–17 years, with a diagnosis of Crohn's or Ulcerative Colitis (UC) at least three months post-diagnosis, and their parents. Pediatric gastroenterology collaborators recommended the three month time since diagnosis to allow for initial medical treatment adjustment. Families were recruited over a 4 1/2-year period from 2008–2012 through physician referral from the pediatric GI clinics at Seattle Children's Hospital and Mary Bridge Children's Hospital in Tacoma WA. All interested participants were screened for eligibility by the physician co-investigator in the respective GI clinic. Parents gave informed consent, and children gave assent before commencement of research procedures.

Inclusion criteria were as follows: (i) child age 8–17 years, (ii) child received a diagnosis of Crohn's or UC and was at least three months post-diagnosis, (iii) child lived with the participating parent or caregiver for at least the last 3 months, (iv) child and parent were willing and able to complete the questionnaires and agreed to participate in the intervention and follow-up evaluations, and (v) child was medically approved to engage in normal activities (e.g., attend school, extracurricular activities). Exclusion criteria were as follows: (i) a chronic disease other than IBD (e.g., pancreatitis, diabetes, epilepsy), (ii) major surgery within the past year unrelated to IBD, (iii) developmental disabilities requiring full-time special education or impairing ability to communicate, and (vi) non-English speaking.

Randomization and assignment

Participants were enrolled by a researcher at the recruitment site prior to baseline assessment and randomization. Randomization was then performed by a different researcher using a computerized random-number generator, stratifying by age (7-11 or 12-18 years old) and then by physician-reported disease severity (quiescent, mild, or moderate/severe based on either the Pediatric Ulcerative Colitis Activity Index-PUCAI for UC patients or the Pediatric Crohn's Disease Activity Index-PCDAI for Crohn's patients) completed during enrollment. Randomization did not occur until baseline assessments for both children and parents were completed. Participants were blind to their group assignment, and were told that they would be randomly assigned to one of two treatment groups, and that the topics they would discuss would vary depending on the group to which they were assigned. They were not informed which condition was the treatment versus control condition.

Condition structure

Participants in both conditions continued with their regular medical care as recommended by their health-care team. Following baseline assessment and randomization, all participants

met with a trained therapist (Master's degree or higher) for three sessions spaced approximately 1 week apart (mean time spread from session 1 to session 3 = 18.6 days, SD = 6.6). Study therapists were trained in and administered both interventions. Participant families in both conditions had the choice of having these sessions either in the hospital clinic (35.7% of the sample) or, for convenience, their homes (64.3%).The mean session length was 70.68 minutes (SD = 14.31). In both treatment conditions, parents and children participated in the sessions together. At the end of the session, the therapist met separately with the child (5 minutes) and the parent (5 minutes) to discuss any topics they might have felt uncomfortable discussing in each other's presence, reiterate the importance of data collection and completing homework assignments, and role playing as time allowed. The participating parent was encouraged to share what was discussed as well as the handouts with the non-participating parent. Between sessions, parents and children in both conditions were asked to complete homework assignments related to the content of his/her respective treatment condition. A total of 89.5% of SLCBT participants and 87.1% of ES participants completed between-session homework packets.

Experimental Conditions

Social learning and cognitive-behavioral therapy conditions (SLCBT)—The SLCBT treatment condition is a form of CBT based on two principles derived from previous research: (i) consistent with social learning theory[28] parents who respond solicitously to the child's illness reports and parents who report GI symptoms themselves (i.e., who may model illness behavior) tend to have children with more GI symptoms,[29] and (ii) beliefs about the significance of symptoms, perceptions of one's pain coping efficacy, and the type of coping strategies used to manage them may influence symptom and disability reports.[30-34] Over the course of three sessions, parents and children were taught to think about and cope with symptoms in ways that encouraged wellness, rather than illness behavior. Specifically, for both parents and children, this included instruction in cognitive-behavioral coping strategies of relaxation, stress management, and cognitive techniques (e.g., examining and altering self-talk). Cognitive strategies presented and practiced included identifying and changing maladaptive cognitions such as catastrophizing. Parents also received training to differentially attend to and reinforce wellness behaviors, rather than respond solicitously to illness behaviors, which could potentially reinforce them. Active skill practice in-session and identification and assignment of skills learned during the session to practice between sessions occurred throughout the intervention phase.

Education Support Comparison Condition (ES)—The use of an education-based control group is a standard control comparison in trials of CBT.[35,36] Our ES condition consisted of educational content focused on the gastrointestinal system, food labels, and nutrition. The ES condition controlled for therapist and patient time and attention and was designed to provide a credible comparison condition without including content specific to the SLCBT intervention as outlined above. Parents and children in the ES condition met with the therapist for three sessions approximately equal in timing to the SLCBT condition. Therapists were instructed to not endorse any specific food or diet recommendations.

Condition comparability and treatment fidelity—To assess the comparability of the treatment arms on measures of treatment participation, we measured the number of sessions completed by participants. 93.4% and 89.4% of participants completed the three sessions of the SLCBT and ES interventions, respectively (p = .45). To assess comparability of participant expectations about the two conditions, both parents and children were asked to rate their beliefs about the intervention with questions about how logical this type of therapy seemed. This scale was then mailed back to the study office in a sealed stamped envelope and thus not seen by the therapist. There were no significant differences between groups on participant ratings of the credibility of the intervention (p = .42).

Fidelity to the protocols associated with each condition was assessed by experienced intervention trainers who listened to audiotapes of at least one session for 23% of the cases who completed treatment. These sessions were scored to determine whether the therapist had included the appropriate elements for that treatment condition. Sessions were sampled from each therapist, and were selected within therapists on a random basis. Treatment fidelity was assessed on 38 cases (102 separate sessions) and was found to be at 96.86% of elements included on average for SLCBT, and 100% for ES (NS).

Data Collection Procedures

Assessment data were collected at baseline (T1), 1 week post-treatment (T2) and at follow-up evaluations conducted three, six, and 12 months post-treatment (T3-5). Physicians completed disease severity measures at baseline and during enrollment. At all assessment points, parents completed questionnaires online or by mail (whichever modality they preferred). Children completed assessments through a scheduled telephone call with a highly trained research nurse who was blinded to the participant's treatment assignment. Appointments for assessments were scheduled in advance, and answer keys were mailed to children before the calls. Answer keys guided children through the questions and response options, aiding administration.

Measures

Child and parent demographics and child medical history were completed by parents.

Process Variables

Parent Report only: Parental response to pain behavior was measured using the 13-item Protect subscale of the Adults' Responses to Children's Symptoms (ARCS).[37,38] Sample items of this measure which asses constructs such as parent reinforcement of illness behavior include, "When your child has a stomachache or other GI symptoms, how often do you bring him/her special treats or little gifts?" or "...let him/her stay home from school?" Ratings are made on a 0–4 scale, with higher values indicative of greater solicitousness. Parents completed the items with respect to themselves.

Parent and Child Report: Child catastrophizing and pain coping skills were measured using the Pain Response Inventory (PRI).[39,40] The Pain Response Inventory assesses child responses to pain. For the present study the item stems were slightly modified to include other GI symptoms as well (i.e., "when you have a stomachache or other stomach problems,

how often do you...” for child report and “when your child has a stomachache or other GI problems, how often does he/she...” for parent report). This inventory includes multiple subscales, but the ones targeted by the SLCBT intervention and analyzed in this study were the Catastrophizing and Distract/Ignore scales. The catastrophizing subscale contains 5 items such as, “When you have a stomachache or other stomach problems, how often do you think to yourself that you might be really sick?” This Distract/Ignore subscale contains 5 items such as, “When you have a stomachache or other stomach problems, how often do you do something you enjoy so you won't think about it?” Items are rated on a 0–4 scale, with higher values indicative of greater catastrophizing or greater distract/ignore responses. Parents completed the items with respect to their child and children completed the items with respect to themselves.

Pain beliefs and coping were assessed using the Pain Beliefs Questionnaire (PBQ).[39,41] The Pain Threat subscale with 20 items assesses the perceived duration, frequency, and seriousness of the abdominal pain condition, as well as the intensity and duration of individual pain episodes. For the present study, to more broadly assess the impact of IBD symptoms, we slightly modified items to refer to IBD symptoms (parent questionnaire- i.e., “my child's IBD symptoms hurt a whole lot”) or stomach problems (child questionnaire- i.e., “I get stomach problems all the time”) instead of stomach aches (as noted in the original questionnaire). Two additional subscales assess Emotion-focused Coping Efficacy (items such as, “I know I can handle it no matter how bad my stomach problems are”) and Problem-focused Coping Efficacy (6 items such as, “When I have bad stomach problems, I can find ways to feel better”). Items are rated on a 0-4 scale with higher values indicative of greater pain threat. Children completed the items with respect to themselves, and parents completed the items with respect to their child.

Outcome Variables

Parent report only: Health care utilization was assessed by asking parents to retrospectively report the number of hospital stays and the number of visits to a health care provider (medical doctor/nurse practitioner/physician assistant) their child had for Crohn's or UC. The time frame for these reports were the prior 12 months at baseline, the prior three months at the 3- and 6-month assessments, and in the prior 6 months at 1 year follow up.

School attendance was measured by asking the parent to report on the number of days the child missed school (or other activities such as camp or sports when school was not in session) because of stomachaches or other GI symptoms. The time frames for these reports were the previous 3 months at baseline, 3- and 6-month assessments, and the previous 6 months at 1 year follow up.

Child report only: IBD-specific quality of life (QOL) was assessed using the IMPACT-III,[42] a self-report measure that includes 35 items across six domains: Bowel Symptoms (7 items), Systemic Symptoms (3 items), Social Functioning (12 items), Body Image (3 items), Treatment/Interventions (3 items), and Emotional Functioning (7 items). We utilized a slightly modified version of 33 items suggested by Otley et al.[42] and Perrin et al.[43] Items are

scored on a 5-point Likert Scale. For the purposes of this study we only utilized the total score, which can range from 33 to 175, with higher scores indicating better QOL.

Children's depressive symptoms were measured using the Child Depression Inventory (CDI).[44,45] The CDI is a valid and reliable self-report measure of children's depressive symptoms.[46] It contains 27 self-report items representing depressive symptoms that are rated on a 3-point scale, although we omitted the single item designed to assess suicidal ideation given that depression was not the focus of the study and we were concerned about administering this question to young children using a telephone format. Higher scores indicate greater depressive symptoms. Total scores are computed by taking the sum of the items.

Children's anxiety was measured using the Multidimensional Anxiety Scale for Children (MASC)[47] which provides a reliable and valid assessment of anxiety symptoms across clinically important symptom domains including social anxiety, harm avoidance, separation/ panic, and physical symptoms. The MASC is a 39-item self-report measure which yields the aforementioned subscale scores, a total anxiety score and an anxiety disorders index. The present study utilized the latter, which has a sensitivity of 83%, a specificity of 92%, an overall correct classification rate of 88%, and a kappa was .75. Higher scores indicate greater anxiety. Total scores are computed by taking the sum of the items.

Parent and child report: General activity limitations were measured using the Functional Disability Inventory (FDI).[48] The FDI assesses difficulty in physical and psychosocial functioning as it relates to a child's physical health. The scale contains 15 items rated on a 0-4 scale that ask about difficulty doing regular activities (e.g., walking up stairs, doing chores, watching television). A total score is derived by summing responses to all items. Higher scores indicate greater disability. Children completed the items with respect to themselves, and parents completed the items with respect to their child.

Disease information

Physician Report: Crohn's-disease activity was assessed at baseline using the Pediatric Crohn's Disease Activity Index (PCDAI).[49] The PCDAI has been well documented as a valid, reliable, and feasible instrument to measure disease activity in children with Crohn's disease.[50] Physicians document abdominal pain severity, stool frequency and consistency, and general patient functioning using a 1 week recall period. The most recent laboratory values for hematocrit (HCT %), erythrocyte sedimentation rate (ESR mm/hr), and albumin (g/dL) are also noted, as well as examination findings (including recent weight gain/loss, height, abdominal tenderness, perirectal disease, and extra-intestinal manifestations). Scores can range from 0 to 100, with higher scores indicating more disease activity. Compared to the adult version of the Crohn's Disease Activity Index, the PCDAI is better able to distinguish among quiescent (score of 0-10), mild (score of 12.5-30), and moderate/severe (score ≥30) levels of disease activity.[51] It has also been found to be sensitive to short-term change.[52]

UC-disease activity was also assessed at baseline using the Pediatric Ulcerative Colitis Activity Index (PUCAI).[53] The PUCAI has been shown to be valid, reliable, and responsive

in the assessment of UC disease activity. Scores can range from 0-85, with scores < 10 indicative of remission (quiescent), 10-34 indicating mild disease, 35-64 indicating moderate disease, and 65-85 indicating severe disease.

Flare counts were collected on a subset of patients for which the data were available retrospectively at baseline (for the 12 months pre-consent) and then prospectively for the 15 months post-treatment by checking medical records for an indication of a flare. Flares were determined either by physician records specifically stating the occurrence of a flare and/or, for Crohn's patients, a PCDAI score of 11+, and for UC patients a PUCAI score of 10+.

IBD-specific medical information was collected using a physician measure that included items from the Paris Classification,[54] an evidence-based consensus classification system for pediatric IBD which defines IBD phenotypes. Data were collected at baseline on disease location (rectal [proctitis], left-sided colitis, or entire colon [pan colitis] for subjects with UC and small intestine only [ileitis], small and large intestine [ileocolitis] or large intestine only [colitis] for subjects with CD), the presence of other medical problems (anal, rectal, or vaginal problems such as fissure, fistula, or abscesses), and also indicated if the child was taking daily steroid or pain medications.

Data analysis

Linear mixed-effects regression models were used to compare treatment conditions on the change from baseline for outcome and process measures, adjusting for the two factors used to stratify the treatment randomization (child age and disease severity), and also adjusting for child gender, disease condition (UC or CD), study site, assessment time point (1 week, 3, 6 or 12 months post-treatment) and baseline level of the dependent variable. Linear mixed-effects models allow for specification of a covariance structure that accounts for the within-subject correlation over time.[55] Separate models were estimated for each measure and all models included an interaction between time and treatment condition to estimate the change from baseline for each assessment time and treatment condition. An omnibus test for all post-treatment assessment periods (df = 3) was performed to evaluate an overall effect of the intervention (SLCBT vs. ES), followed by separate significance tests for each post-treatment period. In addition, separate omnibus tests by treatment condition were performed to evaluate overall change from baseline for each treatment condition for all post-treatment periods (df = 3), followed by separate significance tests for each post-treatment period. Bonferroni-Holm post-hoc tests were used to account for multiple comparisons due to the three post-treatments assessments. In addition, 95% confidence intervals are reported for the change from baseline and difference between treatments, and Cohen's d is reported as a measure of the effect size based on the 12-month post-treatment.

Multiple imputation procedures were used to account for missing assessments, and to derive intervention effect estimates consistent with the intention-to-treat (ITT) principle, where all randomized subjects were included in the analyses including those who did not complete treatment. Baseline and follow-up values of the outcome or process measures, and the other covariates included in each model were used in the imputation of the missing values. A set of 10 multiple imputed datasets was generated using Markov chain Monte Carlo estimation,

and the results carried out for each dataset were combined using Rubin's rules to adjust the standard errors for the uncertainty about imputed values.[56,57]

Due to the skewed distributions for the number of health care visits and missed school days, additional analyses using log-linear regression models were conducted to compare these count outcomes over time. Generalized estimating equations (GEE) were used to fit the log-linear models with robust standard error estimates that take into account the within-subject correlation over time.[58] Similar to Poisson regression for count data, the log-linear model is used to estimate adjusted rate ratios (time frame in this analysis used a log link function to model the mean number of health care visits and missed school days as a function of treatment condition and time). A Poisson marginal variance was used in the fitting procedure, but the GEE method does not require the distribution of the outcomes to have a particular parametric form (e.g., a Poisson distribution). An omnibus test for all post-treatment assessment periods (df = 3) was performed to evaluate an overall effect of the intervention (SCLBT vs. ES), followed by separate significance tests for each post-treatment period. Statistical analyses were conducted using SAS statistical software, version 9.3 (SAS Institute, Inc.).

Power

A sample size of 65 participants per condition was determined to have 80% power to detect differences as small as those observed in health care utilization, parental response (ARCS), and pediatric quality of life in our prior study of SLCBT in children with functional abdominal pain at a two-sided 0.05 significance level. To account for attrition and larger variability in IBD than functional abdominal pain patients at least 90 participants were recruited per condition.

ETHICAL CONSIDERATIONS

The study was conducted with the approval of institutional review boards at each site and in accordance with the ethical principles outlined in the Declaration of Helsinki. All participants provided informed consent (parents) and assent (children) at the time of enrollment.

RESULTS

Figure 1 illustrates the disposition of all participants at all stages of the study. 91 participants were randomly assigned to the SLCBT condition and 94 were assigned to the ES condition with over 89% completing all three treatment sessions and one or more follow-ups. Session and follow-up completion rates did not differ by treatment condition, p = .45 and p = .85, respectively.

Sample Characteristics

See Table 1 for complete baseline characteristics of the total sample and the samples for each condition. 90.3% of the participating parents and 47.0% of the children were female. The mean ages were 44.4 (SD=6.9) years for parents and 13.5 (SD=2.7) for children. 87.1% of the parents and 77.9% of the children identified as Caucasian. 68.6% of the sample had a

diagnosis of Crohn's Disease (CD). 63.0% of all patients' disease severity was categorized as quiescent, 28.8% mild, and 8.2% moderate to severe. Parent-report and self-report ratings of pain severity were not included in our analyses due to low baseline pain severity scores in our sample. Parents in the ES condition reported their child had more health care visits in the prior 12 months to baseline for CD or UC (7.1 SLCBT vs 11.5 ES, p = .01; Table 2), but all other comparisons between groups revealed no significant differences in sample characteristics at baseline (Table 1). There were also no significant differences in any parent or child-reported measures for either condition based on whether the treatment sessions were delivered at home or in a clinic setting. As medication usage for steroids and pain medications was captured only at baseline, and other medications were reported at baseline as being used by a very small number of participants, we did not conduct any further analyses using these data.

Process Variables

There was a significant overall treatment effect for several of the process variables, as reported by parents and children, with parents and children in the SLCBT condition showing greater improvement, as predicted, than those in the ES condition (Table 3). Consistent with our prior studies[26,27], parents in the SLCBT condition reported significantly greater reductions in solicitousness compared to parents in the ES condition overall (p = .02), and maintained a small to moderate treatment effect size at 12 months post-treatment compared to the ES condition. Parents in the SLCBT condition reported a significant increase in child coping by distraction/ignoring over time (p = .001), with the largest increase observed 1-week after treatment. Parents in the SLCBT condition also reported significant increases in child problem-focused coping over time. In contrast, parents in the ES condition reported little change over time in child use of distraction/ignoring and child problem-focused coping. The results also indicated significantly greater reduction in parent-reported child catastrophizing one week after treatment in the SCLBT condition as compared to the ES condition.

Children in the SLCBT condition reported a significant decrease in catastrophizing over time (p = .01), whereas children in the ES condition had little evidence of change over time (p = .64). Similar to the parents, children in the SLCBT condition reported a significant increase in their use of distraction/ignoring over time (p = .03), whereas children in the ES condition did not (p = .49). Children in the both conditions reported an increase in problem-focused coping over time.

Outcome Variables

Results for the outcome variables are reported in Tables 4-5. There was a significant overall treatment effect for child-reported IBD-specific quality of life (Table 4; p = .04) and parent-reported number of missed school days due to Crohn's disease or ulcerative colitis (Table 5; p = .02). Children in both conditions reported improved IBD-specific quality of life over time, but children in the SLCBT condition reported significantly greater improvement by 1-week post treatment (Table 4). Children in both conditions also reported less depression over time. Parents in the SLCBT condition reported fewer health care visits and missed school days for Crohn's disease or ulcerative colitis at 6 and 12 months post-treatment, but the

treatment difference was statistically significant ($p < .05$) only at 6 months post-treatment for the number of missed school days (Table 5). The number of hospital stays post-treatment was not compared between the conditions, because only 15 of the children had a hospital stay post-treatment. There was improvement over time for several other outcome variables, but the improvement was similar between the two conditions.

Data on flare counts were available for 56 children in the SLCBT condition and 60 in the ES condition. The average number of months of assessment for flares prior to baseline was similar between the SLCBT and ES conditions (mean (SD) = 14.0 (1.3) versus 14.0 (1.3) months; $p = .89$), as well as post-treatment (mean (SD) = 14.3 (1.3) versus 14.1 (1.1) months; $p = .56$). The mean (range) number of flares prior to baseline was 1.2 (0 to 6) in the SLCBT condition and 1.2 (0 to 8) in the ES condition. Post-treatment, the mean (range) number of flares was 0.6 (0 to 4) for the SLCBT condition and 0.9 (0 to 9) for the ES condition. Log-linear regression was used to compare the number of flares post-treatment between the two conditions, adjusting for the same variables used to compare the two conditions on the outcome and process variables, as well as adjusting for the number of flares prior to baseline. While there were fewer flares overall post-treatment in the SLCBT condition as compared to the ES condition, the difference was not statistically significant (rate ratio = 0.83; 95% CI, 0.41 to 1.32; $p = .42$). However, in an exploratory subgroup analysis, we observed that among children who had two or more flares prior to baseline (18 in the SCLT condition and 17 in the ES), significantly fewer children in the SLCBT condition as compared to the ES condition experienced two or more flares post-treatment (16.7% versus 52.9%; $p = .04$).

DISCUSSION

This study was a large randomized controlled trial including a 1-year follow up period designed to test the efficacy of a brief cognitive behavioral intervention for children with IBD and their parents. The study evaluated treatment effects on process variables related to the intervention methods as well as outcome variables including quality of life, IBD symptoms, and school attendance. As predicted, results indicated that there was significantly more baseline to follow-up improvement in the SLCBT versus ES condition on process measures of parental solicitousness and parent-reported and child-reported child use of distract/ignore to cope with pain. Children's increased use of distract/ignore coping strategies was associated with significant increases, by parent-report, in children's beliefs in their pain coping efficacy. The observation by parents' that children had increased confidence/belief in their problem-focused coping efficacy is consistent with the reports by both parents and children that the children increased their use of distraction/ignoring. It may thus be interpreted that they learned a strategy to cope with pain and this was associated with increased confidence in coping efficacy. Children in the SLCBT condition also reported greater improvement on the outcome measures of IBD-related quality of life overall compared to children in the ES group. Children in the SLCBT intervention missed significantly fewer school days for IBD and exploratory analyses indicated that for children with a higher level of flares (2 or more) pre-baseline, those in SLCBT experienced a greater reduction in flares post treatment compared to those in ES.

The study did not find significant treatment effects for SLCBT compared to ES on child- or parent-reported depression or anxiety. Although depression and anxiety were not specific targets of intervention, higher prevalence of these psychological problems has been reported in children with IBD as noted in the introduction[18,19] and it was of interest to determine if an intervention to improve stress management and coping might have secondary effects on psychosocial function. Children in both conditions reported significant improvement on psychosocial functioning and depression symptoms with no difference between groups. Lack of significant treatment effects in some outcome variables may be due to relatively low levels of active symptoms, restricting the range of possible improvement on those variables. It is also possible, given that prior CBT trials have shown that 12 sessions of CBT is efficacious in treating depression in youth with IBD,[25] that our brief, 3-session intervention was insufficient to reduce depression and anxiety symptoms.

One limitation of the study was that our parent sample was comprised largely of mothers (90%). While in many cases mothers are the primary parent involved in a child's medical care, there is some evidence that fathers also play important roles in health behavior.[59,60] The efficacy of psychosocial treatments may be enhanced if both parents are included in treatment, but further research is needed to test this. Second, the study sample was primarily Caucasian, and thus the results may not generalize to minority children with IBD and their parents. Third, the majority of children with IBD in the study were described as in a quiescent state of disease symptomatology, which may have reduced the ability of this study to demonstrate significant effects of the intervention on some outcome variables. Another limitation was that given the nature of staffing of care providers in our recruitment sites, it was not possible to accurately track the number of patients who were originally made aware of the study. Finally, the psychometric properties of our method for determining flare counts were not determined. Findings on the reduction in number of flares in children with two or more flares pretreatment are intriguing, but require replication due to the small numbers of subjects in that subgroup, the limitations on the flare measure, and the exploratory nature of the analysis.

Nevertheless, this study demonstrated the efficacy of the SLCBT intervention in reducing school absences and improving quality of life, as well as increasing child use of distraction to cope with pain and reducing parental solicitousness. This intervention was relatively short (3 one-hour sessions) and therefore easily implemented in clinical practice. Although disability as measured by the FDI did not change significantly, it may be argued that improvement in functioning in important areas, such as school attendance and quality of life, are of at least equal if not greater importance to IBD management. Learning skills such as distraction and decreased catastrophizing may also have implications for continued self-management and improved future outcomes. Helping parents to decrease solicitous behaviors and to encourage wellness and coping skill use may also have implications for facilitating self-management as children transition to self-care as young adults. Future research may consider intervening earlier post diagnosis to provide education and coping skills and allow earlier improvement at a time when families are beginning to process knowledge about the disease and its implications. Further studies may also consider focusing on children with greater symptomatology, increasing the number of sessions, intervening with more than one caregiver, or building in booster sessions to determine if this would

increase the magnitude of effects. Given the preliminary findings on flare reduction in more severely ill children, studies may consider focusing on this group as well. Investigations into factors that predict treatment response to facilitate targeting interventions would also be useful. Finally, consideration should be given to alternative delivery strategies, such as using an internet-based platform to deliver services to families who may not be able to access services in person.

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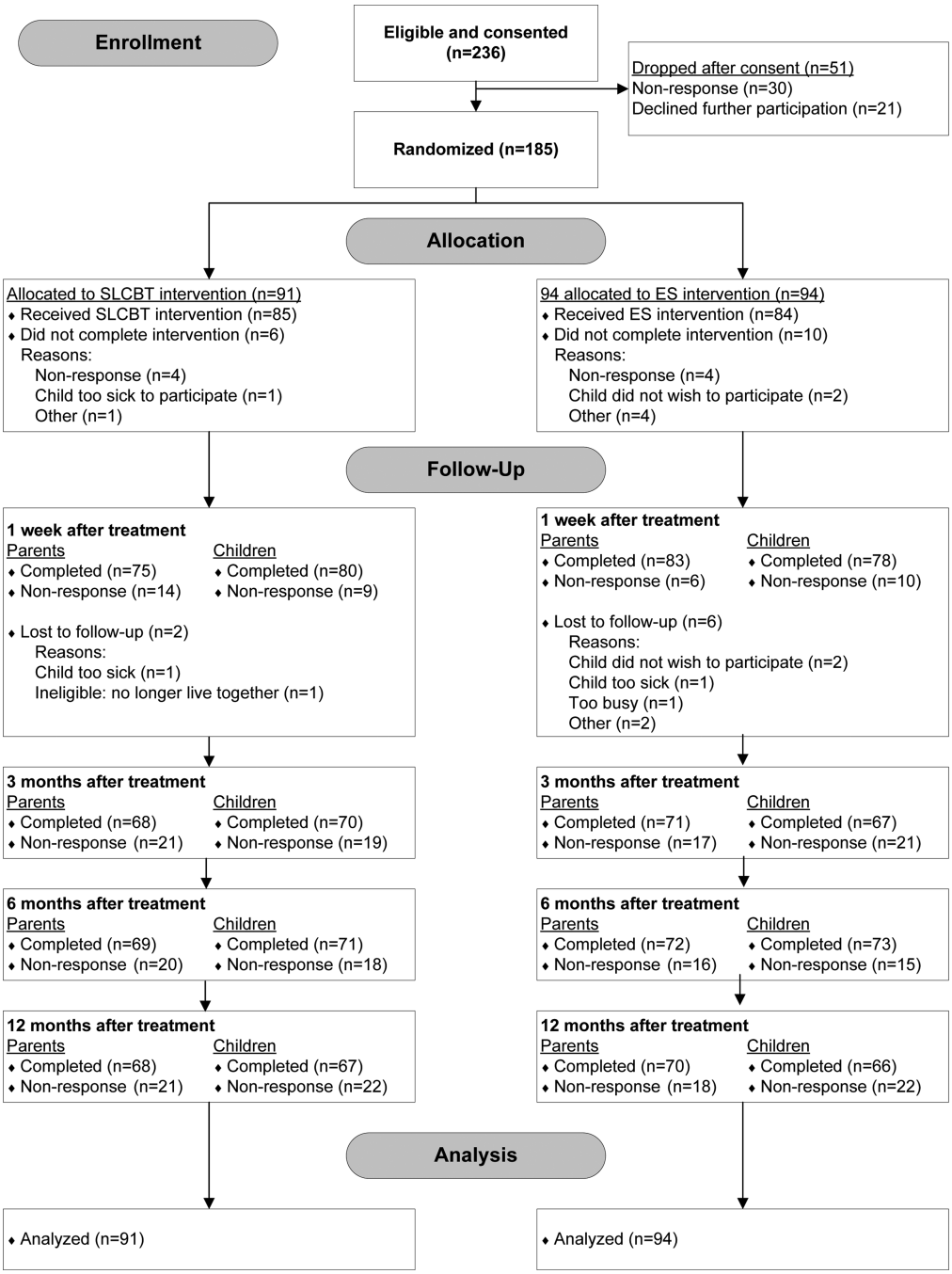

Figure 1.
Study consort diagram

Table 1

Baseline characteristics of the total sample and as a function of treatment condition.

	All N = 185	SLCBT N = 91	ES N = 94	P[1]
Parent				
Age, mean (SD), range	44.4 (6.9) 27 - 67	44.5 (6.6) 38 - 64	43.8 (7.1) 27 - 67	0.26[2]
Gender, n (%)				0.06
Male	18 (9.7)	5 (5.5)	13 (13.8)	
Female	167 (90.3)	86 (94.5)	81 (86.2)	
Race, n (%)				0.91[4]
American Indian/ Alaska Native	1 (0.5)	1 (1.1)	0 (0)	
Asian	5 (2.7)	3 (3.3)	2 (2.1)	
Black or African American	4 (2.2)	2 (2.2)	2 (2.1)	
Native Hawaiian or other Pacific Islander	1 (0.5)	1 (1.1)	0 (0)	
Caucasian	161 (87.1)	79 (86.7)	82 (87.2)	
Mixed race	12 (6.5)	4 (4.4)	8 (8.5)	
Unknown	1 (0.5)	1 (1.1)	0 (0)	
Ethnicity, n (%)				0.24[3]
Hispanic	3 (1.6)	0 (0)	3 (3.2)	
Not Hispanic	181 (97.9)	90 (98.9)	91 (96.8)	
Unknown	1 (0.5)	1 (1.1)	0 (0)	
Educational status, n (%)				0.85
High school degree or less	21 (11.4)	12 (13.2)	9 (9.6)	
Some college or technical school	73 (39.5)	34 (37.3)	39 (41.5)	
4-year college degree	42 (22.7)	20 (22.0)	22 (23.4)	
Some graduate/ professional school or post-baccalaureate degree	48 (25.9)	24 (26.4)	24 (25.5)	
Unknown	1 (0.5)	1 (1.1)	0 (0)	
Marital status, n (%)				0.78
Married/Cohabiting with partner	154 (83.3)	76 (83.5)	78 (83.0)	
Other situation	30 (16.2)	14 (15.4)	16 (17.0)	
Unknown	1 (0.5)	1 (1.1)	0 (0)	
Employment, n (%)				0.47
Full-time	81 (43.8)	36 (39.6)	45 (47.9)	
Part-time	47 (25.4)	26 (28.5)	21 (22.3)	
Not employed	55 (29.7)	28 (30.8)	27 (28.7)	
Unknown	2 (1.1)	1 (1.1)	1 (1.1)	
Parent Crohn's or Ulcerative Colitis, n (%)	42 (22.7)	18 (19.8)	24 (25.5)	0.37
Child				
Age, mean (SD), range	13.5 (2.7)	13.7 (2.5)	13.3 (2.9)	0.30[2]

	All N = 185	SLCBT N = 91	ES N = 94	P[1]
	8 - 17	8 - 17	8 - 17	
Gender, n (%)				0.41
Male	98 (53.0)	51 (56.0)	47 (50.0)	
Female	87 (47.0)	40 (44.0)	47 (50.0)	
Ethnicity, n (%)				0.07[3]
Hispanic	8 (4.3)	1 (1.1)	7 (7.4)	
Not Hispanic	174 (94.1)	88 (96.7)	86 (91.5)	
Unknown	3 (1.6)	2 (2.2)	1 (1.1)	
Race, n (%)				0.61[4]
American Indian/ Alaska Native	1 (0.5)	1 (1.1)	0 (0)	
Asian	5 (2.7)	3 (3.3)	2 (2.1)	
Black or African American	7 (3.8)	4 (4.4)	3 (3.2)	
Native Hawaiian or other Pacific Islander	3 (1.6)	2 (2.2)	1 (0.5)	
Caucasian	144 (77.9)	69 (75.8)	75 (79.8)	
Mixed race	24 (13.0)	11 (12.1)	13 (13.8)	
Unknown	1 (0.5)	1 (1.1)	0 (0)	
Child IBS (Rome III diagnostic criteria-parent report), n (%)	5 (2.7)	3 (3.3)	2 (2.1)	0.68[3]
Child IBS (Rome III diagnostic criteria-child report), n (%)	0 (0)	0 (0)	0 (0)	
Physician-reported				
Disease condition, n (%)				0.15
Crohn's	127 (68.6)	67 (73.6)	60 (63.8)	
Ulcerative colitis	58 (31.4)	24 (26.4)	34 (36.2)	
Disease severity, n (%)				0.40
Quiescent	116 (63.0)	58 (63.7)	58 (62.4)	
Mild	53 (28.8)	28 (30.8)	25 (26.9)	
Moderate or severe	15 (8.2)	5 (5.5)	10 (10.8)	
Location of ulcerative colitis				0.41[3]
Rectal (proctitis)	6 (11.5)	1 (4.3)	5 (17.2)	
Left-sided (colitis)	17 (32.7)	8 (34.8)	9 (31.0)	
Entire colon (pancolitis)	29 (55.8)	14 (60.9)	15 (51.7)	
Location of Crohn's disease				0.69
Small intestine only (ileitis)	30 (25.0)	16 (25.0)	14 (25.0)	
Small & large intestine (ileocolitis)	66 (55.0)	37 (57.8)	29 (51.8)	
Large intestine only (colitis)	24 (20.0)	11 (17.2)	13 (23.2)	
Anal, rectal or vaginal problems, n (%)	15 (8.4)	9 (10.1)	6 (6.7)	0.41
Daily steroid medication, n (%)	41 (22.8)	18 (20.2)	23 (25.3)	0.42
Pain medication, n (%)	8 (4.3)	5 (5.5)	3 (3.2)	0.45
Medications for anxiety, n (%)	6 (3.3)	3 (3.3)	3 (3.2)	0.96

	All N = 185	**SLCBT N = 91**	**ES N = 94**	**p**[1]
Medications for depression, n (%)	10 (5.4)	5 (5.6)	5 (5.3)	0.94
Medications for hyperactivity, n (%)	5 (2.7)	3 (3.3)	2 (2.1)	0.62

[1] Chi-square test, p-value, unless noted otherwise

[2] Two-sample t test

[3] Fisher's exact test, p-value

[4] Caucasian vs. non-Caucasian

Table 2

Baseline process and outcome variables as a function of treatment condition.

Process Variables	All N = 185	SLCBT N = 91	ES N = 94	p[1]
Parent-report only, mean (SD)				
ARCS: Protect (solicitousness) 0-4 scale	1.7 (0.7)	1.7 (0.6)	1.8 (0.7)	0.26
Parent and child-reported, mean (SD)				
Parent-report				
PRI: Child distract/ignore 0-4 scale	2.1(0.7)	2.1 (0.7)	2.1 (0.7)	0.66
Child catastrophizing 0-4 scale	1.2(0.8)	1.2(0.8)	1.2(0.8)	0.75
PBQ: Threat of child pain 0-4 scale	2.2 (0.7)	2.3 (0.7)	2.2 (0.7)	0.51
Child emotion-focused coping 0-4 scale	3.0 (0.7)	3.1 (0.7)	3.0 (0.7)	0.46
Child problem-focused coping 0-4 scale	1.9 (0.8)	1.9 (0.8)	2.0 (0.8)	0.27
Child-report				
PRI: Child catastrophizing 0-4 scale	1.0 (0.8)	1.0 (0.8)	1.0 (0.8)	0.57
Child distract/ignore 0-4 scale	2.3 (0.8)	2.3 (0.9)	2.3 (0.7)	0.96
PBQ: Child perceived pain threat 0-4 scale	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	0.66
Child emotion-focused coping 0-4 scale	3.0 (0.7)	3.1 (0.7)	3.0 (0.8)	0.13
Child problem-focused coping 0-4 scale	2.3 (0.9)	2.4 (0.9)	2.3 (0.9)	0.50
Outcome Variables				
Parent-report only, mean (SD)				
Hospital stays in past 12 months	0.8 (1.4)	0.7 (1.1)	0.8 (1.6)	0.35
Health care visits for Crohn's or UC in past 12 months	9.3 (11.3)	7.1 (5.8)	11.5 (14.6)	0.01
Missed school days for Crohn's or UC in past 3 months	4.8 (9.4)	5.0 (9.5)	4.7 (9.3)	0.82
Child-report only, mean (SD)				
IMPACT: Child IBD-specific quality of life; total score 33-175 scale	130.3 (19.2)	131.2 (16.9)	129.4 (21.4)	0.54
CDI: Child depression 0-54 scale	8.2 (7.4)	7.6 (7.1)	8.8 (7.6)	0.28
MASC: Child anxiety 0-30 scale	8.4 (2.9)	8.2 (2.8)	8.6 (2.9)	0.35
Parent and Child Reported, mean (SD)				
Parent-report				
FDI: Child functional disability 0-60 scale	6.7 (9.1)	6.8 (9.3)	6.6 (6.9)	0.88
Child-report				
FDI: Child functional disability 0-60 scale	6.5 (7.1)	5.6 (5.7)	7.3 (8.2)	0.11

[1]Two-sample t-test, p-value

Table 3

Adjusted mean changes from baseline for process variables.[1]

Variable	Change from baseline					
	1 week Mean (95% CI)	3 months Mean (95% CI)	6 months Mean (95% CI)	12 months		P-value[3]
				Mean (95% CI)	Cohen's d[2]	
Parent-reported						
ARCS: Protect (solicitousness) 0-4 scale						
SLCBT	−0.4 (−0.6, −0.3)*	−0.4 (−0,5, −0.2)*	−0.4 (−0.5, −0.3)*	−0.4 (−0.6, −0.3)*	−0.76	<.001
ES	−0.2 (−0.3, −0.0)*	−0.3 (−0.4, −0.1)*	−0.3 (−0.4, −0.1)*	−0.2 (−0.4, −0.1)*	−0.40	0.003
Difference	−0.2 (−0.4, −0.1)*	−0.1 (−0.3, 0.1)	−0.1 (−0.3, 0.0)	−0.2 (−0.4, −0.1)	−0.36	0.02
Parent and Child-reported						
Parent-report						
PRI: Child distract/ignore 0-4 scale						
SLCBT	0.3 (0.1, 0.4)*	0.2 (−0.0, 0.3)	0.2 (0.0, 0.4)	0.1 (−0.1, 0.2)	0.06	0.001
ES	−0.0 (−0.2, 0.1)	−0.1 (−0.3, 0.1)	−0.0 (−0.2, 0.1)	0.0 (−0.1, 0.2)	0.05	0.47
Difference	0.4 (0.1, 0.5)*	0.3 (0.0, 0.5)*	0.2 (0.0, 0.4)	0.0 (−0.2, 0.2)	0.02	0.002
PRI: Child catastrophizing 0-4 scale						
SLCBT	−0.3 (−0.4, −0.1)*	−0.2 (−0.4, −0.1)*	−0.2 (−0.4, −0.1)*	−0.3 (−0.4, −0.1)*	−0.27	0.009
ES	−0.0 (−0.2, 0.1)	−0.1 (−0.2, 0.1)	−0.2 (0.3, −0.0)	−0.1 (−0.3, 0.0)	−0.13	0.07
Difference	−0.2 (−0.4, −0.1)*	−0.2 (−0.3, 0.02)	−0.1 (−0.2, 0.1)	−0.2 (−0.4, 0.1)	−0.14	0.12
PBQ: Threat of child pain 0-4 scale						
SLCBT	−0.2 (−0.3, −0.1)*	−0.1 (−0.3, 0.0)	−0.2 (−0.3, −0.0)*	−0.2 (−0.4, −0.1)*	−0.36	0.03
ES	−0.0 (−0.1, 0.1)	−0.1 (−0.3, 0.0)	−0.1 (−0.3, 0.0)	−0.1 (−0.3, 0.0)	−0.23	0.28
Difference	−0.2 (−0.3, −0.0)	−0.0 (−0.2, 0.1)	−0.0 (−0.2, 0.1)	−0.1 (−0.3, 0.1)	−0.13	0.18
PBQ: Child emotion-focused coping 0-4 scale						
SLCBT	0.3 (0.1, 0.4)*	0.3 (0.1, 0.4)*	0.3 (0.2, 0.4)*	0.4 (0.2, 0.5)*	0.54	<.001
ES	0.2 (0.1, 0.3)*	0.2 (0.1, 0.3)*	0.1 (0.0, 0.3)*	0.2 (0.1, 0.4)*	0.34	0.001
Difference	0.0 (−0.1, 0.2)	0.1 (−0.1, 0.2)	0.1 (−0.0, 0.3)	0.1 (−0.0, 0.3)	0.20	0.35
PBQ: Child problem-focused coping 0-4 scale						
SLCBT	0.5 (0.3, 0.7)*	0.5 (0.3, 0.6)*	0.4 (0.2, 0.5)*	0.4 (0.2, 0.5)*	0.48	<.001
ES	0.0 (−0.1, 0.2)	0.2 (−0.0, 0.3)	0.1 (−0.1, 0.2)	0.0 (−0.2, 0.2)	0.03	0.13
Difference	0.5 (0.3, 0.6)*	0.3 (0.1, 0.5)*	0.3 (0.1, 0.5)*	0.3 (0.1, 0.6)*	0.44	<.001

Variable	Change from baseline					
	1 week Mean (95% CI)	3 months Mean (95% CI)	6 months Mean (95% CI)	12 months		P-value[3]
				Mean (95% CI)	Cohen's d[2]	
Child-report						
PRI: Child distract/ignore 0-4 scale						
SLCBT	0.3 (0.1, 0.5)*	0.3 (0.1, 0.5)*	0.1 (−0.1, 0.3)	0.1 (−0.1, 0.4)	0.14	0.03
ES	−0.0 (−0.2, 0.2)	0.0 (−0.2, 0.3)	0.1 (−0.1, 0.3)	−0.0 (−0.3, 0.2)	−0.02	0.49
Difference	0.3 (0.0, 0.5)	0.3 (−0.0, 0.5)	−0.0 (−0.3, 0.2)	0.2 (−0.1, 0.5)	0.16	0.04
PRI: Child catastrophizing 0-4 scale						
SLCBT	−0.1 (−0.3, 0.0)	−0.2 (−0.3, 0.0)	−0.1 (−0.3, 0.1)	−0.3 (−0.5, −0.1)*	−0.42	0.01
ES	−0.0 (−0.2, 0.1)	0.1 (−0.1, 0.3)	−0.0 (−0.2, 0.1)	0.0 (−0.2, 0.2)	0.03	0.64
Difference	−0.1 (−0.3, 0.1)	−0.2 (−0.4, −0.0)	−0.1 (−0.3, 0.2)	−0.3 (−0.5, −0.1)*	−0.44	0.01
PBQ: Child perceived pain threat 0-4 scale						
SLCBT	−0.1 (−0.2, 0.1)	−0.1 (−0.3, 0.0)	−0.0 (−0.2, 0.1)	−0.1 (−0.2, 0.1)	−0.11	0.13
ES	0.1 (−0.0, 0.2)	0.0 (−0.2, 0.2)	0.0 (−0.2, 0.2)	0.1 (−0.1, 0.2)	0.08	0.47
Difference	−0.2 (−0.3, −0.0)	−0.2 (−0.3, 0.0)	−0.0 (−0.2, 0.1)	−0.1 (−0.3, 0.1)	−0.19	0.07
PBQ: Child emotion-focused coping 0-4 scale						
SLCBT	0.2 (0.1, 0.4)*	0.2 (0.1, 0.4)*	0.1 (−0.0, 0.3)	0.2 (−0.0, 0.3)	0.24	0.03
ES	0.1 (−0.1, 0.3)	0.1 (−0.1, 0.3)	0.1 (0.0, 0.3)	0.2 (0.0, 0.3)	0.24	0.30
Difference	0.1 (−0.0, 0.3)	0.1 (−0.1, 0.3)	−0.0 (−0.2, 0.1)	0.0 (−0.2, 0.2)	0.00	0.38
PBQ: Child problem-focused coping 0-4 scale						
SLCBT	0.4 (0.2, 0.5)*	0.4 (0.2, 0.6)*	0.2 (−0.0, 0.4)	0.1 (−0.1, 0.4)	0.16	<.001
ES	0.3 (0.1, 0.4)*	0.2 (−0.0, 0.4)	0.3 (0.1, 0.4)*	0.2 (0.0, 0.4)	0.24	0.03
Difference	0.1 (−0.1, 0.3)	0.2 (−0.0, 0.4)	−0.1 (−0.3, 0.1)	−0.1 (−0.3, 0.2)	0.08	0.05

[1]Estimated mean change from baseline based on linear mixed-effects regression model, adjusted for child gender, child age, disease condition and severity, study site and baseline level of the process variable.

[2]Cohen's d effect sizes based on the change between 12 months post-treatment and baseline; interpreted as: small (0.20), medium (0.50), or large (0.80).

[3]Omnibus test (df = 3) to evaluate overall change from baseline for all post-treatment periods (SLCBT or ES), and omnibus test (df = 3) to evaluate overall effect of intervention (Difference).

*Bonferroni-Holm post-hoc test for change from baseline for SLCBT or ES, and for SLCBT/ES treatment difference ($p < 0.05$)

Table 4

Adjusted mean changes from baseline for outcome variables.[1]

Variable	Change from baseline					
	1 week Mean (95% CI)	3 months Mean (95% CI)	6 months Mean (95% CI)	12 months		P-value[3]
				Mean (95% CI)	Cohen's d[2]	
Child-Reported						
IMPACT: Child IBD-specific quality of life 35-175 scale						
SLCBT	6.3 (3.1, 9.6)*	5.9 (2.4, 9.4)*	4.9 (1.0, 8.9)*	5.5 (1.6, 9.5)*	0.37	0.003
ES	2.1 (−1.2, 5.3)	3.2 (−0.5, 6.8)	5.3 (1.3, 9.3)*	5.6 (1.6, 9.6)*	0.37	0.04
Difference	4.3 (1.0, 7.5)*	2.7 (−1.4, 6.8)	−0.4 (−4.3, 3.6)	−0.1 (−4.4, 4.3)	0.00	0.04
CDI: Child depression 0-54 scale						
SLCBT	−3.2 (−4.3, −2.1)*	−3.8 (−5.0, −2.7)*	−2.3 (−3.5, −1.1)*	−3.0 (−4.2, −1.7)*	−0.52	<.001
ES	−3.1 (−4.1, −2.0)*	−3.2 (−4.4, −2.1)*	−3.2 (−4.2, −2.1)*	−3.6 (−4.9, −2.3)*	−0.63	<.001
Difference	0.1 (−1.3, 1.0)	−0.6 (−1.9, 0.7)	0.8 (−0.5, 2.2)	0.6 (−0.9, 2.1)	0.11	0.10
MASC: Child anxiety 0-30 scale						
SLCBT	−0.2 (−0.9, 0.5)	−0.4 (−1.2, 0.4)	−0.6 (−1.3, 0.2)	−0.6 (−1.5, 0.3)	−0.21	0.53
ES	−0.2 (−0.8, 0.5)	−0.3 (−1.0, 0.4)	−0.4 (−1.2, 0.3)	−0.8 (−1.7, 0.1)	−0.26	0.37
Difference	−0.0 (−0.7, 0.6)	−0.1 (−0.9, 0.8)	−0.2 (−1.0, 0.7)	0.2 (−0.9, 1.2)	0.05	0.97
Parent and Child-reported						
Parent-Report						
FDI: Child functional disability 0-60 scale						
SLCBT	−0.1 (−2.5, 2.3)	−1.7 (−3.8, 0.3)	−1.6 (−3.8, 0.6)	−1.3 (−3.5, 1.0)	−0.12	0.41
ES	−0.3 (2.5, 1.9)	−1.0 (−2.9, 0.8)	−0.2 (−2.3, 1.9)	−0.4 (−2.8, 2.0)	−0.04	0.82
Difference	0.2 (−2.6, 3.0)	−0.7 (−3.0, 1.7)	−1.4 (−4.0, 1.2)	−0.9 (−3.6, 1.9)	−0.08	0.86
Child-report						
FDI: Child functional disability 0-60 scale						
SLCBT	0.1 (−1.3, 1.5)	0.3 (−1.3, 1.9)	0.3 (−1.5, 2.0)	0.2 (−1.5, 2.0)	0.02	0.99
ES	0.0 (−1.4, 1.3)	0.1 (−1.6, 1.7)	0.2 (−1.4, 1.7)	0.1 (−1.6, 1.8)	0.01	0.99
Difference	0.1 (−1.2, 1.5)	0.2 (−1.5, 2.0)	0.1 (−1.8, 2.0)	0.1 (−2.0, 2.2)	0.01	0.99

4 To calculate the change from baseline at post-treatment for the number of health care visits in the past 3 months, baseline numbers were divided by four as an estimate of the number of health care visits in the 3 months prior to baseline.

[1]Estimated mean change from baseline based on linear mixed-effects regression model, adjusted for child gender, child age, disease condition and severity, study site and baseline level of the outcome.

[2]Cohen's d effect sizes based on the change between 12 months post-treatment and baseline; designated as small (0.20), medium (0.50), or large (0.80).

[3]Omnibus test (df = 3) to evaluate overall change from baseline for all post-treatment periods (SLCBT or ES), and omnibus test (df = 3) to evaluate overall effect of intervention (Difference).

[*]Bonferroni-Holm post-hoc test for change from baseline for SLCBT or ES, and for treatment difference, SLCBT – ES ($p < 0.05$)

Table 5

Adjusted rate ratios for number of health care visits and number of missed school days for Crohn's or ulcerative colitis.[1]

Variable		3 months RR (95% CI)	6 months RR (95% CI)	12 months RR (95% CI)	P-value[2]
Number of child health care visits, past 3 months	SLCBT vs ES	1.11 (0.73, 1.66)	0.74 (0.50, 1.06)	0.82 (0.56, 1.19)	0.16
Number of missed school days, past 3 months	SLCBT vs ES	0.98 (0.54, 1.75)	0.43 (0.22, 0.80)*	0.62 (0.34, 1.13)	0.02

[1] Estimated rate ratio based on GEE log-linear regression model, adjusted for child gender, child age, disease condition and severity, study site and number of health care visits (12 months prior to baseline) or number of missed school days (3 months prior to baseline).

[2] Omnibus test (df = 3) to evaluate overall effect of intervention (difference).

* Bonferroni-Holm post-hoc test for treatment difference ($p < 0.05$)