Conducting Psychological Intervention Research in Pediatric Clinical Settings: Strategies and Implications

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Practice-based psychological intervention research that is conducted by practitioners in pediatric clinical settings raises special challenges that need to be met to maximize opportunity for success. Based on our experiences in intervention research conducted in clinical settings by practicing pediatric psychologists and health care providers, we consider issues in designing and implementing intervention research, resource development, interdisciplinary collaboration, ethical issues, data analysis, and application of findings in clinical practice. Recommendations to enhance the implementation of psychological intervention research in pediatric clinical settings include balancing feasibility versus validity in study design, considering multiple approaches to study designs and data analyses, identifying and managing ethical issues, facilitating interdisciplinary collaborations, developing resources, and enhancing opportunities for research training.

Keywords: intervention research, practice-based research

One of the most important directions for research in pediatric psychology concerns the development and implementation of intervention research that is conducted by practitioners in pediatric clinical settings. Various authors identified the isolation of research from clinical practice and the need for more practice-based intervention research in pediatric psychology (Drotar & Lemanek, 2001; Rapoff, 2010a). However, a number of difficult challenges pose salient barriers to developing and implementing psychological intervention research conducted by practitioners in pediatric clinical settings (Drotar, 2006).

Clinical pediatric settings are fast paced and designed to provide clinical care for large numbers of patients rather than conduct research, which requires additional time and can disrupt clinic procedures. Pediatric health care providers’ engagement in patient care limits their time to participate in intervention research. Participation in psychological intervention studies also places additional time burdens on children and adolescents, many of whom are already coping with the strenuous demands of pediatric chronic conditions and their treatments. The unique characteristics of pediatric clinical settings and populations increase variation in relevant clinical outcomes, limit prospects for experimental control, and can raise salient threats to the validity of conclusions that are based on psychological intervention research (Campbell & Stanley, 1966; Drotar, 2006).

On the other hand, psychological interventions delivered by practitioners in pediatric clinical settings have the considerable advantages of greater ecological validity, potential generalizability, and clinical significance compared with interventions conducted apart from the clinical context. In order to maximize this potential, investigators need to anticipate challenges that arise in designing and implementing such research. Various sources have provided guidance to investigators about psychological research with pediatric populations (Drotar, 1989, 2000; Roberts & Steele, 2009) but have
not considered the special challenges of practice-based intervention research in pediatric clinical settings. To address this need, this article describes challenges and implications for researchers and practitioners who are contemplating practice-based psychological intervention research in pediatric clinical settings. The manuscript is based on the perspective of psychologists who are practicing and/or conducting research in a pediatric setting.

**Context: Setting and Research Projects**

Our research program in The Center for Treatment Adherence and Self-Management at Cincinnati Children’s Hospital Medical Center has evaluated the effectiveness and efficacy of adherence promotion interventions in pediatric outpatient clinical settings delivered by practicing pediatric psychologists, pediatric subspecialists, and nurses (Cortina, Somers, Rohan, & Drotar, 2013; Herzer, Ramey, Rohan, & Cortina, 2012; Hilliard, Ramey, Rohan, Drotar, & Cortina, 2011; Rohan et al., 2013). As shown in Table 1, three intervention studies have been, or are being, conducted. The first is a study of the outcomes of comprehensive psychological intervention delivered to children and adolescents with pediatric chronic health conditions who were referred for clinically significant adherence problems (Cortina et al., 2013; Herzer et al., 2012; Hilliard et al., 2011). The other two studies evaluated adherence promotion interventions delivered by health care providers (physicians and nurses) in two separate chronic illness populations: (a) children with moderate to severe asthma who demonstrated problems with asthma control (Rohan et al., 2013), and (b) juvenile idiopathic arthritis (JIA; Cortina et al., 2013).

**Challenges and Lessons Learned in Designing and Implementing Practice-Based Psychological Intervention Research**

Our experiences in designing and implementing psychological interventions in clinical pediatric settings suggested several strategies that may be useful to others in planning studies, developing interdisciplinary collaborations, obtaining resources, identifying ethical considerations, conducting data analyses, and applying the findings in clinical practice. We recognize that specific strategies may not be universally applicable and will need to be operationalized differently depending on the setting.

**Issues in Study Implementation: The Importance of the Specific Research and Clinical Setting**

The nature of collaboration with providers and the ease of implementing psychological intervention will vary with clinical setting characteristics, history of collaboration among individual providers and researchers, setting and institutional affiliation of potential collaborators (e.g., independent practice, university, or hospital), specific institutional incentives for conducting research, and proximity and availability of graduate and/or fellowship training programs. The fact that the collaborators in our studies shared the same hospital affiliation and appointments facilitated this work. Collaborators who have different institutional appointments and settings will need to explore whether a potential collaboration to conduct intervention research is of mutual benefit, consider potential resources, anticipate logistical issues in accessing patients, and so forth that are characteristic of that setting. In general, psychologists bring expertise in psychological intervention research and study design to the collaboration, while pediatric providers have expertise in clinical management of specific chronic conditions and access to populations. New collaborations take time and energy to become established (see Drotar, 2013, for a more detailed discussion of interdisciplinary research collaboration).

**Issues in Designing and Planning the Study: General Considerations**

In designing psychological intervention research in pediatric clinical settings, investigators need to consider the trade-offs between feasibility versus preservation of internal and external validity. Key aspects of feasibility include level of burden of participation for patients and their families, and the time required from psychologists and/or health care providers who deliver the intervention. A high level of burden related to study procedures can reduce participation, increase attrition, decrease sample size, and limit internal and external validity.
Table 1
Description of Intervention Studies Conducted by The Authors

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Design</th>
<th>Outcome measures</th>
<th>Fidelity</th>
<th>Duration of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1 (Cortina et al., 2013): Comprehensive psychological intervention for nonadherence to medical treatments</td>
<td>Children and adolescents with chronic conditions who demonstrated significant adherence problems to prescribed oral medication</td>
<td>Multicomponent: Behavioral problem solving, psychoeducational feedback concerning adherence, motivational interviewing conducted by psychologists (7–30 sessions)</td>
<td>Single group: Interrupted time series</td>
<td>Primary: Adherence (MEMS) Secondary: Behavioral Assessment Schedule for Children, Child Depression Inventory, Posttraumatic Stress Index, PEDsQL, Health Care Utilization</td>
<td>Provider self-report, chart review</td>
<td>Variable: 1–7 months, mean of 5 months postintervention</td>
</tr>
<tr>
<td>Study 2 (Rohan et al., 2013): Health care provider-based adherence promotion in pediatric asthma</td>
<td>Children and adolescents with moderate to severe asthma treated with inhaled steroids who demonstrated problematic asthma control</td>
<td>Feedback concerning adherence to treatment based on MEMS and problem solving conducted by physicians and nurses (two sessions)</td>
<td>Randomized controlled trial</td>
<td>Primary: Adherence (MEMS) Secondary: Asthma Control Test, PEDsQL, Health Care Utilization</td>
<td>Provider/Self-Report</td>
<td>3 months postintervention</td>
</tr>
<tr>
<td>Study 3 (Cortina, 2013): Health care provider-based adherence promotion in JIA</td>
<td>Children and adolescents with JIA who were prescribed oral medication</td>
<td>Feedback concerning adherence to treatment based on MEMS and problem solving conducted by nurses (2 sessions)</td>
<td>Randomized controlled trial</td>
<td>Primary: Adherence (MEMS) Secondary: PEDsQL</td>
<td>Audiotapes of interventions, fidelity checklist</td>
<td>9 months postintervention</td>
</tr>
</tbody>
</table>

Note. JIA = Juvenile Idiopathic Arthritis; MEMS = Medication Event Monitoring System; PEDsQL = Pediatric Quality of Life Inventory.
Provider burden is another important feasibility issue: Interventions conducted in clinical care settings that require providers to spend much more time than is typical for their practice will be more difficult to implement in the context of clinical demands such as productivity requirements. This will reduce the likelihood that intervention findings will be applied in practice. On the other hand, interventions designed to be most feasible for health care providers to conduct may not be sufficiently powerful to create change in intervention targets.

The randomized clinical trial (RCT) design is widely recognized as the gold standard for intervention research because it minimizes the threats to validity of findings relative to alternative research designs (Hacksaw, 2009). However, owing to limited numbers of potential participants and other study design considerations, RCTs may not be feasible for some practice-based intervention studies. For example, it is challenging to identify a suitable comparison group that controls for relevant variables and is also ethically sound, in that it meets or exceeds the current standard for psychological intervention in a clinical setting. Moreover, an RCT may not be the most effective method to extend practice-based applications of empirically supported psychological interventions. For example, if positive effects of psychological interventions have already been demonstrated and ideally replicated with a specific clinical model of intervention in practice settings, which may not be feasible or necessary using a traditional RCT design.

Another difficult design issue in practice-based intervention research concerns the potential for contamination of intervention delivery to control groups. For example, if one trains providers to deliver a new and as yet untested intervention, it may be very difficult for providers to refrain from providing elements of the intervention with control patients. In such instances, monitoring the fidelity of providers’ interventions with intervention and control patients is very important. Another option for larger practices is to train subsets of providers to deliver the intervention, at least initially, and compare the outcomes with control patients seen by other providers. This has the disadvantage of confounding intervention group with the specific providers who conducted the intervention.

Decisions regarding eligibility criteria for participants in intervention studies in pediatric clinical settings also involve difficult trade-offs between internal and external validity (Campbell & Stanley, 1966). For example, eligibility criteria that are very broad, and include the wide range of comorbid psychological (e.g., depression) and health problems that are typically encountered in practice, will certainly increase the generalizability of the study to practice. On the other hand, broad eligibility criteria will also increase variability in the outcomes of interest, and can raise potential confounds that make it more difficult to detect a statistically significant difference in response to psychological interventions that are tested. Moreover, the presence of significant comorbid problems in a clinical sample can stretch the limits of the applicability of empirically supported psychological interventions, which may not have been delivered to diverse clinical populations.

Selection of outcome measures in psychological intervention research in pediatric clinical settings requires investigators to consider issues such as reliability, validity, and potential sensitivity to change in response to the intervention, and clinical relevance (Drotar, 2006). Investigators will generally select a primary outcome measure that is expected to be most sensitive to change in response to a specific model of intervention. Secondary outcome measures can also be very helpful in describing the sample and detecting the impact of intervention on relevant psychological and/or health outcomes that might also be expected to improve. However, the selection of measures to optimize study design should be balanced with feasibility considerations, such as ease of administration of measures in clinical settings and time and energy required from participants and research staff.

Planning the Study: Specific Examples

In Study 1, we evaluated whether a comprehensive, psychological intervention model involving specific components (e.g., problem solving, cognitive–behavioral therapy, psychoeducation) that have been shown to promote adherence to medical treatment in RCTs would be effective when delivered in clinical practice to patients with clinically significant adherence
problems (Cortina et al., 2013). In order to evaluate the effectiveness of multicomponent interventions delivered by psychologists (faculty and fellows), we used a single group study design including baseline, intervention, and follow-up phases that was directly applicable to clinical practice. On the other hand, this design limited the inferences we could make about the effectiveness of our intervention model compared with alternative approaches or no intervention. Moreover, we could not evaluate the efficacy of the specific intervention components that were delivered. Nevertheless, because psychological interventions often involve multiple components in clinical practice, this was an ecologically valid approach.

We used an RCT design in two studies of the efficacy of adherence promotion interventions delivered by health care providers (pediatric subspecialists and nurses). In designing Study 2, which focused on pediatric asthma, we were aware of at least one other study that tested the effectiveness of feedback concerning adherence using electronic monitoring and problem solving to enhance treatment adherence to inhaled corticosteroids for pediatric asthma patients (Spaulding, Devine, Duncan, Wilson, & Hogan, 2012). Because the previous study used a single-group, uncontrolled design, we chose to use an RCT to compare the effects of the health care provider-based adherence intervention with usual clinical care (Rohan et al., 2013). Relative to previous research, this design allowed stronger inference about intervention efficacy, yet preserved the ecological validity of delivering the provider-based intervention in the context of clinical care. We followed similar reasoning in designing Study 3, which also tested the efficacy of provider-based adherence feedback and problem-solving intervention compared with usual clinical care, but with a different chronic illness population: those with JIA (Cortina, 2013).

Selection of eligibility criteria also posed challenges for study design. In Study 1, we selected patients who were referred for clinically significant nonadherence to a prescribed daily oral medication that could be monitored electronically. We used electronic monitoring of adherence to medical treatment based on a medication event monitoring system (MEMS) to establish eligibility criteria (e.g., threshold for nonadherence) and to evaluate intervention outcome. In contrast to many previous studies of adherence promotion interventions, (Kahana, Drotar, & Frazier, 2008), we did not screen out children and adolescents with significant co-morbid psychological problems because these reflected typical clinical presentations of patients referred for psychological services in our setting.

In Study 2, the primary eligibility criteria were presence of moderate to severe asthma, daily treatment with an inhaled corticosteroid, and clinically significant problems in asthma control among patients who were seen by pediatric pulmonologists in our hospital (Rohan et al., 2013). We selected the latter criterion because we wanted to identify a clinically relevant population in need of adherence promotion intervention. In Study 3, our primary eligibility criteria involved the diagnosis of JIA and prescribed oral medication among patients who were followed by pediatric rheumatologists in our hospital (Cortina, 2013). Ideally, including patients with JIA whose nonadherence was severe enough to disrupt their disease course and/or quality of life would have enhanced the clinical significance of our study. However, this option was not feasible because we did not have a sufficiently large sample of children and adolescents with JIA to accommodate such a sampling plan.

Selecting the dose of the intervention, or number of sessions to conduct, posed a dilemma in designing our studies because pediatric adherence promotion research has not identified the optimal number of sessions or compared the efficacy of different numbers of sessions (Kahana et al., 2008). For this reason, we selected the number of intervention sessions in each study based primarily on feasibility and clinical considerations. For example, in Study 1, psychologists’ clinical judgments of patient needs informed the number of intervention sessions. The downside of this decision was a highly variable number of intervention sessions (range = 7 to 30) for individual patients (Cortina et al., 2013). In Studies 2 and 3, we wanted to test the efficacy of an adherence promotion intervention delivered by health care providers that was feasible for them to provide in their clinical practice. For this reason, each of these studies tested the efficacy of a relatively small number of adherence promotion intervention sessions (N = 2; Cortina, 2013; Rohan et al.,
2013) compared with the average number of sessions ($N = 9$) in interventions conducted by psychologists, trainees, or research assistants in previous research (Kahana et al., 2008). In making this decision, we ran the risk that this relatively small number of intervention sessions would not be sufficient to result in detectable clinically meaningful change.

Because the primary focus of our research was to evaluate the impact of adherence promotion interventions, we used objective behavioral measures of adherence (MEMS for oral medications and the Smart Inhaler for inhaled steroids) as the primary outcome in each of our studies. We selected the MEMS because it is well recognized as a valid measure of adherence compared with self-report measures that overestimate adherence (Rapoff, 2010b). Moreover, both the MEMS and Smart Inhaler yielded daily data that we used to give feedback to children and families concerning their treatment adherence to facilitate problem solving and also increased statistical power to detect changes in response to intervention. On the other hand, the MEMS required added expense and staff time, which can limit its application in clinical settings.

Secondary outcomes measures were used in each of our studies. For example, in Study 1, we used measures of psychological status such as the Behavioral Assessment System for Children (Reynolds & Kamphaus, 2004), Children’s Depression Inventory (Kovacs, 1992), and Post-Traumatic Stress Reaction Index (Shemesh et al., 2006) to document comorbid psychological symptoms that could influence intervention outcomes. In each of our studies, we also included a patient-reported outcome, such as health-related quality of life (Varni, Burwinkle, Seid, & Skarr, 2003), and measures drawn from chart reviews—such as health care utilization and disease severity—that might be expected to change in response to adherence promotion intervention. Study 3 also included a measure of provider and family acceptance of the health provider-based intervention.

Implementing Interdisciplinary Collaborations Concerning Intervention Research

As is true for most research conducted with pediatric populations (Drotar, 2013), collaboration with a wide range of professionals (e.g., pediatricians, nurses, social workers) can facilitate successful implementation of all phases of psychological intervention research in pediatric clinical settings and enhance translation to clinical practice. For example, in Study 1, health care providers referred patients for psychological interventions to improve their problematic adherence. In our studies of provider-based intervention (Studies 2 and 3), pediatricians and nurses reviewed our proposed study to advise us on design and feasibility. These collaborating health care providers also let families know about the availability of our intervention research projects and addressed their questions and concerns.

We have found that the conduct of psychological intervention and data collection in pediatric clinic settings need to have the full support of providers to provide clinic space and accommodate study procedures in the flow of clinic visits. To be most feasible, intervention delivery needs to be minimally disruptive to the flow of patient care. For example, in our research (Studies 2 and 3), health care providers’ flexibility in applying a problem-solving model of adherence promotion intervention to their follow-up visits for chronic illness care enhanced study implementation. Once our studies were completed, collaborating health care providers were very helpful in reviewing the data and contributing their ideas about the findings, especially about potential clinical implications. If the long-term goal of the study is to apply the findings into clinical practice, providers’ ideas about how best to accomplish this difficult task are invaluable.

In implementing our intervention studies, we identified a number of strategies to facilitate collaboration with health care providers. For example, we discussed each study with providers when it was still in the formative stages. Involving providers prior to the beginning of the study helped to anticipate barriers to implementation, gave them an opportunity to raise their concerns and potential reservations early in the process, and provided an opportunity for collaborative dialogue about solving design and implementation challenges (Drotar, 2013). We also gave periodic updates to health care providers about study progress, engaged them in discussion of challenging issues in implementa-
tion, and facilitated discussion of the clinical implications of study findings.

Health care providers who conducted the intervention were also coauthors on relevant publications (e.g., Rohan et al., 2013). To facilitate the collaborative process of preparing manuscripts based on our intervention findings, we discussed plans for coauthorship, including potential publication outlets with our collaborating health care providers. As it turned out, our studies that included collaborating health care providers as interventionists were pilot and feasibility studies, which we intended to publish in psychology journals with broader circulation (e.g., *Pediatrics*). Larger-scale intervention studies that collaborators agree to submit to high impact medical journals should be registered on clinicaltrials.gov, given the requirements of these journals.

**Resource Development**

Resources such as time from coinvestigators (psychologists and health care providers, research assistants, clinic staff) and supplies (e.g., test materials) are necessary to conduct psychological intervention research in pediatric settings. Health care providers who are highly engaged in the design and conduct of a study, and who are potential coauthors on published findings, have greater incentive to identify resources to implement the project (e.g., staff time, funds for supplies; Drotar, 2013). It should be noted that some smaller-scale intervention studies conducted in practice settings may require relatively few resources to support interventionists. For example, in our research, psychologists and health care providers who conducted the interventions billed for their services. However, we needed funds to support research assistants who organized the study and recruited patients, ordered test supplies, and purchased devices for electronic monitoring of treatment adherence. We paid for MEMS, Smart Inhalers, and other supplies with funds available through the hospital division and a departmental program that funds pilot studies of interventions to change methods of health care delivery. We have also supported our intervention research through time from unpaid student volunteers, graduate students, and fellows who have been funded from other sources (e.g., institutional or training grants).

**Identifying and Managing Ethical Issues in Study Design and Implementation**

Psychological intervention research in pediatric clinical settings raises ethical issues that need to be carefully considered in study design and implementation (Drotar, 2006). One of these is that patients with clinically significant psychological problems who are assigned to a comparison group need to receive psychological interventions that are consistent with current standards of clinical care in the setting. Another relevant ethical issue is who should conduct the recruitment and consent process. In our research, we felt that if psychologists, physicians, or nurses who provided clinical care for potential participants and their families conducted the informed consent for study participation, this could be potentially coercive to participants because of their ongoing relationship with providers. For this reason, in each of our studies, we decided that research assistants would conduct the consent process. A practical downside of this approach was that it required additional research assistant time.

A second issue related to informed consent is the need to clearly present all of the study participation requirements, including potential burdens compared with nonparticipation in the study. For example, in all of our studies, participants agreed to the additional demands of completing outcome measures, including electronic monitoring of treatment adherence. In Studies 2 and 3, participants had to agree to be randomized to one of two groups: (a) usual care from health care providers, or (b) usual care and psychological intervention involving feedback concerning adherence to treatment and problem solving to address barriers to adherence. We emphasized to all patients and families that in the event that they did not choose to participate, they would still receive psychological care (Study 1) or their usual medical care from their health care providers (Studies 2 and 3).

Another difficult ethical issue is the use of a baseline period to collect data on the primary study outcome prior to the start of intervention. A baseline period is highly desirable in order to evaluate the effectiveness of an intervention using a pre–post study design, which lends itself
to evaluating interventions conducted in clinical practice (Cortina et al., 2013). However, it may not be realistic or clinically indicated to implement more than a brief baseline period for patients with clinical problems that warrant expedient psychological intervention. Moreover, it is not ethically justified to delay the delivery of a necessary psychological intervention solely for the purpose of establishing a baseline. In Study 1, we implemented a study design involving baseline, intervention, and follow-up phases. Based on ethical considerations, we chose not to delay the start of intervention for patients with clinically significant nonadherence in order to obtain a baseline. However, it was possible to obtain baseline data for some patients while their psychological assessment and treatment planning were conducted. Although the RCTs in Studies 2 and 3 did not require a baseline period, the study designs would have been strengthened by its inclusion.

An important ethical issue can arise when a new intervention model is found to be successful with a specific clinical problem and population. In such situations, the research team would ideally work with collaborating providers and others in the practice to ensure training in the new intervention model and opportunity for patients and families to receive the new intervention. However, successful dissemination and translation of findings will vary as a function of the resources of clinical teams (see Application of Intervention Findings in Clinical Practice section).

**Data Analytic Methods**

The selection of data analytic methods for evaluating the efficacy and clinical effectiveness of psychological interventions that are delivered in practice warrants close attention. Statistical methods for evaluating RCTs have been well described (Hacksaw, 2009). Methods to analyze psychological intervention effects in single groups or case series in pediatric clinical settings have not been widely used in published research in pediatric psychology. However, a number of methods are applicable. Assuming the evaluation plan has an acceptable number of observations (Tabachnick & Fidell, 2007), time series analysis has several salient advantages compared with alternative methods, such as control for autocorrelation (e.g., current data points may be dependent on previous data), modeling of available data for individuals across time rather than focusing on mean differences between time points (Borckardt et al., 2008), and inclusion of different numbers of observations in relevant study periods (e.g., baseline, during intervention, and postintervention). A salient advantage of time series methods is that they estimate the statistical significance of change over time for individual participants, which allows more robust inference about the nature of change in response to intervention than visual inspection of data. A full discussion of these methods is beyond the scope of this article. However, multiple methods are available for quantifying single case intervention effectiveness (Manolov, Solanas, Sierra, & Evans, 2011; Smith, 2012). In addition, see Rohan (2013) for more extensive discussion and an illustration of the application of time series analysis for case studies and series in pediatric psychology. We used time series methods to evaluate the effectiveness of interventions in Studies 1 and 2 (Cortina et al., 2013; Rohan et al., 2013).

**Application of Intervention Findings in Clinical Practice**

One of the most important potential advantages of practice-based psychological intervention research in pediatric clinical settings involves the potential to disseminate research findings and apply them in clinical practice. The fact that study procedures and ongoing collaborations with health care providers have been developed can facilitate applications of intervention research in clinical practice. Our interventions have been implemented in clinical practice in varying degrees depending on specific populations, study designs, and resources. For example, we have implemented the multicomponent model of psychological intervention that we tested in Study 1 as standard clinical practice for patients with clinically significant nonadherence problems (Cortina et al., 2013) as well as other presenting problems (e.g., pill swallowing, conduct problems).

In contrast, in Study 2, we could not sustain the health care provider-based intervention with children with asthma because of resource constraints (e.g., cost of MEMs). Yet our study facilitated our progress in collaborative clinical
management with health providers in our hospital’s asthma center. For example, the medical team’s involvement in our study increased their interest in learning about adherence promotion interventions and making these available to patients. This interest led to expansion of psychological services for children and adolescents with asthma, as well as educational programs to train pediatric pulmonologists in adherence promotion.

Because Study 3 is still in progress, it is too soon to determine whether, and to what extent, the findings will be applied in the clinical practice of health care providers in the management of JIA. However, we conducted provider training for adherence promotion with a range of health care providers across our institution and believe that these methods can be implemented effectively with providers who are caring for patients with JIA. Moreover, the JIA health care team is routinely collecting data on disease activity, health care utilization, and health-related quality of life, which should enhance future prospects for using these measures to evaluate adherence promotion interventions.

Limitations

Our experiences in conducting intervention research occurred in a large academic medical center and were supported by participation of fellows and graduate students and resources from our hospital. Moreover, our studies have focused on adherence promotion interventions. For this reason, the potential generalizability of our experiences to other populations, types of psychological interventions, and pediatric clinical settings is an open and important question. We believe that many of the principles that we have used to plan and implement studies, develop collaborations with providers, identify relevant ethical issues, conduct data analysis, and apply findings in clinical practice are potentially generalizable and can be adapted to fit a range of interventions, available resources, interdisciplinary collaborations, and settings. We strongly encourage others to share their experiences in designing and implementing psychological intervention research in a range of clinical settings to determine to what degree our observations are generalizable or need to be modified based on specific setting, population, or intervention-based considerations. Descriptions of challenges and strategies in conducting psychological intervention research in private pediatric practice and/or community hospital settings would be particularly instructive.

Future Directions

Consider Alternative Research Designs

Investigators who are interested in applications of psychological intervention research in a range of clinical settings may wish to consider a range of study designs that best fit their setting and the state of the art in specific areas of intervention research. For example, Campbell et al., (2000) described a continuum of research in complex intervention studies, including an initial preclinical or theory building phase (Phase 1), in which the primary focus is on selecting of model of intervention and relevant outcomes based on experiences with patients, families, and providers; Phase 2, which involves developing intervention content based on patient and provider input; Phase 3, which involves designing and implementing a pilot RCT to determine feasibility and sample size; Phase 4, an RCT based on a reproducible protocol; and a final Phase 5, which involves implementing and replicating intervention effects in uncontrolled clinical settings. Published reports reflecting each of these phases of psychological intervention research with various populations in pediatric clinical settings are needed.

One approach that can be applied across multiple pediatric settings is to make extensive use of case studies and case series to develop and test psychological interventions that are delivered in clinical practice by psychologists and health care providers. Conducting N of 1 trials (multiple cross-over studies in single individuals) can be used to improve the clinical impact of interventions (Gabler, Duan, Vohra, & Kravitz, 2011). Other clinically relevant options for research designs to test psychological interventions in pediatric clinical settings include practical clinical trials (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005), which have broader criteria for inclusion and evaluation of outcomes than traditional RCTs and comparative effectiveness studies, which compare alternative interventions delivered in clinical practice (Kraemer & Frank, 2010). These approaches have been underutilized
in psychological intervention research in pediatric clinical practice settings but have potential utility. Psychological interventions that are typically evaluated by pediatric psychologists are delivered in the context of highly structured research protocols. In contrast, psychological interventions that are delivered in clinical practice are individualized and highly tailored to patients’ needs. Such tailoring increases clinical applicability but can also limit the validity of specific psychological interventions that are conducted in multiple clinical settings. Nevertheless, it may be possible to standardize the principles or components of an intervention but deliver them flexibly based on clinical need. For example, in a modular approach to psychological intervention (Chorpita, Daleiden, & Weisz, 2005), clinically relevant intervention components are delivered only to those children who need them, (e.g., providing cognitive–behavioral therapy to patients whose depressive symptoms disrupt treatment adherence). Systematic application of the modular approach has been used to guide interventions delivered in clinical settings to children and adolescents with a wide range of behavioral problems (Chorpita et al., 2005), but, to our knowledge, the approach has not been extensively used to evaluate the effectiveness of psychological intervention research with pediatric clinical populations. In Study 1, we used this approach with children and adolescents with various chronic health conditions who demonstrated clinically significant adherence problems (Cortina et al., 2013). A challenging key feature of the modular approach is the development of objective and reproducible criteria or algorithms to determine which children should receive specific intervention components.

**Develop Multiple Strategies to Promote Psychological Intervention Research in Pediatric Clinical Settings**

Several professional initiatives may facilitate the development of psychological intervention research that is conducted in pediatric clinical settings. Ideally, pediatric psychologists who are conducting intervention research in pediatric clinical settings should present and publish their experiences so that we can learn from one another. Forming a special interest group (SIG) in the Society of Pediatric Psychology for researchers and practitioners who are conducting psychological intervention research in pediatric clinical settings would enhance dissemination of experiences, study methods, and findings. Alternatively, using the structure of available SIGs to compare and contrast experiences in psychological intervention research across different populations and topics would be an efficient means of facilitating cross-cutting knowledge.

Establishing and sustaining productive ongoing interdisciplinary collaborations among researchers and practitioners in pediatric psychology, and pediatric and nursing providers in a range of clinical settings, will be critical to make clinically relevant scientific progress in psychological intervention research. For this reason, publishing reports of strategies of successful versus problematic interdisciplinary collaborative intervention research and ways to enhance such collaborations in a range of settings will be very instructive (Drotar, 2013). Another potential direction for future practice-based intervention research in pediatric psychology that has been used effectively by pediatric subspecialists is collaborative practice networks (Blum & DBPNet Steering Committee, 2013; Crandall et al., 2011). In these networks, providers in different settings conduct multiple studies including evaluations of their practices. Advantages of such networks include enhanced sample size, use of common outcome measures, and application of quality improvement methods to evaluate the impact of iterative changes in clinical practice.

A final direction involves the application of practice-based research to enhance available opportunities for training researchers and practitioners to conduct psychological intervention research in pediatric clinical settings. The scientist-practitioner model of training clinical psychologists provides a foundation for additional training to enhance competencies to conduct intervention research in pediatric clinical settings. We have found that research-related competencies of graduate and postdoctoral level trainees can be extended to include developing interdisciplinary collaborations, designing and implementing psychological interventions in practice settings, anticipating and managing ethical issues, and learning alternative study design and data analytic methods (Drotar et al., in press). Developing increased mentoring op-
opportunities for graduate students, postdoctoral fellows, and faculty to conduct psychological intervention research in pediatric clinical settings will ultimately enhance scientific progress and dissemination of interventions into clinical practice.

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