Commentary: Conducting Randomized Controlled Trials of Psychological Treatment to Improve the Outcomes of Recurrent Abdominal Pain: Contributions and Challenges

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Contributions of this RCT

In this issue, Robins and colleagues presented the results of a randomized controlled trial (RCT) that documented the efficacy of cognitive behavioral treatment (CBT) for reducing the frequency of pain and school absences in a group of children with recurrent abdominal pain (RAP). This is an important clinical population for several reasons: (a) relatively large numbers of children and adolescents are affected with RAP (Campo, Jansen-McWilliams, Comer, & Kelleher, 1999); (b) RAP has significant functional impact on children's school, physical activities, and health care utilization (Wasserman, Whittington, & Rivara, 1988); and (c) RAP persists into adulthood among a relatively large percentage of patients (Walker, Guite, Duke, Barnard, & Greene, 1998). Despite its clinical importance, RAP is a complex condition that is very difficult to manage within current models of medical treatment (Tarkan, 2004). Although RAP commonly presents to primary care physicians and pediatric gastroenterologists as a “medical” condition, this condition reflects a heterogeneous constellation of symptoms with a multifactorial etiology (e.g., somatic lifestyle, critical life events, learned response patterns, and family environment) and does not typically improve with medical treatment alone (Friedrich & Jaworski, 1995). This is also the case for other pediatric conditions that involve recurrent pain, for which psychological treatments are emerging as effective front line interventions. However, as Eccleston, Morley, Williams, Yorke, and Mastroymnnpoulos (2002) have highlighted, few RCTs have evaluated psychological treatments for nonheadache chronic pain in children, and available trials have had significant limitations, including the failure to assess nonpain-related outcomes such as functioning, mood, and quality of life. Robins et al. have addressed this need by using a short-term five-session model of family centered CBT that replicated and extended previous work by Sanders, Shepherd, Clegorn, and Woolford (1994).

One clear strength of this study is the potential clinical relevance of the treatment, which is brief, focused, manualized, and reproducible. One guiding principle of the intervention approach was a social learning conceptual model of RAP that fits well with current scientific knowledge of the importance of family reinforcement in influencing children's experience of pain and subsequent disability (Chambers, 2003). The intervention was designed to interfere with the vicious cycle of maladaptive family interactions (e.g., the child's maladaptive response to pain and the response of family members to the child's symptoms) (Friedrich & Jaworski, 1995; Kazak, Simms, & Rourke, 2002) by combining conjoint parent-child sessions and individual sessions with children. Based on data from empirically supported interventions (Sanders et al., 1989, 1994; Janicke & Finney, 1999) and studies of influences on the functional impact of abdominal pain (Walker et al., 1998), sample themes of individual sessions included education concerning recurrent pain and its antecedents and consequences, education and practice in pain management, cognitive strategies to reduce catastrophizing, and increasing adaptive communication and partnership between parents and children. The emphasis on reducing negative functional consequences of RAP was a particularly salient feature of this intervention.

To evaluate their intervention model, Robins et al. used a comprehensive measurement approach based on multiple sources (e.g., parent and child) and methods (subjective self-report and objective data) that included...
outcomes such as the intensity, frequency, and duration of abdominal pain, the perceived interference of pain with activities of daily living and the impact of the intervention on school attendance and health care utilization. This comprehensive measurement approach was necessary to detect differences in the frequency and intensity of RAP symptoms as well as the functional impact of such symptoms. Changes in symptoms of RAP (or other conditions involving recurrent pain) do not necessarily result in changes in functional impact and vice versa (Palermo, 2000). Children with RAP can present with very different profiles of pain frequency and intensity in relation to functional impact. For example, some children with frequent pain and high intensity pain may demonstrate surprisingly high levels of functioning at home and at school. On the other hand, children who demonstrate relatively mild RAP may have great difficulty functioning in day-to-day activities, in school, and so forth.

In fact, the outcomes that were assessed by Robins et al. were not equally sensitive to changes in response to psychological intervention. For example, contrary to hypotheses, no differences were found in children’s functional disability or somatization but were found in pain symptoms and school absences. One intriguing question is: Why were intervention differences found in one area of functioning but not in others? One reason may be that the different target outcomes (e.g., pain management and symptom reduction, school absence, activity limitation in response to RAP) involve very different demands, skills, and role expectations to achieve optimal functioning. Consequently, different areas of functioning could be affected differently by a similar intervention approach.

Methodological and Logistical Challenges

The considerable accomplishments of the study by Robins et al. should be considered in the context of the extraordinary methodological and logistical challenges of conducting RCTs with children with RAP and their families. For example, in implementing their research, Robins et al. faced a number of relevant logistical challenges. One of these was the challenge of developing a strong collaboration with pediatric gastroenterologists as well as community primary care practices, to encourage referrals to the study (Robins, personal communication, September 23, 2004, Cleveland, Ohio). Such collaborative relationships are increasingly important to the conduct of psychological research, given the Health Insurance Portability & Accountability Act of 1996, because physician contact with the family is necessary to introduce the study to families and meet ethical obligations related to protected health information.

Another important logistical issue in this study concerned engaging and sustaining families in the intervention. Some families, especially those with multiple stressors, could not attend the intervention visits, even when they were contacted multiple times (Robins, personal communication, September 23, 2004, Cleveland, Ohio). Other families did not trust the label of “psychological” intervention but descriptions of “pain management coping and coaching” proved to be acceptable. In addition, a number of families were more interested in the psychological intervention arm than they were in standard care. Although they agreed to be randomized to either arm of the study, they dropped out when they received the standard care intervention, which can be a problem in RCTs of psychological intervention (Schwartz, Chesney, Irvine, & Keefe, 1997).

The documentation of standard or usual customary care (e.g., the number and duration of visits, specific medical interventions, and type of education and support) is always a difficult challenge in any RCT (Schwartz et al., 1997) as it was for Robins et al. In fact, the specific parameters that defined standard care in Robins et al.’s RCT were not clear, and individual variation in the parameters of standard care was not described. Standardized forms that document visits from chart review or computerized records would help to improve the description and documentation of standard care or treatment as usual in RCTs of psychological interventions.

Assessment of treatment or intervention fidelity is another important aspect of RCTs (Bellg et al., 2004). Such assessment can determine whether the psychological intervention was delivered in accord with the hypothesized model consistently across the duration of the trial and whether children and families adhered to the intervention protocol (Bellg et al., 2004). Because Robins et al. did not describe treatment fidelity, the level of engagement, participation, and use of strategies by children and parents in the CBT condition could not be ascertained. Hypothesized intervention effects were obtained for some outcomes provides presumptive evidence for treatment fidelity. It would be unlikely for the intervention to demonstrate such effects if the intervention was not delivered effectively. Nevertheless, it is possible that the power of the intervention to influence different outcome domains was weakened by less than optimal treatment. Moreover, although work with parents was an integral component of the CBT condition, no formal assessment of parental responses toward their children’s pain behaviors either at baseline or after intervention was obtained.
For this reason, we do not know whether this component of treatment was effective in changing parental styles of reinforcement in response to pain and pain-related behaviors. Such parental behaviors would be important to assess in future studies of family CBT with children with RAP.

Despite the comprehensiveness of Robins et al.'s measurement plan, several potential limitations in the choice of specific assessment tools to measure intervention effects should be noted. For example, the use of a retrospective pain index, rather than a prospective description of pain, is potentially problematic as this may not accurately reflect the level of pain actually experienced by children. Retrospective measures of pain require children to average or summarize their ratings and introduce potential bias in their reports. In contrast, prospective measures of pain, particularly using newer methods such as electronic pain diaries have proven to be feasible, reliable, and valid for measuring the experience of chronic and recurrent pain in children (Palermo, Stork, & Valenzuela, 2004). In addition, the Functional Disability Inventory (Walker & Greene, 1991), which was used to assess functional impact of RAP, may not have been sensitive to intervention effects because of a restricted range. For this reason, there is a need to develop measures that are sensitive to functional impairments specifically related to chronic or recurrent pain in children (e.g., Palermo, Witherspoon, Valenzuela, & Drotar, 2004).

Another set of measurement challenges in RCTs of psychological interventions in pediatric pain includes documentation of cost-effectiveness and cost-offset of psychological interventions. Although Robins et al. did not find significant treatment effects on health care utilization, there are other potential methods of documenting time and economic costs that can be used in pediatric pain intervention trials. For example, descriptive studies have documented a wide range of costs to families of children with chronic pain including other types of health care use (e.g., emergency room visits, doctor visits, complementary therapy approaches, etc.), time off from parental work schedule, and parking, gas, and child care expenses to attend clinic appointments (Bennett, Huntsman, & Lilley, 2000).

Analyses of data from a prospective RCT such as that conducted by Robins et al. present another challenge. The authors are to be commended for testing the clinical significance of intervention effects by using a number-needed-to-treat analysis (Cook & Sackett, 1995; Tabachnick & Fidell, 2001). Assessment of clinical significance is often omitted in studies of psychological interventions with pediatric populations (Drotar & Lemanek, 2001). Analysis of the number needed to treat noted that one in three children needed to be exposed to the combined intervention to benefit from it. In general, the intervention yielded large effect sizes for reducing abdominal pain, and these improvements were maintained up to a year, which is impressive. On the other hand, the sample size limited the tests of individual differences in treatment response such as whether family CBT is more effective with a specific age group or gender. Finally, it should be noted that the use of analysis of variance to assess intervention effects in this prospective study has disadvantages compared to hierarchical linear modeling approaches, including limited description of individual differences in change over time and assumptions of comparable number and timing of measurements across subjects, which is not realistic for many studies of psychological intervention (Weinfurt, 2000).

Our critique of Robins et al.'s important RCT suggests several recommendations for future research concerning psychological interventions for RAP in pediatric populations. One recommendation would be to replicate the family CBT intervention model in different settings. Ultimately, the application of psychological interventions such as this to larger numbers of patients in a range of clinical settings will be important but is clearly a tall order. To enhance generalizability of intervention effects, documenting the most powerful ingredients of the CBT intervention used by Robins et al. will be important. Because the multiple components of CBT were utilized in a comprehensive package in the present study, it was not clear which of the specific components were necessary and sufficient to achieving clinically relevant reductions in abdominal pain and functional impact. It is possible that nonspecific interventions of support and education were the most powerful determinants of the treatment effects as opposed to the specific cognitive behavioral components of the intervention model. Consequently, additional research will need to clarify the source of the effect. But one intervention study, even an excellent one, can only do so much in developing the scientific state of the art in a particular area of research. Robins et al. have helped to set a benchmark for RCTs of psychological interventions for RAP for others to attain and if possible, exceed.

Received October 13, 2004; accepted October 22, 2004
References


