Commentary: The Journal of Pediatric Psychology Should Adopt the CONSORT Statement as a Way of Improving the Evidence Base in Pediatric Psychology

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The CONSORT statement (www.consort-statement.org) was developed to improve standards of reporting of randomized clinical trials (RCTs) in medical journals. It currently includes 22 items used by reviewers and editors to ensure consistent and full reporting of the results of an RCT. It also aids researchers in the plan and execution of RCTs. The Journal of the American Medical Association was one of the first journals to adopt the CONSORT items as guidelines to ensure quality reporting of RCTs; since that time over 80 medical journals have adopted these standards for the reviewing and reporting of RCTs. Recent reviews of the quality of RCT reporting have demonstrated that the introduction of the CONSORT statement has a demonstrable impact on the completeness of reporting in numerous medical journals (Moher, Jones, & Lepage, 2001).

Neither psychology as a field nor subspecialty areas of psychology have yet adopted CONSORT guidelines for the review and publication of RCTs. Division 12 (Society of Clinical Psychology) Task force on Promotion and Dissemination of Psychological Procedures of the American Psychological Association (Chambless et al., 1996) began reviewing evidence on psychological interventions and enjoined researchers to report their RCT results completely, so that evidence-based recommendations could be forwarded. Yet perennial concerns about the quality of reporting in psychology of evidence-based material available for review remain (Chambless & Ollendick, 2001). As outlined in the accompanying article (Stinson et al., this issue), most of the clinical trials published in the Journal of Pediatric Psychology (JPP) already meet some of the 22 CONSORT criteria. However, many important items are reported only infrequently or not at all. In fact, of the 22 items, 14 items were identified as reported in less than 25% of the trials in JPP between 1998 and 2001. Although this seems troubling, other psychology and behavioral medicine journals likely fare no better, and may fare worse (Davidson et al., in press).

The CONSORT statement was devised for medical interventions and thus might be considered inappropriate for the reporting of psychological interventions. However, as noted by Stinson and others, all CONSORT items can be reported by psychosocial interventions, and only one item—successful blinding of treatment provider and participants—is difficult to attain. Interestingly, the reporting of the blinding status is attainable by psychosocial interventions; the presence or absence of the report of blinding meets or does not meet the CONSORT criteria, not the success of these procedures. It is of course possible, and highly desirable, to successfully blind the major assessor of the outcome of the RCT, and the test of the success of the blinding plan for assessors is not regularly reported in psychosocial RCTs.

The CONSORT guidelines are strongest in reporting on key threats to internal validity; however, the CONSORT guidelines have been criticized for their relative inattention to external validity (Glasgow, McKay, Piette, & Reynolds, 2001). Only one vague item of the CONSORT asks for information on generalizability. On the other hand, 21 items request concrete, tangible report of internal validity issues. Some have argued for the augmentation of the CONSORT guidelines, with reporting criteria focused more exclusively on external validity issues (Glasgow et al.). The representativeness of the setting, the sustainability of the intervention from the point of view of the caregiver and the patient, will effect eventual practice change and should be essential for effectiveness studies. Moreover, the CONSORT criteria do not address clinical versus statistical significance.

In addition, the CONSORT criteria, though reasonable, are not sufficient to cover the unique reporting needs for psychosocial interventions. The Evidence-Based Be-
behavioral medicine (EBBM) Committee of the Society of Behavioral Medicine has proposed five additional CONSORT items for the review and reporting of psychosocial interventions (Davidson et al., in press; see Table I).

Intervention fidelity is presumably higher in medical interventions than in psychosocial interventions. Because of the regulations governing manufacture of drugs, for example, a dose of 10 mg of morphine should be the same for a 10-year-old child in Seattle or an older adult in Halifax. The same cannot be stated about cognitive behavioral therapy or other psychosocial interventions. The CONSORT statement (Item 4) does ask for the “precise details of the interventions intended for each group and how and when they were actually administered.” But more detail about provider fidelity, patient adherence, treatment allegiances, and training and supervision of the providers should be reported for psychosocial interventions. This level of description is not unusual in pediatric psychology interventions and is consistent with the Chambless criteria for empirically supported psychological interventions (Chambless & Ollendick, 2001).

The adoption of the 22-item CONSORT statement and the EBBM five additions by JPP would have four major beneficial outcomes. First, the CONSORT statement will help investigators improve the quality of the conduct of clinical trials in pediatric psychology because it will guide their attention to important details including randomization generation, report of blinding status and success, and the collection of adverse events. Second, important details that are currently omitted will be reported in a standard way for readers of JPP, facilitating comprehension of these reports. Third, trials will be more easily retrievable through electronic searches, aiding practitioners in their efforts to provide evidence-based practice to their patients and clients. Fourth, it will be easier for investigators conducting systematic reviews and meta-analyses to retrieve the needed data from each article.

The adoption of the CONSORT will not remedy an important issue, namely, the small number of RCTs (an average of fewer than 5 per year) published in JPP. The journal does not appear to be responsible for this low rate of RCT publication, and it may reflect the paucity of trials in pediatric psychology evident in the series on empirically supported therapies in JPP (Spirito, 1999). However, special efforts to highlight RCTs by means of a special section on RCTs or accompanying each RCT with a commentary might be useful. Priority publication that reduced time to publication might help attract more RCTs to the journal. A phase-in of the CONSORT as a requirement for the journal during which the CONSORT was recommended but optional and education of authors and reviewers would make the introduction of this change easier.

JPP should adopt the CONSORT statement and the five EBBM items for all clinical trials published. Few will dispute the need for improvement in the reporting of psychosocial interventions. The CONSORT statement will not remedy all the current limitations of how RCTs are planned, conducted, and reported. However, it provides an opportunity for the journal to improve the quality of clinical trials in our field, as well as the quality of the reporting and, consequently, the quality of systematic reviews. And, most important, improved methodology of trials is necessary to determine the best interventions for the children whom we serve.

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References


Table I. Additional Behavioral Medicine Intervention Reporting Criteria

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<thead>
<tr>
<th>Paper section and topic</th>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>Results</td>
<td>23</td>
<td>Manner of testing and success of treatment provider fidelity. (N/A okay)</td>
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<tr>
<td>Results</td>
<td>24</td>
<td>Patient adherence. (N/A okay)</td>
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<tr>
<td>Results</td>
<td>25</td>
<td>Patient and therapist treatment allegiance or preference. (N/A okay)</td>
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<tr>
<td>Methods</td>
<td>26</td>
<td>Training of treatment provider(s). (N/A okay)</td>
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<tr>
<td>Methods</td>
<td>27</td>
<td>Supervision of treatment provider(s). (N/A okay)</td>
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