A Randomized Controlled Trial of a Cognitive-Behavioral Family Intervention for Pediatric Recurrent Abdominal Pain

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Objective   To investigate whether the combination of standard medical care (SMC) and short-term cognitive-behavioral family treatment (CBT) in the treatment of recurrent abdominal pain (RAP) was more effective than SMC alone.   **Methods**   Children recently diagnosed with RAP via physician examination were randomized into SMC ($n = 29$) and SMC plus CBT ($n = 40$) groups. Outcome measures included multiple dimensions of child and parent reported child pain, somatization, and functional disability, and school absences and physician contacts.   **Results**   Children and parents participating in the combined SMC + CBT intervention reported significantly less child and parent reported child abdominal pain than children in the SMC intervention immediately following the intervention and up to 1 year following study entry, as well as significantly fewer school absences. Significant differences in functional disability and somatization were not revealed.   **Conclusions**   These results, in combination with previous studies, add support to the effectiveness of CBT intervention in reducing the sensory aspects of RAP. Results are discussed with respect to the cost-benefit of integrated medical and short-term psychological services.

Key words   recurrent abdominal pain; cognitive-behavioral intervention; children; adolescents; clinical trial; cost-benefit.

Pain complaints are a common concern in school-aged children and adolescents referred for medical care. Recurrent abdominal pain (RAP), in particular, represents a common reason for primary care visits and subsequent referrals to subspecialty pediatric practitioners (Campo, Jansen-McWilliams, Comer, & Kelleher, 1999; Finney, Lemanek, Cataldo, Katz, & Fuqua, 1989). Studies suggest that between 30 and 60% of children and adolescents with abdominal pain continue to experience significant pain as adults (Walker, Garber, Van Slyke, & Greene, 1995; Walker, Guite, Duke, Barnard, & Greene, 1998). Yet, there is considerable frustration voiced by parents and health care professionals with respect to effective assessment and management of abdominal pain complaints. Children often experience noteworthy functional impairment, including reduced school attendance (Heath, 1985; Wasserman, Whitington, & Rivara, 1988), academic productivity (Kusche, Cook, & Greenberg, 1993; Kolbe, Collins, & Cortese, 1997), and participation in physical activities (Walker & Greene, 1988). Health care providers note both the time and expense related to repeated office visits, laboratory testing, and referral to subspecialty medical care, without clear evidence of benefit (Frazer & Rappaport, 1999). Likewise, there are links between child onset abdominal pain and adult functional gastrointestinal disorders such as irritable bowel syndrome (Blanchard & Scharff, 2002; Walker, 1999b) raising concerns as to the long-term implications of abdominal pain concerns, both of functional impact and of financial cost (Walker et al., 1995).

RAP is not a diagnostic entity, but rather is a description of a common pattern of symptoms with no agreed upon definition or etiology uniformly applied (von Baeyer & Walker, 1999). Apley's 1975 definition is historically most often used in research studies. Accordingly, RAP is characterized as pain that waxes and wanes, occurs for three or more episodes over a 3-month period or longer, and is severe enough to affect activities. A dimensional approach suggests that mild symptoms can be present in healthy children, whereas more severe symptoms or disability reflect a more extreme version of normative processes (Walker, 1999a) Despite ambiguities in definition and etiology, researchers and practitioners agree that RAP represents a complex interaction between physical pain sensation and psychological responses to pain, as well as the ecological context in which these interactions occur (Frazer & Rappaport, 1999). There are conceptual models published that aid a clearer understanding of the nature and direction of these interactions. For example, as early as 1984, Levine and Rappaport (1984) suggested that RAP results from the interaction of four "primary forces", including somatic, lifestyle and habit, milieu and critical events, and temperament and learned response patterns. Since that time, conceptual models have evolved, moving from assessing pain as a unitary construct to assessing multiple outcomes (Walker, 1999a). Poorer family environments, parent reinforcement of sick role behaviors, and parental over involvement in pain behavior are thought to be associated with ineffective coping with chronic pain (Chambers, 2003). A broad social learning perspective incorporating these findings is advocated (Chambers, 2003).

Standard pediatric care of children with RAP typically involves medical evaluation and supportive follow up, as well as medication in some cases depending upon the gastrointestinal symptoms (Weydert, Ball, & Davis, 2003). Referrals to mental health practitioners are often made following "normal" medical evaluations, and treatment options are exhausted. This practice would seem to inadvertently reinforce a mind–body dichotomy in which pain is viewed as either "organic" or "nonorganic", thereby hindering more sophisticated understanding of effective assessment and treatment models in both practitioners, patients, and families.

In an era of greatly increasing health care costs and accountability, it is essential to demonstrate clinical efficacy of interventions, particularly for high incidence problems such as RAP, which is thought to occur in approximately 10% of school-age children (McGrath, 1999). There is much increased attention paid to empirically supported treatments in pediatric psychology. In a recent review of empirically supported treatments for RAP, Janicke and Finney (1999) reviewed nine published intervention studies vis-à-vis guidelines established by the Task Force on Promotion and Dissemination of Psychological Procedures (1995). Review of cognitive behavioral interventions for RAP fit within the "probably efficacious" as opposed to the "well established" classification, as only one investigatory team has published a well-controlled cognitive-behavioral study meeting criteria for a well-established intervention study (Janicke & Finney, 1999). The work of Sanders and colleagues indicated that cognitive-behavioral intervention for RAP was more effective than a wait list intervention (Sanders et al., 1989), and the addition of psychological treatment helped children reduce their pain symptoms more quickly, thoroughly, and for longer periods of time than standard medical care (SMC) (Sanders, Shepherd, Cleghorn, & Woolford, 1994). There is a well-recognized need to further establish the empirical support of cognitive-behavior interventions for RAP (Janicke & Finney, 1999).

The purpose of this study was to investigate whether the combination of SMC and short-term cognitive-behavioral family therapy (CBT) in the treatment of RAP was more effective and efficient than SMC alone. Effectiveness was operationalized as significant reductions in the sensory aspects of pain, and efficiency was operationalized as significant reductions in school absences and utilization of health care services. We utilized a social learning theory conceptual model of RAP, emphasizing the spiral of skill deficits within the child as well as the maintenance of the symptom within the context of the family (Friedrich & Jaworski, 1995; Kazak, Simms, & Rourke, 2002). We sought to both replicate and extend previous work in this area by (a) utilizing a five-session treatment intervention both to minimize direct mental health costs and to allow for additional replication, (b) including multiple dimensions of child pain (e.g., intensity, frequency, and duration) and somatization across raters, (c) examining the functional impact of RAP by including child ratings of impact on daily activities, as well as measuring school absences, and (d) addressing issues of health care utilization by assessing number of physician contacts (both phone calls and office visits) as a health care proxy. The primary outcome was (a) reduction in the sensory aspects of pain, including intensity, frequency, and duration of abdominal pain, and (b) reduction in the cognitive dimensions of the pain experience, namely perceived interference with activities of daily living. The secondary

outcome was the impact of the intervention on school attendance and health care utilization, namely phone calls and visits to the physician's office. We predicted that children participating in the combined SMC + CBT group would demonstrate reduced parent and child reported child abdominal pain, parent and child reported child somatization, child reported functional disability, physician contacts, and school absences, compared with children and parents participating in the SMC group alone, and that these difference would be maintained over the course of a year follow-up. These results will help better address issues related to the feasibility of integrated medical and psychological services for RAP.

Method
Participants

Patients consecutively presenting to one of four pediatric gastroenterologists through the outpatient service of a private, nonprofit children's hospital, as well as a community sample of children referred directly for the study by their primary care physician were invited to participate during the period of August 1998 through April 2000. The study was advertised through a one-time inclusion in the hospital's newsletter, mailed to 250,000 families in three contiguous states of the USA. Participants were not currently receiving cognitive or behavioral therapies for RAP. Each child met Apley's (1975) criteria for nonspecific RAP, on the basis of direct physician diagnosis: pain that waxes and wanes, occurs for three or more episodes over a 3-month period or longer, and is severe enough to affect day-to-day activities.

One hundred and eight child–parent dyads were identified as potential participants during the enrollment period and were invited to participate. Twenty-two participant pairs were excluded; one child was excluded after being diagnosed with an organic reason for the RAP, and four children had received psychological treatment within the past year and were excluded. The remaining 17 declined to be part of the study, citing geographic distance as the primary reason and conflicting after school activities as the next most common reason. The remaining sample of 86 were randomly assigned using a coin-flip method to the experimental (SMC + CBT) or control (SMC) groups; 46 were allocated to the CBT + SMC condition and 40 to the SMC condition. Forty-three received the allocated CBT + SMC intervention; one family was subsequently lost to follow up, and two families were discontinued due to seeking additional behavioral health intervention. Within the 40 participants random-

ized into the SMC condition, six did not remain in the study, stating that they preferred to be in the CBT + SMC arm, two were lost to 3-month follow up (one phone disconnected), and three were discontinued (two participated in behavioral health treatment and one dropped out following 3-month follow up). This left a complete sample of 69 patients, 40 in the CBT + SMC group and 29 in the SMC group. Figure 1 displays the flow of participants through each stage of the study. Data on the full set of 69 patients completing up to one-year follow-up are reported here.

Demographic characteristics are presented in Table I. The final sample consisted of 69 children diagnosed with RAP, aged 6–16 years ($M = 11.25$, years $SD = 2.45$ years). There were more females (56.5%) and the racial composition, as determined by parental response, showed the sample was largely Caucasian (88.4%), with three African-Americans (4.3%) and five participants coded as "Other" (7.2%). The Hollingshead educational level (Hollingshead, 1975) showed averages synonymous with the completion of partial college ($M = 5.26$, $SD = 1.17$). Likewise, the average Hollingshead occupational level was equivalent to a small business owner or manager ($M = 6.78$, $SD = 1.93$). Both community (63.8%) and tertiary participants were included in the sample. No statistically significant differences were evident between groups with respect to age ($t = 1.76$, $p < .084$), gender ($\chi^2 = .09$, $p < .77$), race ($\chi^2 = 1.56$, $p < .21$) or parent occupation (Mann–Whitney $U = 504$, $p < .43$). By contrast, there was a statistically significant difference with respect to parent education, with the SMC + CBT group showing a higher rank ($U = 328$, $p < .005$). We were unable to determine potential differences on these sociodemographic variables between those agreeing as opposed to not agreeing to participate in the study, as these data were not collected.

Measures

Abdominal Pain Index (Child and Parent versions) (Walker & Greene, 1989).   The Apdominal Pain Index (API) asks respondents (either children or parents) to rate various aspects of the child's abdominal pain across the past 2 weeks. Six items are included: (a) how often the child had abdominal pain (not at all to every day), (b) how many times a day the child usually had the pain, (none to constant during the day), (c) how long the pain lasted (a few minutes to all day), (d) how much the pain hurt (11-point Likert-type scale, with the anchors of 0 = no pain and 10 = the most pain possible), (e) the most the child's stomach hurt (11-point Likert-type scale), and
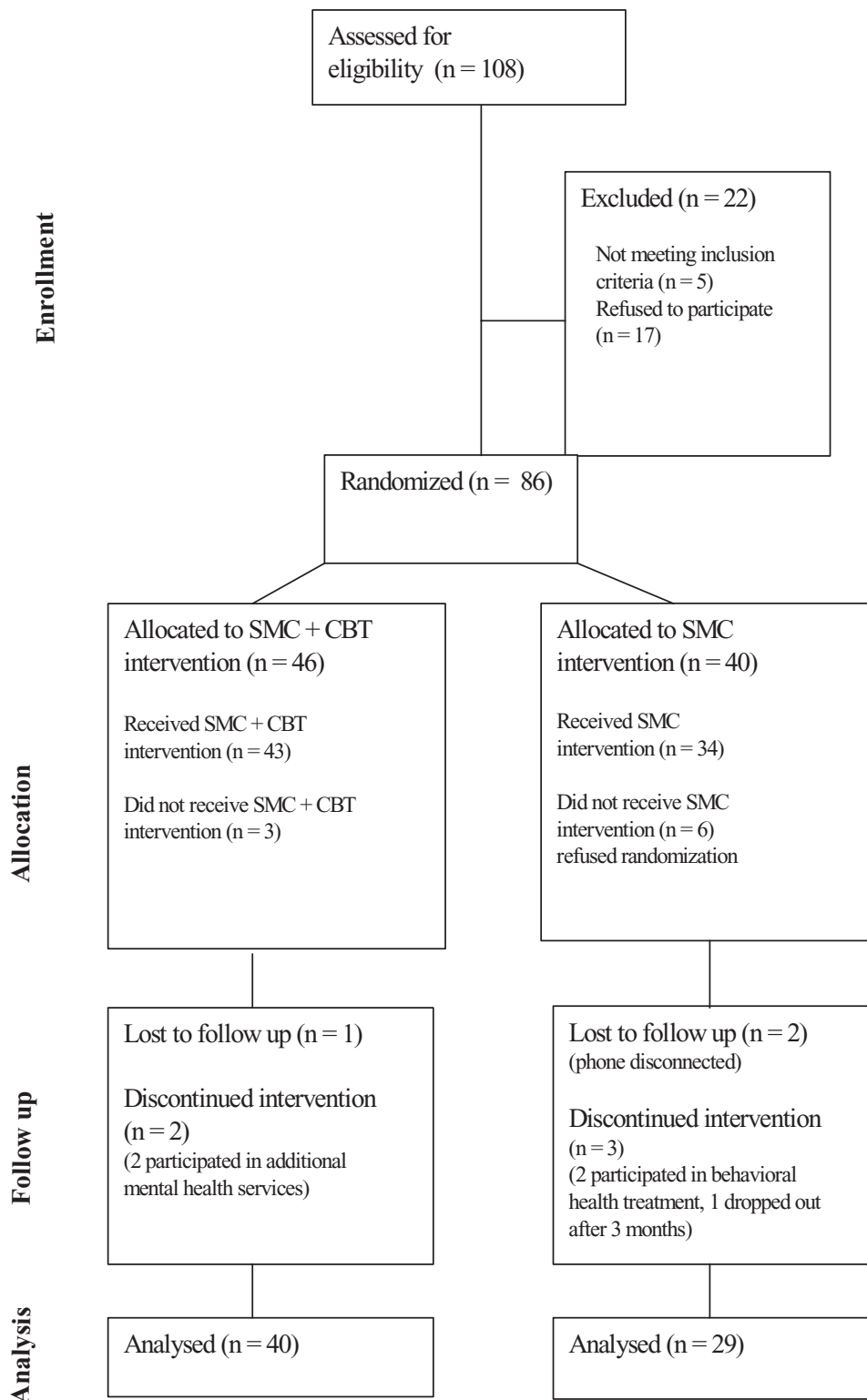
Figure 1. Flow Diagram of Participants.

(f) how much the child's stomach currently hurts (11-point Likert-type scale). Items 1 and 2 were converted to a 6-point Likert-type scale, and item 3 was converted to an 8-point Likert-type scale, using the same number of response options per item as in the questionnaire. A total score obtained by summing all six items was utilized; higher scores represented greater reported pain (possible range 2–50). Alpha reliabilities for the API

Table I. Demographic Characteristics of Participants

| Demographic Variable | Groups | | Difference | $p <$ |
	SMC	SMC + CBT		
Gender				
Male	12	18		
Female	17	22	$\chi^2 = .09$	.77
Race or ethnicity				
Anglo	24	37		
African American	2	1		
Other	3	2	$\chi^2 = 1.56$	.22
Mean age in years (SD)	11.85 (2.3)	10.83 (2.5)	$t = 1.76$	.084
Hollingshead occupation index	6.55	6.95	$U = 504$	.43
Hollingshead parent ed. index	4.79	5.62	$U = 328$	.005

SMC = Standard Medical Care and SMC + CBT = Standard Medical Care and Cognitive-Behavioral Treatment.

were reported to range from .80 to .93 across three samples of school children, clinic patients, and former clinic patients. Initial evidence of criterion related validity was examined through correlation with the Pain Response Inventory for Children (Walker, Smith, Garber, & Van Slyke, 1997).

Child Somatization Inventory (Parent and Child versions) (Garber, Walker, & Zeman, 1991; Walker & Garber, 1993). The Child Somatization Inventory (CSI), like the API, allows use of both child and parent respondents. It includes 36 symptoms derived from other somatization measures where items are rated on a 5-point scale ranging from not at all (0) to a whole lot (4). Respondents are instructed to rate how much the child was bothered by the symptoms over the past 2 weeks. Symptoms include headaches, pains in the heart, hot or cold spells, nausea, and difficulty swallowing. Validation studies of the CSI, using both pediatric and community samples, suggests that scores obtained are moderately stable (test-retest reliability) (Walker & Greene, 1991). Validity was established for the CSI through studies demonstrating good concurrent and construct validity (Garber, Walker, & Zeman, 1991; Walker & Garber, 1993). A total score, obtained by summing the ratings, was utilized (possible range 0–140); higher total scores represented greater somatization.

Functional Disability Inventory (Child version) (Walker & Greene, 1988, 1991). The Functional Disability Inventory (FDI) covers 15 activities that span multiple contexts, including school, home, recreation, and social interaction. Children rate how difficult it was for them to perform each activity over the past few days using a 5-point severity scale, ranging from no trouble to impossible. "When people are sick or not feeling well it is sometimes difficult to them to do their regular activities. In the last few days, would you have had any physical trouble or difficulty doing these activities?" Difficulties in performance are not specifically attributed to pain. Sample activities include walking to the bathroom, being at school all day, reading or doing homework, and running the length of a football field. Walker and Greene (1991) reported acceptable internal consistency (.85–.92) and 2-week test-retest reliability (.80) coefficients. Evidence of validity was examined by correlations with school absence ($r = .44, p < .001$) and somatic symptoms ($r = .45, p < .001$) (Walker & Greene, 1991). A total score was obtained on the FDI (possible range 15–75); higher scores represented greater functional impact.

Procedure

Once participants were assessed with RAP by either the pediatric gastroenterologist or referring primary care physician, informed parental consent and child assent were obtained according to guidelines of the hospital's Institutional Review Board, as well as in accordance with ethical standards maintained by the American Psychological Association. Parents completed a demographic data sheet, including occupation and highest year of parent education, as well as the baseline measures. Parents at baseline completed the CSI and API; children at baseline completed the CSI (child), API (child), and FDI. Parents completed the CSI and API, and children completed the API, CSI, and FDI via telephone interview again 3 months following study entry (Time 2) (SMC or SMC + CBT) and after having completed the CBT intervention, and once again 6–12 months following study entry (Time 3). School attendance data was obtained via direct school attendance records for the 12-month period following study entry, and was prorated to accommodate summer break. Only dates marked as "absent" were included. The number of physician office visits and telephone calls around stomach pain concerns for the 12-month period was obtained directly from physician offices. Each participant received a $25-reimbursement check by mail after completing the 12-month follow-up; participants randomized into the CBT arm also received a $25-reimbursement check by mail after completing the five sessions. There was no charge for participation in the trial.

Participants were randomly assigned to one of two treatment groups: (a) SMC ($n = 29$), or (b) SMC + CBT ($n = 40$). Randomization occurred dichotomously using a coin flip following completion of consent procedures

and baseline measures. Use of this procedure ensured that it was not possible to anticipate future group assignments on the basis of past assignments. No attempt was made to balance the size of the two groups. Once the predetermined number of participants for one group was obtained, further enrollment did not direct participants to the other group, thereby resulting in unequal sample sizes. Each single coin flip was witnessed by an additional person to help limit possible corruption. The sequence of randomization was concealed, such that the person enrolling participants did not know in advance which treatment each participant would receive (Altman et al., 2001). The physicians administering the SMC treatment were blinded to group assignments for the duration of the study. However, neither the participants nor those administering the CBT treatment were blinded to group assignment.

SMC entailed "usual and customary" medical treatment, consisting of follow-up office visits, education, support, instructions to maintain a diet high in fiber content, as well as possible oral medication and supplements to increase dietary bulk, decrease acid, or increase motility, all as deemed medically appropriate by the treating gastroenterologist or primary care physician, for the duration of the study. There was individualization of the medical treatment to meet the needs of the particular child and family, thereby allowing a "real world" accounting of medical treatment. Children and families randomized into the cognitive behavioral intervention group received SMC, and participated in a five-session intervention following baseline measurement, detailed below. As a result of randomization, each participant had an equal chance of being prescribed or taking medications.

The participants, objectives, activities, and homework of each CBT session are shown in Table II. The major goals of the intervention were to present a model of recurrent pain to both children and parents, instruct children in the active management of pain episodes, model and practice pain management techniques on the

Table II. Description of Intervention Protocol

Session and Who	Objectives	Activities
1. Child and parent	a) Develop understanding of child's pain	a) Assess frequency, duration, location, intensity, antecedents, and consequences through detailed clinical interview with child and parent and completing preintervention study measures
	b) Increase repertoire of pain management techniques	b) Model and practice breathing, imagery, and relaxation techniques
	c) Increase understanding of connection between stress and pain perception	c) Provide model of stress and pain connection
		d) Homework: Practice pain management techniques twice a day. Chart stomach pain.
2. Child	a) Increase repertoire of pain management techniques	a) Review pain chart, antecedents, and consequences
	b) Encourage child to "take control" of abdominal pain.	b) Discuss "self-talk" and help child learn to challenge negative predictions, and learn use of positive self-statements
		c) Homework: Practice pain management. Chart pain and self-statements
3. Child	Increase child's awareness of positive and negative self-talk and impact on pain.	a) Review self-talk and positive self-statements
		b) Introduce snowballing and catastrophizing.
		c) Homework: Continue active pain management. Stop snowballing, use positive self-statements. Use distraction techniques
4. Child and parent	Increase "partnership" between child and parent in active management of pain	a) Help parents reframe role from "protector" to "coach" by parental encouragement of behavior incompatible with being sick, minimizing discussion of pain, encouraging parental coping, limiting parental somatization, and limiting secondary gains from sick behavior
		b) Homework: Continue active pain management, including cognitive strategies
5. Child and parent	a) Assess progress	a) Complete post-intervention measures
	b) Reinforce gains and prepare for continued coping	b) Review relaxation, cognitive techniques, and distraction tools.
		c) Prepare for 3 month follow-up phone assessment

basis of a cognitive-behavioral model, and assist parents in developing more adaptive responses to their child's pain. Parent training was specifically included due to empiric support that involving parents in the treatment of pediatric chronic pain was important in maintaining treatment gains related to the effects of modeling and reinforcement over time (Chambers, 2003).

CBT interventions were scheduled bimonthly; each session lasted approximately 40 min Participants were not charged for receiving the CBT intervention. The parent and child were seen conjointly for three of the five sessions, and there was a review of the goals and activities with both parent and child prior to and following each session. Parents were encouraged to become proficient in the same skills as the children. Session 4 included use of cartoons depicting a child character stating "My stomach hurts!" The child wrote in thoughts and feelings, as well as active coping strategies (e.g., "1, 2, 3—breath in, breath out", "Should I go to the nurse or do my relaxation? I should do my relaxation—breathe, breathe", and "I should be fine. I'm not going to throw up because I'm just nervous, so I should be fine"). There was homework assigned following each session, providing additional practice of skills learned and reviewed in the session. Either one postdoctoral fellow who also served as the project coordinator or a predoctoral psychology intern facilitated the sessions. The principle investigator, project coordinator, and psychology predoctoral intern met at regular intervals to review the treatment of all study participants and effective implementation of the treatment goals. The specific goals and activities for each session were discussed and reviewed prior to the session, and the responses of participants were also reviewed following each session to ensure consistent implementation of the protocol, yet allow for some individual case flexibility.

Data Analysis

All dependent variables were measured on the interval level. The number of visits to doctors' offices and physician phone contacts, and the number of school absences were each evaluated on one occasion, at 12 months following study entry. Therefore, the two variables were compared using independent samples t tests. All other dependent variables were obtained on three occasions: (a) immediately after consent and prior to initiation of the active intervention (i.e., at baseline), (b) at the conclusion of CBT treatment (i.e., 3 months following baseline), and (c) 6–12 months following study entry.

Despite randomization, significant differences were present between groups at baseline for the Parent ver-

sion of the CSI, $t = 1.98$, df (67), $p = .05$, with higher scores in the SMC group. Therefore, to be consistent, data obtained on three occasions were all evaluated using repeated measures analyses of covariance (ANCOVA). Separate repeated measures ANCOVAs were completed for the Parent version of the CSI, the Child version of the CSI, the Parent version of the API, the Child version of the API, and the FDI. In each instance, pretest scores served as covariates to offset the impact of initial group differences. Given the final sample size, it was not possible to examine differential intervention effects by blocking on children's age, gender, and parent education. Therefore, the three demographic variables were also included as covariates with the pretest scores. The net effect was to equate groups on pretest scores, children's ages, genders, and parent education levels. The use of parent education as a covariate was necessitated by its significant correlation with the Parent version of the CSI ($r = -.260$, $p = .043$). Parent education did not correlate significantly with the Child version of the CSI, the Parent or Child versions of the API, or the FDI (all ps ≥ .05). Nevertheless, to be consistent parent education was utilized as a covariate in all the repeated measures ANCOVAs.

Dependent variables were adjusted posttest scores obtained 3 months and again 6–12 months following study entry. The initial goal was to evaluate all participants at 6 months and then again at 12 months subsequent to study entry. However, there was unintended variation in obtaining follow-up data at precisely these intervals, as well as some missing data at either 6 or 12 months follow-up. Rather than discard cases, and further reduce statistical power, it was decided to group the 6 and 12 month follow-up periods together and create three data assessment points (baseline, 3 month, and 6–12 months). Eighty-two percent of participants completed the 12-month follow-up.

Clinical significance was assessed for the repeated measures ANCOVAs by using two methods. The first comprised the interpretation of standardized parameter estimates (i.e., B coefficients). The B coefficients allowed the rate of change to be compared between the SMC and SMC + CBT groups across time from baseline to 3 months, and again, from baseline to 6–12 months following study entry (Tabachnick & Fidell, 2001). Second, a Number Needed to Treat (NNT) analysis was completed for each statistically significant outcome (Cook & Sackett, 1995). The larger an effect, the smaller the NNT and the fewer individuals that will need to be treated to see a positive outcome.

Two power analyses were performed. Each concentrated on the least powerful contrast (i.e., either the independent-samples t tests or the between groups

comparisons at any one-time point for the repeated measures ANCOVAs). First, a priori power was evaluated. Assuming two-tailed p = values (Faul & Franz, 1992), a medium effect size (d = .50, as per Cohen, 1988) and power = .80, the analysis revealed that 51 participants were required for each of the two groups. However, 51 participants in each group were not available at the end of the study, as greater than expected seasonal variation in the presentation of RAP (low incidence during winter months) decreased participant recruitment during our funding period. A second power analysis was conducted after the data collection and prior to initiation of the primary analyses. Respective sample sizes were 29 for the SMC control group and 40 for combined SMC + CBT intervention. Here too, the power analysis employed two-tailed p = values. Expected differences were estimated using large, medium, and small effect sizes (d), where a large d = .80, a medium d = .50, and a small d = .20. Results showed power = .90 for large effect sizes, .52 for medium effect sizes, and .13 for small effect sizes. Consequently, the study was sensitive to large between-group differences because the probability was greater than 80% that obtained sample differences would hold true for the population.

Results

Means for variables measured on three occasions are presented in Table III. Observed scores are reported for baseline performances. Both unadjusted (observed) and adjusted (covaried) means are reported for variables evaluated 3 months following baseline and at 6–12 months following study entry.

Examination of mean scores suggests changes in levels of abdominal pain, somatization, and functional disability across both the SMC and SMC + CBT groups at 3 months and 6–12 months following study entry, in the predicted directions. Both SMC and combined SMC and psychological interventions reduced child and parent reported pain and somatization, as well as child reported functional disability.

No effects (Group, Time, or Group × Time) were significant for the repeated measures ANCOVAs directed to the FDI or the Child and Parent versions of the CSI. Alternatively, the main effect for Group was significant for both the Parent and Child versions of the API, respectively, F = 4.05, df (1, 46), p = .04 and F = 4.41, df (1, 45), p = .04. As a consequence of employing baseline scores as covariates, Group × Time interactions were unlikely to reach statistical significance for any of the repeated measures ANCOVAs.

An examination of adjusted means 3 months and 6–12 months following study entry (Table III) indicated that on both occasions the SMC + CBT group obtained lower scores on the Parent version of the API. Standardized parameter estimates were used to judge the clinical significance of the findings. The B coefficients indicated that the rate of change was 4.5 points between groups on Parent APIs at 3 months following study entry and 4.2 points at 6–12 months following study entry. Both effect sizes were large. For instance, at 3 months following baseline, the effect size reveals that for every one point obtained by SMC + CBT group on the Parent version of the API, the SMC group received 4.5 points. Therefore, the SMC + CBT group reported significantly less child abdominal pain at 3 months following baseline. The effect also was maintained at 6–12 months following study entry. For every one point obtained by SMC + CBT group on the Parent version of the API, the SMC group received 4.2 points. In addition, clinical significance was

Table III. Unadjusted and Adjusted (Covaried) Scores by Time and Group

	Time									
	Baseline		Immediately After Treatment				6–12 months After Baseline			
	SMC	SMC + CBT	SMC		SMC + CBT		SMC		SMC + CBT	
Variable	Observed Mean	Observed Mean	Observed Mean	Adjusted Mean[a]	Observed Mean	Adjusted Mean[a]	Observed Mean	Adjusted Mean[a]	Observed Mean	Adjusted Mean[a]
FDI	24.0	24.8	18.9	18.9	18.2	18.3	19.9	19.4	18.8	19.1
CSI parent	19.3	14.1	12.4	10.7	8.1	9.2	10.5	8.6	6.7	7.8
CSI child	22.4	16.3	13.9	11.9	7.9	9.1	13.3	11.8	8.5	9.4
API parent	27.9	24.7	21.3	20.2	14.9	15.7*	22.0	20.7	15.8	16.5*
API child	24.1	20.7	20.4	19.5	15.5	16.2*	22.2	21.2	15.0	15.7*

SMC = standard medical care, SMC + CBT = standard medical care and cognitive-behavioral treatment, FDI = Functional Disability Inventory, CSI = Child Somatization Inventory, and API = Abdominal Pain Index.

[a]Adjusted means represent a group's mean after the baseline score, age, gender, and parent education were covaried.

*p < .05.

assessed though an NNT analysis. The NNT comparison showed that one in every three children exposed to the SMC + CBT treatment benefited on the Parent version of the API (95% confidence limit = 1.6–7.8).

With respect to scores from the Child version of the API, adjusted means (Table III) indicate that the SMC + CBT intervention group obtained significantly lower scores across occasions. Clinical significance was also evaluated for results from the Child version of the API. *B* coefficients revealed that the rate of change was 3.4 points at 3 months following study entry in favor of the SMC + CBT group and 5.4 points at 6–12 months following study entry. Therefore, results across both the Parent and Child versions of the API were uniform in supporting the effectiveness of the SMC + CBT intervention in reducing sensory aspects of child pain. In each instance, the effect sizes were large and they were maintained for up to a year past study entry. Like that for the Parent version of the API, the NNT showed that one in every three children in the SMC + CBT condition benefited on the Child version of the API (95% confidence limit = 1.4–4.4). Consequently, as measured by both the Parent and Child versions of the API, the intervention was considered to be successful because the ratio of improvement was one for every three participants treated. For the Child version of CSI, neither the main effect for Time, Group, nor the Group × Time interaction was significant during the repeated measures ANCOVA.

For variables measured once at 12 months following study entry, the independent-samples *t* test was not statistically significant for the total number of visits and phone calls to doctors' offices, *t* = 0.15, *df* (67), *p* = .881. However, it was significant for the number of school absences, *t* = 2.04, *df* (67), *p* = .047. A comparison of means revealed that children in the SMC + CBT intervention group were absent from school less often than those in the SMC control group (respectively, *M* days = 9.0 vs. 14.5).

It is recommended that randomized control trials be analyzed according to an intention-to-treat (ITT) basis (Sabin, Lepri, & Phillips, 2000). The analyses were repeated according to ITT and showed no differences.

Discussion

The purpose of this study was to better understand the effectiveness and efficiency of medical and behavioral health services in the treatment of pediatric RAP. A randomized controlled design was utilized to assess the impact of a five-session CBT on the sensory and cognitive reduction of pain, in addition to school attendance

and utilization of health care services. Results suggested that children and parents participating in the combined intervention group reported significantly less abdominal pain, as measured by the six dimensions of pain assessed by the API, following intervention and again at 6–12 months follow-up. In addition, children participating in the combined intervention group demonstrated significantly fewer school absences. No differences were found between the SMC + CBT intervention group and the SMC control group on three of the five dependent variables measured on multiple occasions: child reported functional disability, and child and parent reported child somatization. There were no differences found with respect to physician contacts as well.

The most consistent outcome took place for the API where results from both the child and parent versions indicated less overall pain within the SMC + CBT intervention group. The API is a multidimensional measurement of pain, and includes items assessing frequency, duration, and intensity of abdominal pain. These results are consistent with those previously reported (Sanders et al., 1994) and lend additional support to the efficacy of a CBT intervention in addressing pain symptoms, over a 6–12 month follow-up period, over SMC alone. Furthermore, these results closely parallel empiric research examining behavioral treatments for another commonly occurring pediatric pain disorder, recurrent pediatric headache, as psychological treatments were seen to significantly reduce reported pain in headache samples (Holden, Deichmann, & Levy, 1999).

Neither the child nor parent report CSI demonstrated significant differences between groups as a result of the SMC + CBT intervention. The CSI assesses being bothered by a wide range of somatic symptoms. It is possible that the sample size affected the child CSI result, as it appears to be a small effect size and the current study was sensitive to large but not small effect sizes. There is evidence to suggest that older children and adolescents may be the best reporters of internal phenomenon (Kamphaus & Frick, 2002), particularly when these phenomenon are more mild, and hence parents might not have been aware of their child's experience of somatic symptoms not involving RAP.

The child report FDI did not demonstrate significant differences between groups as a result of the SMC + CBT intervention. One possible explanation lies within the restricted range of responses obtained on this instrument (possible range 15–75; total sample observed scores = 18.7–24.8). The majority of items on the FDI are related to activities of daily living. Children at baseline, despite significant pain reports, did not endorse significant

functional impairment as measured by this instrument. On the other hand, the CBT intervention focused on the perception of and ways of coping with pain. Thus, instruments assessing pain beliefs and use of relevant coping strategies might have been more revealing.

In an era of both increased accountability and efforts toward community based intervention, integration of treatment across health care systems is a potentially powerful paradigm (Power, DuPaul, Shapiro, & Kazak, 2003). Furthermore, there is a need to document the "cost-benefits" of pediatric psychological interventions to be compatible with the changing economics of health care delivery (Rae, 1998). Some outcome studies have demonstrated a medical cost-offset effect, even when the cost of providing the psychological intervention was taken into account (Chiles & Lambert, 1999). Although both groups participating in the study evidenced reductions in pain, these results suggested that combined medical and behavioral health intervention reduced child pain better than standard medical intervention alone. It can be argued that behavioral intervention for this commonly occurring functional pain disorder in children may prove to be economically feasible as well. The NNT comparison showed that three children needed to be exposed to the SMC + CBT treatment for one child to benefit. Although this CBT intervention would have added approximately $500 per participant in direct costs within the first 3 months of treatment (5 sessions at $100 per session), there were indirect cost savings through significantly reduced school absences, possibly translating to reduced parent work absences and hence increased job productivity. On the other hand, decreased medical care utilization through reduced physician contacts over one year was not demonstrated, contrary to the results of a previous study (Finney, Riley, & Cataldo, 1991).

There are a number of important limitations to note. Unintended bias may have been introduced into the study. For example, using a coin flip randomization procedure may have introduced selection bias—that is, the groups may have differed in measured baseline characteristics (such as parent education) because of the way participants were assigned (Altman et al., 2001). The sample size also limited the ability to detect small and medium between-group differences. Some potentially useful analyses, such as gender affects, as well as differences in children in each group who were significantly improved, were not practical due to the limited sample size. Loss of participants and unintended variation in collecting data precisely at 6- and 12-month follow-up made it advisable to collapse 6- and 12-month follow-ups into a single 6–12-month follow-up. Although our previous research suggested that children referred by pediatric gastroenterologists had higher self-reported pain levels at baseline than children referred by community physicians (Robins, Smith, & Proujansky, 2002), we were not able to examine this Group × Sample × Time issue due to limitations in sample size.

There are a number of future directions suggested by the study results. We were unable to determine if the CBT intervention resulted in reduced medication use, as this variable was dropped early in the study because of challenges in accurately tracking in-home medication use. Although many children were prescribed medication secondary to their reports of stomach pain, qualitative follow-up revealed that the medication was not at all consistently utilized, within both the SMC and SMC + CBT groups. Future research might include medication use as an outcome variable, utilizing improved reporting methodology, such as a daily electronic diary (Walker & Sorrells, 2002). In addition, there is data to suggest that drop-in group appointments and other community based health care interventions are effective (Noffsinger et al., 1999). It would thus be useful to know whether this protocol could be administered in a community setting, for example, primary care office, school, or community center, involving groups of parents or children, thereby further reducing cost as well as barriers to care. More frequent data collection, again utilizing available electronic technologies, would increase both the reliability of the follow-up data as well as inform us about the nature of change in this sample. Finally, it would be instructive to learn from participants what they thought were the most effective components of the treatment package.

Together, these results suggest that empirically grounded psychological interventions for RAP in pediatrics, although perhaps adding to short-term financial cost, could add value within a framework of integrated services. Assessing consumer (physician, parent, and third party payer) acceptability of psychological interventions for commonly occurring pain disorders in pediatrics is a necessary next step to help bridge the gap between accumulating evidence from clinical trials and current standards of care.

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