Commentary: Randomized Controlled Trials of Psychological Interventions with Pediatric Populations: The Time has Come and the Journal of Pediatric Psychology is Ready

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The field of intervention research in pediatric psychology has evolved to the point that there are a sufficient number of controlled clinical trials, especially randomized controlled trials (RCTs), to warrant a special ongoing section of the Journal of Pediatric Psychology (JPP) that will be devoted to this topic. There will be a rolling deadline for this section so that manuscripts can be submitted at any time. We are optimistic that an ongoing section of this Journal will serve not only to highlight RCTs of psychological interventions but also to stimulate publication of the results of RCTs for psychological interventions, which are very much needed in the field of pediatric psychology (McGrath, Stinson, & Davidson, 2003). One reason to develop this special section of the Journal is that controlled intervention studies, especially RCTs, raise difficult methodological, practical, and ethical challenges that need to be considered by researchers, reviewers, and editors.

To address this need, the purpose of this special section will be to publish original work in any of the following areas: (a) New data from RCTs of psychological interventions, including preventive interventions, conducted with a range of pediatric populations; (b) Key methodological and data analytic problems involved in RCTs and examples of approaches to their solution; (c) Relevant logistical problems in conducting RCTs in pediatric settings and examples of innovative approaches to their solution; (d) Critical ethical issues in conducting RCTs with pediatric populations and potential approaches to their solution; and finally, (e) Theoretical contributions that relate to development of RCTs with pediatric populations. Relevant manuscripts will include data concerning the results of RCTs, critical reviews, and descriptions, including brief reports concerning pilot and feasibility studies, innovative methodologies and statistical approaches that are applicable to RCTs.

As recommended by McGrath et al., (2003) and Stinson, McGrath, & Yamada, (2003), empirical reports of data from RCTs that are submitted to this special section will be expected to conform to the CONSORT statement criteria developed to improve standards of reporting RCTs in medical journals (Altman et al., 2001) and with the five additional CONSORT items that have been proposed for review and reporting of psychosocial interventions (Davidson et al., in press; McGrath et al., 2003; Stinson et al., 2003). The CONSORT criteria were designed to accomplish the following: (a) Improve the quality of the conduct of clinical trials by guiding investigators’ attention to important details including the method of randomization, report of blinding status etc.; (b) Provide important details to be reported in a standard way for readers of journals such as JPP, and facilitate comprehension of these reports by readers; (c) help to make the published data from RCTs more easily retrievable, thus increasing the ease of conducting systematic reviews and meta analyses from articles that report RCTs.

It is fitting that Stark and colleagues’ report of RCT designed to increase calcium (CA) intake in children with juvenile rheumatoid arthritis (JRA) is the publication that launches our special section. This study has a number of important features. First of all, it is a prevention-focused intervention research that was designed to enhance bone mass density in children with JRA who, similar to other children with chronic health conditions such as cystic fibrosis and Crohn’s disease are at greater risk of low bone mass density and hence onset of osteoporosis earlier in their development (Mackner, McGrath, & Stark, 2001). Despite its importance to the field, prevention-focused intervention research has not received sufficient attention in published work in JPP (Kazak, 2002; La Greca, 1997; Roberts, 1992). To address this need,
Stark and colleagues have designed an interesting and well-thought-out intervention model. This six-sessi
behavioral intervention involved parents and children in separate groups. In their group, parents were provided
with nutritional information and child behavior management strategies that were focused on motivating chil
ren to eat foods presented to them and reach their goals for calcium intake. Parents were given feedback via
graphs of their children’s average CA intake at each meal and total CA intake per day during previous weeks,
information about strategies to increase their children’s CA intake, and individualized suggestions concerning
ways to incorporate high CA foods into their children’s diets.

One important feature of this intervention model was that educating parents concerning the need to enhance
their children’s CA intake was accompanied by behavioral management skills to assist them in motivating
their children to make changes in their diet. These strategies included use of rewards and differential attention,
identification of rules and consequences for mealtimes, contingency management, and problem-solving to assist
parents in managing barriers to the implementation of consumption of high CA foods and meeting daily CA
goals. The integration of behavioral management strategies with parental education is important because it is
often very difficult for parents to modify their children’s diets and enhance their nutritional status, even when this
enhances their children’s health (Mackner et al., 2001).

Children were also educated concerning the importance of a high CA diet and how to identify high CA foods.
One interesting feature of the child-focused intervention was the use of an in vivo practice meal at each treatment
session that required children to consume their CA goal for that meal to obtain a reward. Children were also taught
behavioral methods such as differential attention and shaping and the use of sticker charts to monitor progress.
Engaging both parents and children in interventions designed to establish healthy behavior concerning food
intake may be more powerful in maintaining intervention effects than interventions that involve either parents or

One noteworthy feature of the methods employed by Stark and colleagues was tracking of parental adherence
to the behavioral protocol by assessing the accuracy of the parents’ rewarding and withholding of stickers on
their children’s sticker charts. Such monitoring of adherence is an important but often overlooked feature of
psychological intervention trials. Parents and children do not necessarily follow through with psychological
intervention protocols, which can be demanding. For this reason, nonadherence is one of the reasons that
psychological interventions may not work. However, investigators would not be able to detect the potential
impact of nonadherence to psychological intervention protocols unless they plan a method to accomplish this.

Another strength of Stark and her research team’s study was the investigators’ plan to enhance the integrity of the intervention by: (a) Providing treatment manuals for each intervention and separate manuals for parent and child groups of the behavioral intervention; (b) Extensive training of interventionists via role playing; and (c) Weekly supervision throughout the project that included review of videotaped treatment sessions. Such safeguards designed to enhance the integrity of psychological interventions are necessary because multifaceted psychological interventions are challenging to implement.

However, even if investigators use methods to enhance the integrity of psychological interventions that are delivered, this will not necessarily prevent change or drift in treatment integrity over time that can weaken intervention effects. For this reason, another useful method would have been to include a direct evaluation of how the treatment was delivered. One way to do this, which is time intensive and expensive, is to have raters who are unaware of the group assignment review either audio or videotapes of the sessions in accord with a predetermined schema that summarizes the critical components of the intervention. Such data can document the delivery of key components in treatment versus comparison groups, the potential overlap or contamination of interventions across groups, as well as the consistency of intervention delivery over time. Such documentation is important irrespective of the outcome of the study. In the event of a successful intervention, it can be useful to document individual differences in the relationship of treatment fidelity to outcomes (e.g., to test whether the fidelity of the intervention moderates the effects). On the other hand, if an intervention is not found to be effective, one potential explanation and clear threat to internal validity of the study could be problems in treatment fidelity (e.g., less than optimal implementation of the planned intervention) or overlap in the treatment delivered in the intervention group and with the control group.

In designing their successful RCT, Stark and colleagues faced and met a number of challenges, all of which are part and parcel of conducting RCTs of psychological interventions. Not surprisingly, a key challenge concerned participant recruitment. Recruitment of participants in such studies is especially critical given the available pool of children and adolescents with chronic
illnesses at individual sites are limited. Moreover, in most studies the available pool of participants is whittled down by exclusionary criteria and some families of children with chronic illnesses do not attend clinic regularly and hence are much less available for participation in intervention studies. The issue of clinic attendance and access to care may selectively limit the participation of important groups such as ethnic-minority children and adolescents with chronic illnesses who face substantial barriers to care (Brown, Fuemmeler, & Forti, 2003). In fact, Stark and colleagues found that only a minority of potentially eligible children and their families participated in their study. Based on research with other chronic illness populations, one would anticipate that the families of participants would be both more motivated and higher functioning than nonparticipants (Riekert & Drotar, 1999). For this reason, the generalizability of Stark and colleagues’ approach to broader populations and to clinical care settings needs to be established, which is generally the case in RCTs that are delivered in a rigorous fashion with highly selected populations (Drotar & Lemanek, 2001).

Finally, investigators such as Stark and her research group also face substantial burdens retaining participants in psychological interventions, which are clearly more time intensive and emotionally demanding than RCTs that test medication effects (L. J Stark, personal communication, July 26, 2004). To enhance the participation of eligible families in future intervention research, Stark and colleagues recommend a number of strategies that other investigators might consider such as reducing the number of sessions and tailoring behavioral strategies to address barriers to the intervention experienced by individual families.

Another challenge faced by Stark and colleagues in designing their RCT that is shared by all who are brave and persistent enough to conduct psychological intervention research is the choice of a control or comparison group. A comparison group needs to be ethically sound and provide what is at the very least “treatment as usual” in a given setting (Street & Luoma, 2002). Participation in intervention research should never preclude families from receiving comprehensive and psychological care that is ordinarily available in that particular setting. However, the nature and content of treatment, as usual, concerning psychological intervention can be very difficult to define and also varies substantially from site to site. For this reason, investigators need to document the content and structure of intervention that is provided in treatment as usual and the comparison group condition.

Some families may have a preference for more help than can be provided in treatment as usual conditions. Consequently, when they are randomized to this group, they may drop out more than the families in the target-intervention group, which can pose a major threat to the internal validity of findings. For this reason, some investigators may choose to do what Stark and her colleagues did, that is to compare alternative interventions, both of which provide greater levels of care than treatment as usual (Schwartz, Chesney, Irvine, Keefe, 1997). In Stark et al.’s study, the purpose of the enhanced standard of care group was to approximate the typical delivery of dietary counseling that would be available in clinical settings in the number and length of sessions but to contain the identical nutritional information as in the behavioral intervention, and include suggestions for diet and feedback on their children’s average CA intake at each meal and total CA intake per day. In fact, Stark and colleagues’ choice of control group provides a strong test of the proposed intervention model while clearly offering all participants ethically sound intervention that exceeded what they could expect by not participating in the research.

But, alas, there is no escape from the threats to validity of interpretation of findings from psychological intervention studies: The behavioral intervention employed by Stark and colleagues contained more sessions than the enhanced standard of care group. For this reason, it is possible that the increased frequency of contacts between interventionists and family members in the behavioral intervention (N = 6 vs. N = 3 in the control) rather than the innovative behavioral strategies that were employed may have been the key variable that accounted for the intervention effects. There is no way to be sure given the present design. For this reason, one eventual goal would be to isolate the most powerful ingredients of this intervention (Drotar & Lemanek, 2001; Drotar, in press).

But first things first: Stark and colleagues are to be commended for designing an excellent intervention, a well-documented control group that surpassed what is standard or customary intervention in many clinical settings, for clearly documenting the control intervention, and for persisting in their work in the face of all the challenges that were thrown their way.

In some respects, psychological-intervention researchers can be compared to explorers who are willing to risk mistakes as well as potential failure in the service of enhancing science and helping children and their families in the process. In fact, the opportunity to utilize psychological research to improve the quality of psychological care that is provided to children is one of the joys of conducting intervention research that can.
help assuage the frustrations that can accompany such work (L. J. Stark, personal communication, July 26, 2004). The editors and editorial board of the Journal hope that others will follow the lead of Stark and her research team and submit manuscripts to the ongoing section concerning RCTs.

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