
DEVELOPMENT OF A PARENT TRAINING PROGRAM FOR CHILDREN WITH PERVASIVE DEVELOPMENTAL DISORDERS[†]

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Parent delivered interventions based on applied behavior analysis (ABA) for children with Pervasive Developmental Disorders (PDDs) have been evaluated using primarily single-subject design methodology or small case series. While the results of these evaluations are encouraging, an important next step is to standardize the interventions to allow for replication across sites, in studies with large samples and measures of long-term, clinically meaningful outcomes such as improvements in children's functioning and their relationships with parents. Accordingly, the Research Units on Pediatric Psychopharmacology and Psychosocial Interventions (RUPP Autism Network) assembled a detailed manual for a structured behavioral parent training (PT) program, developed treatment fidelity and training procedures, and conducted a pilot, feasibility study. The PT program is part of a large scale, multisite study intended to determine the efficacy of *combined* pharmacological treatment and behavioral intervention to improve behavior and adaptive functioning in children with PDD. This paper discusses the rationale for this project. A companion paper provides the results of our feasibility study on the PT program. Copyright © 2007 John Wiley & Sons, Ltd.

INTRODUCTION

Pervasive Developmental Disorders (PDDs[†]), such as Autistic Disorder, Asperger's Disorder, and PDD—Not Otherwise Specified, affect between 40 and 60 children

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[‡]For purpose of this paper, we refer to PDD to include children diagnosed with Autistic Disorder, Asperger Disorder, and Pervasive Developmental Disorder—Not Otherwise Specified.

per 10 000 (Fombonne, 2003). For children with PDD and their families, the effects of these disorders are often severe and chronic. Core features of PDD include deficits in social interaction and communication as well as repetitive and restrictive patterns of behavior. These deficits are often also associated with serious behavior problems such as tantrums, aggression, self-injury, destructive behavior, hyperactivity, and noncompliance. In fact, recent surveys suggest nearly 50–70% of children with PDD present with co-occurring behavioral and emotional problems (Gadow, Devincent, Pomeroy, & Azizian, 2004; Tonge & Einfeld, 2003). Because these secondary behavior problems usually interfere with habilitative and educational efforts, these are often the target of treatment.

Interventions commonly used for children with PDD include various psychotropic medications, psychosocial treatments, and special education programming (National Research Council, 2001; Scahill & Martin, 2005). The goals of treatment include decreasing the core symptoms of PDD, enhancing specific communication and socialization skills, and reducing problematic behaviors. Pharmacologic interventions have typically focused on reducing specific maladaptive symptoms such as hyperactivity, aggression, self-injury, stereotypes, or explosive behavior (McDougle et al., 2000; Posey & McDougle, 2000). The empirical basis for the use of medication in children with PDD has expanded in recent years, but remains far from adequate (Handen & Lubetsky, 2005; McDougle, Posey, & Stigler, 2006; RUPP Autism Network, 2002). Psychosocial treatments have a long history of use within the PDD field and there are several well established comprehensive programs (Dunlap & Fox, 1996; Greenspan & Wieder, 1997; Harris, Handleman, Arnold & Gordon, 2000; Lovaas & Smith, 2003; Marcus, Schopler, & Lord, 2000; McGee, Morrier, & Daly, 1999; National Research Council, 2001; Rogers, Hall, Osaki, Reaven, & Herbison, 2000; Romanczyk, Lockshin, & Matey, 2000; Schreibman & Koegel, 2005; Smith, Donahoe, Davis, 2000b; Strain & Cordisco, 1994). These psychosocial and educational programs vary in their theoretical underpinnings but the majority have been heavily based on applied behavior analysis (ABA).

Research methodologies for evaluating psychosocial interventions have included primary single-subject designs. Some investigators, particularly within the field of ABA, assert that single-subject design, in which a small number of individuals are studied intensively to identify interventions that have sizeable effects for that individual, are almost always preferable to randomized controlled trials (RCTs) (Johnston, 1988). Other investigators view RCTs in which interventions are provided to groups of individuals with outcomes compared across groups as the 'gold standard' because they allow for rigorous tests of intervention effects in large, well-characterized samples of individuals (Lord et al., 2005). This lack of accepted consensus on research methodologies often have led to very discrepant conclusions about the same interventions. For example, focusing on single-case studies, Odom

et al. (2003) concluded there was strong evidence in support of ABA methods for parent training (PT). In contrast, others have asserted that the evidence base was too limited to draw a conclusion of the efficacy of PT when restricting their review to RCTs (Diggle, McConachie, & Randle, 2002).

In an effort to provide guidance that would move the field forward with respect to psychosocial interventions, a recent task force empanelled by the National Institute of Mental Health proposed a model that integrated these two perspectives (Smith et al., 2007). In the model, assembling techniques with support from single-subject studies into a manual that could be implemented with fidelity across research sites (and ultimately in typical community practice settings) so that the intervention could be tested in large scale randomized controlled trials (RCTs) was recommended (Lord et al., 2005; Smith et al., 2007). The groundwork laid by more than two decades of single-subject research in interventions based on ABA support the general strong consensus that these interventions have the best empirical support of all psychosocial treatments for PDD (Bregman, Zager, & Gerdtz, 2005; Kazdin & Weitz, 2003; Schreibman & Ingersoll, 2005). This work also makes it possible to take the recommended steps of manual development and large scale testing. Such testing of an exportable intervention in a well-characterized sample will provide guidance to clinicians regarding the types of parents and children who can benefit from the intervention as well as the magnitude of benefit that can be achieved. The use of a structured but clinically flexible manual also permits replication. Taken together, manual testing in a large scale, randomized trial is an important step to move behavioral analytic interventions from delivery to small numbers of children in specialized centers to wider dissemination.

In a previous study, we showed that risperidone was superior to placebo in reducing tantrums, aggression, self-injury, and repetitive behavior in children with PDD (Arnold et al., 2003; McDougle et al., 2006; RUPP Autism Network, 2002). Short-term gains in these target behaviors were stable over time and relapse was common when medication was discontinued (RUPP Autism Network, 2006). Despite improvements in target behaviors such as tantrums and aggression, only modest improvement in core symptoms and adaptive behavior was observed (Williams et al., 2006). It was, therefore, decided to attempt to achieve greater gains in these areas by combining an effective medicine with behavioral intervention for children with PDD and significant behavioral challenges. The current RUPP Autism Network study was undertaken to determine if combined treatment—risperidone plus a psychosocial treatment—would expand treatment response and prevent relapse.

In creating a manualized program, the RUPP Autism Network looked to develop a behavioral intervention program that (a) had empirical support for each component, (b) could be implemented within a comprehensive outpatient setting, (c) could be uniformly delivered in a multisite study, (d) could be replicated in a separate

investigation, and (e) could potentially be applied more broadly in clinical settings. The purpose of this paper are to describe the process of development of the RUPP behavioral PT program and application of treatment fidelity procedures for multisite implementation. This paper is intended to offer a model for the development of a behavioral intervention program for children with PDD which may be implemented in a large RCT multisite study. Results from our pilot study of this program are described in the companion paper (RUPP Autism Network, in press).

CHOICE OF PARENT TRAINING

The empirical support for ABA techniques in the PDD literature is unequivocally impressive and has resulted in skill acquisition in the areas of communication and socialization as well as attenuation of associated challenging behaviors (Bregman et al., 2005; Bristol et al., 1996; Horner, Carr, Strain, Todd, & Reed, 2002; Koegel & Koegel, 1995; Lovaas, 1987; Matson, Benavidez, Compton, Paclawskyj, & Baglio, 1996; Maurice, Green, & Luce, 1996; Schreibman, 2000; Wolfe & Neisworth, 2005). In the behavior analytic literature, the persons administering specific behavioral interventions may be highly trained behavior analysts, teachers, trained one-on-one therapists, or parents. Single-subject studies on training parents indicate that parents can learn ABA techniques for reducing problem behaviors and increasing compliance, as well as for increasing communication and other adaptive skills (Charlop & Trasowech, 1991; Ducharme & Drain, 2003; Kaiser et al., 2000; Lerman et al., 2000; Moes & Frea, 2002; Smith, Buch, Gamby, 2000a; Symon, 2005) In most studies, the amount of PT has been relatively small, totaling fewer than 20 h. There have been a small group of RCTs of PT and parent management therapy (PMT) for children with PDD[§] (Drew et al., 2002; Jocelyn, Casiro, Beattie, Bow, & Kneisz, 1998; Ozonoff & Cathcart, 1998; Schreibman & Koegel, 1996, 2005; Smith, Groen, Wynn, 2000c; Sofronoff, Leslie, & Brown, 2004; Tonge et al., 2006). However, these RCTs have all been conducted at single sites (and therefore did not test the replicability of effects across sites) and have involved too few participants to draw firm conclusions about how effective the intervention is and for whom.

Many of the comprehensive treatment programs for children with PDD include a PT component and typically involve instruction in a range of techniques that have been validated in separate, single-subject design studies (Dunlap & Fox, 1999; Harris et al., 2000; Koegel, Koegel, Harrower, & Carter, 1999; National Research Council,

[§]The distinctions between parenting training (PT), parent directed therapy, parent delivered, and parent management training (PMT) are less than clear in the literature. PMT is often viewed as training parents to 'manage' problematic behaviors whereas PT has been used to describe programs where teaching a child is included. As our program includes both, we have used PT to describe our program.

2001; Rogers et al., 2001; Salt et al., 2002). However, the extent to which PT contributes to the overall outcome is difficult to determine from these studies. These PT approaches share many common elements. For example, most seek to identify antecedents and consequences occurring in the environment which may be contributing to a behavior of interest. Parents are also typically taught to record the child's response in everyday settings and then to modify the child's behavior through environmental manipulation (prevention and antecedent management). Instruction in communication, play, or social skills may also be included. Appropriate use of positive reinforcement, extinction, and other reduction techniques are also often covered. Yet, despite the wide use of PT in many programs that serve children with PDD, there is a striking lack of *empirically validated* PT program manuals that have been published for this population. Therefore, there is a clear need for the development of a PT program manual that can be evaluated in a multicenter randomized study (Lord et al., 2005; Schreibman, 2000; Smith, 1999).

Training parents has achieved considerable support in large scale RCTs of typically developing children with other disorders such as ADHD and ODD to address a range of disruptive behaviors and noncompliance (Barkley, Edward, Laneri, Fletcher, & Metevia, 2001; Briesmeister & Schahefer, 1998, Kazdin, 2003; McMahan & Forehand, 2003; Wells, Pelham, Kotkin, Hoza, & Abikoff, 2000). This model of treatment delivery also has a long history of use among families of children with developmental disabilities, although few RCTs have been conducted (Baker, 1996; Baker et al., 1997; Lutzker & Steed, 1998). These programs targeted a range of behavior problems, adaptive behaviors, and increasing a child's overall compliance. In these populations, PT has typically been applied in outpatient and/or group settings. It is not certain that the favorable outcomes with other disorders also would be achieved for children with PDD, given the chronicity and severity of PDD. However, the single-case literature and small RCTs do provide initial evidence that time-limited PT could be efficacious even in this population.

IDENTIFYING PT PROCEDURES FOR PDD

After committing to a PT approach, the RUPP Group turned its attention to identifying the specific components and techniques to be included in such a program. The development of the PT program was a joint effort by the RUPP Autism Network under the leadership of two senior behavior analysts, Benjamin Handen (B. H.), Ph.D., BCBA and Cynthia Johnson (C. J.), Ph.D., BCBA. The program drew from prior research, other PT program materials for children with autism, developmental disabilities, and other disruptive behavior disorders (e.g., Baker, 1996; Bondy

& Frost, 2002; Cordisco, Laus, Hanna, & Rapp, 1994; Cunningham, Bremner, & Secord, 1998; Hall & Hall, 1998; Harris & Weiss, 1998; Maurice et al., 1996; Maurice, Green, & Foxx, 2001), and the investigators' own materials accumulated from many years of behavior analytic clinical and research work in the field of autism and developmental disabilities. By design, subjects in the study were to have a diagnosis of a PDD as well as severe behavior problems (aggression, tantrums, self-injury, significant noncompliance). Hence, the goals of PT in this study were to increase overall compliance as well as skills acquisition and to further decrease problem behaviors in a heterogeneous group of children with PDD from 4 to 16 years of age. The initial version of the manual was presented to therapist teams and investigators from each of the Network sites during a day long planning session. The PT manual was revised and presented again to PT therapists from each site in a 3 day workshop. This was followed by a 6 month pilot study of the PT manual involving 17 subjects from four sites (University of Pittsburgh, Indiana University, Yale University, Ohio State University). During the pilot study, parents at each site rated the content of sessions and the utility of homework and materials. This information provided an index of consumer satisfaction which was reviewed to make modifications to the PT program. PT therapists conducted weekly teleconferences providing another forum for refinement. Finally, two senior PT therapists (B. H. and C. J.) viewed videotapes of the PT pilot sessions to certify therapists. This qualitative review also provided another opportunity to refine teaching materials and delivery. Revisions include primarily editing the content of the materials for clarity and ease of delivery.

The final version of the PT program consisted of 11 core, 3 optional, and 3 booster sessions, as well as initial and follow-up home visits. Each individual parent session was 75–90 min in duration. One or both parents were welcome to attend. The children with PDD also may attend but were not required to do so. Prior to beginning treatment, a number of baseline measures were obtained with each family. Measures included outcomes instruments which were also used by therapists to individualize interventions. Specific information was gathered via parental interview on target behaviors at home and/or in the community (e.g., frequency, intensity, and impact of the family). In addition, parents completed a reinforcement survey schedule which was used to individualize specific treatment procedures. Finally, Standardized Observational Analogue Procedures (SOAP) were conducted to observe the child's response to routine demands, obtain information on the context and possible function of the child's maladaptive behaviors and the context in which they occur; and observe parental response to the child's behavior. Based on prior work in functional analysis, the SOAP includes four conditions: (a) free play (demand-free interaction between parent and child); (b) shared attention (in which parental attention is limited); (c) demand (involving multiple parental requests); and (d) tangible restriction (in which favorite activities are removed from the child) (Hanley, Iwata, & McCord, 2003;

Kennedy, Meyer, Knowles, & Shukla, 2000; Repp & Horner, 1999). Standard procedures were followed for each 10 min session to include standard toys available, instructions provided to the parents, and therapist instructions. The SOAP is repeated at the end of the PT program. The video recordings of parent and child behaviors during the SOAP sessions can be coded as an exploratory outcome measure.

The first six core sessions provided families with instruction in basic behavioral techniques designed to prevent or decrease negative or noncompliant behaviors and to promote positive, pro-social behaviors. Topics included preventive, antecedent management techniques, positive reinforcement procedures, extinction, and compliance training. A subsequent set of five core sessions focused on functional communication, teaching skills, and techniques to promote generalization and maintenance. These 11 sessions, along with 3 optional sessions (time-out, contingency contracting, and crisis management), took place over a 16-week period during the RUPP study. The booster sessions (two by telephone and one face to face) occurred during an 8-week extension phase of the study. Booster sessions were designed to review previously discussed intervention strategies, to troubleshoot current implementation of those strategies, or to develop interventions for any newly emerging problems. An outline of the sessions is provided in Table 1.

The treatment sessions employed direct instruction, modeling, and role-playing to promote skill acquisition by parents, and observed the parents directly implement skill with their children when feasible. Sessions also included activity sheets which provided an opportunity for parents to practice and demonstrate understanding of the skills. Activity sheets fit with a particular session and included such activities as having parents identify antecedents and consequences of a problem behavior, providing a list of simple requests with which the child is likely to refuse, or having parents develop a task analysis for a grooming skill. Most sessions also included a set of four to six video vignettes of a mother and child engaging in activities related to the session topic. Finally, families were given homework assignments to practice new skills learned in PT sessions. Although homework assignments paralleled the session content, the actual behavior change targets and the application of the parent management skills were individualized for each child. An example of a cover page of a session which includes session overview, goals, parent objectives, and materials needed is provided in Figure 1.

Two home visits were conducted in addition to the individual clinic sessions. The first home visit occurred between the second and third PT session; the second home visit occurred immediately after the 16th week of PT. Home visits were scheduled at a time of day that parent(s) identified as problematic (e.g., after school or before bedtime). Home visits typically required 1–2 h and included a set of tasks for the PT therapist such as a tour of the family home and outside areas, a walk-through of places in which daily activities occurred, and further discussion of times and situations when

Table 1. Sessions and topics.

<i>Sessions</i>	<i>Skills/activities</i>
Session 1: Behavioral model and behavior assessment	<ol style="list-style-type: none"> 1. Introduce overall goals 2. Introduce concepts of functions of behavior, antecedents and consequences of behavior, and how to evaluate behavior
Home visit (between weeks 2 and 3)	Continue with discussion of antecedents to behavior problems and develop preventive strategies
Antecedent management	Develop daily schedule and identify points of intervention to decrease behavior problems
Session 2: Preventive strategies	<ol style="list-style-type: none"> 1. Introduce concept of reinforcers – to strengthen desired behaviors and teach new behaviors 2. Teach token economy
Session 3: Daily schedules	<ol style="list-style-type: none"> 1. Specific methods on how to enhance compliance and how to manage noncompliance
Session 4: Reinforcement	<ol style="list-style-type: none"> 1. Review positive consequences (increases a behavior), negative consequences (decreases a behavior), and planned ignoring (also decreases the behavior)
Session 5: Compliance training	<ol style="list-style-type: none"> 2. Provide instructions on optional topics as appropriate (time-out, contingency management, crisis management)
Sessions 6: Consequences <i>Flex Session</i> : Flexible session to review and repeat a session as necessary	<ol style="list-style-type: none"> 1. Establishment of alternative, replacement behaviors, systematic reinforcement of these behaviors
Session 7: Functional communication training	<ol style="list-style-type: none"> 1. Provide parents with tools on how to teach new adaptive, leisure, and coping skills 1. Generate strategies to consolidate positive behavior changes, establish new additional skills.
Sessions 8 and 9: Teaching skills Generalization and Maintenance	<ol style="list-style-type: none"> 2. Provide instructions on optional topics as appropriate (time-out, contingency management, crisis management, or review /repeat session material as necessary)
Sessions 10 and 11: Maintenance of gains and identifying future goals	
FLEX SESSION: Flexible session to introduce optional session material review and repeat a session as necessary	
Home visit (between weeks 16 and 17)	

Overview - The purpose of this session is to introduce the idea of replacing a functional behavior, most often a functional communication behavior, to reduce or eliminate an inappropriate or undesirable behavior. We wish to convey that challenging behaviors (usually excessive behaviors) serve a function or purpose for the individual engaging in the behavior, relate this back to the earlier conducted functional assessment, and the advantages of this approach.

Goals

1. Review concepts from previous session, home data collection, (and optional observation of skill with parent and child).
2. Introduce concept of functional equivalence training
3. Introduce procedural steps of functional equivalence training
4. Provide examples of functional equivalence training
5. Discuss relevance of functional equivalence training relative to this child

Parent Objectives

1. Parents will have completed home data collections
2. Parents will demonstrate with their child the skill introduced from last session (optional)
3. Parents will give an example of a functional communication / equivalence behavior in response to FCT activity sheet
4. Parents will generate a functional equivalence behavior for their child

Materials Needed

1. Parent Handout on Functional Communication / Equivalence Training
2. Session and Home Activity sheets for Functional Communication Training
3. Video vignettes
4. Functional Communication Treatment Fidelity Checklist
5. Parent Adherence Log
6. Behavior Support Plan

Figure 1. Session G – functional communication/equivalence teaching.

problem behaviors occurred. Naturalistic observation was also an important component of the home visit. The PT therapist recorded observed problematic behaviors, temporal antecedents, and consequences. The initial home visit gave the PT therapist an opportunity to observe family interaction patterns in a naturalistic setting and to become familiar with the physical layout of the home. This information was subsequently used to tailor treatment techniques (e.g., how the physical layout of the home might be altered to promote more independence; where time-out should be conducted). The follow-up visit provided an opportunity to observe adherence and practical utility of the PT strategies in a naturalistic setting.

Selecting Aspects of PT to Address Unique Characteristics of PDD

Several aspects of the PT manual were emphasized to address characteristics unique to children with PDD. These included the use of visual strategies, teaching functional communication, and devoting ample instructional time to discuss the concepts of generalization and maintenance. Visual strategies are commonly used in children with PDD (Bondy & Frost, 2002; Bryan & Gast, 2000; McClannahan & Krantz, 1999; Mesibov, Browder, & Kirkland, 2002) to teach independence, academic, self-help, and safety skills. These strategies capitalize on the relative strengths in visual processing versus weak receptive language in children with PDD. Use of visual schedules also promotes greater predictability for children with PDD who often become anxious when confronted with unexpected situations. They help focus the attention of the child who is overwhelmed by stimulation in his or her environment. Visual information allows longer and more thorough processing time than verbal information and is often more effective than verbal prompts for children with communication disorders. Therefore, to promote greater predictability in the environment and decrease the disruptive behavior that may come from the child's incomplete comprehension of daily events, we included visual strategies in PT for parents to use in the home and community settings.

The PT manual contained specific material designed to assist parents in identifying the function of the child's behavior. Parents were first taught to recognize that destructive or disruptive behaviors could serve as a method through which the child influences the behavior of others; next, parents were taught to reinforce more appropriate communicative behavior (e.g., Carr et al., 2002). Together, the inclusion of visual supports and use of a functional communication approach was adapted to the skills and needs of children. Additionally, the video vignettes provided exemplars applicable to a broad range of children. Finally, the PT manual devoted two sessions to the concepts of generalization and maintenance. These sessions are to address the well-documented difficulty of expanding behavior change across settings and over time in this population (Bregman et al., 2005; Frankel, Simmons, Fichter & Freeman, 1984).

Use of Video Training Vignettes

A set of developed videotape vignettes was developed to accompany the PT manual, as has been done in programs for parents of children with ADHD (Cunningham et al., 1998) and early onset conduct problems (Webster-Stratton, 1996). The videotape vignettes depict common challenging behaviors in children with PDD. Many vignettes model specific skills to supplement direct instruction. Other vignettes are intended to promote learning by showing parent-child interaction

marked by a flawed parent management strategy. The parent is asked to identify the error made in the vignette. Thus, the video vignettes serve as a check on the parents' acquisition of PT techniques and provide an opportunity for the therapist to clarify any potential confusion.

BALANCING THE COMPETING NEEDS OF FLEXIBILITY AND STANDARDIZATION

Although manual development is an essential prerequisite for testing a behavioral intervention in a RCT, flexibility in delivery of PT is also important. This flexibility was necessary not only to address the heterogeneity of the children with PDD in the study but also to meet the needs of different parents. In general, therapists followed the order of sessions as outlined in the PT manual. The order was designed to maximize the benefit of antecedent control strategies and to provide a logical accumulation of knowledge about behavior management for the parents. However, to meet the needs of individual children and parents, the PT manual permitted the therapist, in consultation with the multisite clinical panel, to alter the order of the sessions. The PT manual contained a set of optional sessions. Optional sessions included specific techniques that might not be applicable to all children (e.g., time-out, contingency management, crisis management). There was also flexibility built into many of the optional sessions, where the therapist could choose from among a set of the optional session goals based on the characteristics of the child. Further, the PT manual included a Behavior Support Plan (BSP), which was a working document of individualized procedures to be used with a child. The BSP was completed with the parents at each individual treatment session, adding any new treatment procedures that had been implemented over the course of the PT program.

ESTABLISHING AND MAINTAINING TREATMENT INTEGRITY AND FIDELITY

Training of Therapists

Development and distribution of a treatment manual does not guarantee that the treatment will be delivered as intended. Training and supervision of therapists and continuous monitoring are essential steps toward assuring that treatment procedures are implemented in a consistent manner. Indeed, in the absence of clear documentation that the treatment was delivered consistently, there is little assurance that the study treatment is being accurately tested. There is limited literature on

training and supervision of therapists for multisite interventions, even though these are critical to operations of such studies. One study reported an association between the quality of therapists' training and the outcomes of a clinical trial (Crits-Christoph et al., 1998). Better trained therapists achieved better treatment outcomes. Another study reported that therapists in a large clinical trial perceived continuous supervision as more important than the manual (Najavits et al., 2004). For the current project, a standardized set of quality assurance procedures was developed to assure that PT was implemented in a uniform manner. These procedures governed qualifications of therapists, training of therapists to mastery of the PT manual, and supervision (including on-site supervision, weekly telephone conferencing, and site visits by senior behavior analysts).

PT therapists for this project were masters or doctoral prepared clinicians with prior training in behavior therapy with children. Prior to launching the pilot study of the program, PT therapists participated in a 3-day workshop conducted by two senior behavior analysts. The workshop included a session by session review of the manual and didactic materials, examination of homework assignments and their review, use of accompanying video vignettes, in home procedures, and therapist treatment fidelity ratings. PT therapists and investigators at all sites were provided the following materials: (a) PT manual that included therapist scripts for presenting the content, tasks to be accomplished for each session, and associated materials; (b) instructive videos on tape and or DVD; (c) session activity sheets (e.g., forms to be used to respond to video vignettes); (d) homework tasks/forms; (e) parent handouts (i.e., written summaries of the material covered during each session); and (f) data collection forms.

Treatment Fidelity Procedures

To ensure uniformity in applying the PT program, methods for measuring treatment fidelity were established. *Treatment fidelity* refers to the delivery of the treatment as intended (treatment integrity) as well as subject compliance to the delivered treatment (in the case of PT, this was referred to as adherence). To evaluate treatment integrity, following Waltz, Addis, Joerner, and Jacobson (1993), all sessions were videotaped. Treatment Fidelity Checklists, which contained the essential elements of each session, were completed by therapists during each session. During the pilot study, the senior behavior analysts (B. H. and C. J.) independently rated at least 1 session of all the 11 core sessions from all therapists. As a result of the pilot study experience, Treatment Fidelity Checklists were revised to be more clearly operationalized for each of the session goals for the randomized study. The final checklists included Session Integrity Goals (therapeutic aims of the session) and Parent Adherence Goals (actions on the part of the parent that indicated comprehension of concepts for each

session and homework completion). Each goal was rated by the therapist on a scale of 0–2 (anchored to poor, partial, or complete attainment/understanding, respectively). Adherence to the PT program was also monitored by session attendance and completion of assignments. We agreed to provide flexibility regarding re-scheduling sessions due to unexpected events. However, if a family missed a session without notifying the therapist or missed two sessions in a row (even with notification), the parents were contacted by the therapist to determine the reasons for missed sessions and a plan to facilitate attendance at sessions was developed.

A minimum criterion of 80% of the maximum possible score (sum of the 0–2 scores) was established for therapist certification for each PT session. Feedback was provided to therapists for each videotape viewed and therapists were required to attain certification on each of the core PT sessions. If criterion rating was below 80% from independent rating, the therapist was required to submit a videotape of the corresponding session with another parent. Only certified therapists were permitted to conduct PT in the randomized trial. The Treatment Fidelity Checklist was also used to assess reliability between therapist ratings and external ratings of the two senior behavior analysts. An example of a Treatment Fidelity Checklist is provided in Figure 2.

While a large percentage of the sessions were observed to ensure therapist integrity and to certify therapists, an additional random sample of 10% of each certified therapist's taped sessions was examined quarterly for session integrity, parent adherence, and interrater reliability by the lead behavior analysts. Therapists were required to maintain session integrity ratings of at least 80%, parent adherence of at least 65%, and interrater reliability of at least 80%. In addition to weekly monitoring by therapists, parent adherence was monitored by reviewing a monthly generated report of summarized adherence data. If ratings fell below criteria, the two lead behavior analysts reviewed the issues during a telephone call with the therapist and his/her supervisor. The therapist subsequently submitted a written remediation plan.

Additional Quality Assurance Procedures

In addition to viewing videotaped sessions, the senior behavior analysts conducted weekly teleconferences with all PT therapists to review progress, participate in case presentations, and respond to questions raised or difficulties encountered. The intent of these calls was to develop a 'common therapeutic culture' among the therapists and facilitate a consistent approach to addressing clinical issues. Senior behavior analysts were available on an 'as needed basis' to the therapists for telephone consultation/email. In addition, the senior behavior analysts conducted annual visits to each of the study sites to maintain training integrity and to avoid therapist drift.

General Instructions: The clinician should complete a Treatment Fidelity Checklist for each session immediately after the session to indicate the degree to which the session Goals and Parent Objectives were accomplished. The Goals pertain to clinician behavior while the objectives relate to parent response. If a goal was not introduced or covered the clinician should provide an explanation of what occurred. A place is provided for this at the end of the checklist. **This form should be used for any visit which covers this material. Enter the date for which the rating is applicable in the space provided. This will allow for documentation of all topics covered. Only circle 0, at the last session, if the session material was not covered at any session in the study.**

The following scale should be used to rate the degree to which session goals were attained.

- 0 = Goal was not introduced or covered by the clinician
- 1 = Goal was partially achieved
- 2 = Goal was fully achieved

Goals:	Rating:	Date:
1. Review concepts from previous session & home data collection.	0 1 2 N/A	___/___/___
2. Introduce concept of functional equivalence training.	0 1 2 N/A	___/___/___
3. Introduce procedural steps of functional equivalence training.	0 1 2 N/A	___/___/___
4. Provide examples of functional equivalence training.	0 1 2 N/A	___/___/___
5. Discuss relevance of functional equivalence training relative to this child.	0 1 2 N/A	___/___/___
A total score of 8 (80%) and higher reflects adequate treatment fidelity.	Total Score: ____	

The following scale should be used to rate the degree to which the parent participated, responded correctly, and completed activities.

- 0 = Parent did not demonstrate skill or understanding
- 1 = Parent understood or responded correctly to a few of the queries
- 2 = Parent understood and responded correctly to nearly all queries (incorrect response of less than 2)

Parent Objectives:	Rating:	Date:
1. Parents will have complete home data collections.	0 1 2 N/A	___/___/___
2. Parents will demonstrate with their child the skill introduced from last session (optional).	0 1 2 N/A	___/___/___
3. Parents will give an example of a functional communication / equivalence behavior in response to FCT activity sheet.	0 1 2 N/A	___/___/___
4. Parents will generate a functional equivalence behavior for their child.	0 1 2 N/A	___/___/___
A total score of 5 (80%) and higher reflects adequate treatment fidelity (excluding optional 2.)	Total Score: ____	

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Figure 2. Treatment Fidelity Checklist example.

Training of New Therapists

In the life of a large scale, multisite study, therapist attrition is expected. This raises the issue of training new therapists without disrupting the study. Specific procedures were developed to train new therapists in an efficient manner. The new therapist would view a set of ‘expert’ videotapes (made with subjects who had participated in the pilot study) for each of the PT sessions, would sit in with currently certified

therapists for a minimum of six sessions, and would spend a half-day meeting with the PT developers to review the PT manual and view tapes together. Finally, the new therapist was assigned a *nonstudy* training case. As in the pilot study, the PT sessions were videotaped and all session tapes were sent for external review and discussion as needed with the senior behavior analysts and site supervisors. Once the first two PT sessions met earlier described fidelity criteria, the new therapist was permitted to initiate PT with a randomized study family. This system allowed the new therapist to become certified for a given session a couple of weeks prior to conducting that same session with a study family.

DISCUSSION

The behavior analytic literature provides a rich body of single-subject studies demonstrating the efficacy of specific behavioral techniques commonly used in PT programs. Furthermore, parents have been included in many comprehensive programs serving children with PDD (Dunlap & Fox, 1999; Harris et al., 2001; Marcus et al., 2000; Rogers et al., 2000; Smith et al., 2000b). However, *large* scale, multisite, randomized studies of PT in children with PDD are uncommon. Indeed, there are only a few small randomized group design studies that have evaluated many of the individual procedures that are often used in PT programs for children with PDD (Drew et al., 2002; Jocelyn et al., 1998; Ozonoff & Cathcart, 1998; Sheinkopf & Siegel, 1998; Smith et al., 2000c; Sofronoff et al., 2004). Thus, although there is accumulated evidence that parent-mediated interventions are effective in children with PDD, widespread dissemination and evaluation of exportable treatment programs have been quite limited. An essential prerequisite for a multisite study of a behavior therapy intervention is the development of a manual that can be delivered uniformly by competent therapists and is acceptable to parents. To be successful in children with PDD, such a manual must balance uniformity with flexibility. Uniform delivery of the behavioral intervention assures the structured treatment program is indeed the program being tested. Flexibility permits responsiveness to individual needs of the child and family and presumably promotes acceptability by parents. The development and testing of a structured PT program in a large scale randomized trial also promote the dissemination of PT in PDD. Preliminary feasibility and efficacy data on this PT program are provided in the companion paper (RUPP Autism Network, in press).

The PT program described in this paper was developed for a multisite study. The goal of the study is to evaluate the additive effects of PT to medication for enhancing compliance, improving adaptive behavior, and decreasing severe problem behaviors above and beyond the effects of medication alone. The choice of PT as the

psychosocial component for the current study was based on the desire to provide an exportable, short-term treatment comprised of techniques with empirical support. The pilot study of the PT program allowed further refinement of the materials and treatment fidelity procedures. Nevertheless, the PT program has limitations. First, this PT program is of lesser intensity and shorter duration of treatment than many ABA treatment programs for young children with PDD (Lovaas & Smith, 2003; Smith et al., 2000b). Second, although this program offers some flexibility in the delivery of the intervention, it cannot be described as an individualized intervention. Third, the outcome measures are primarily parent completed checklists and clinician ratings rather than individualized outcomes (e.g., frequency counts of specific behaviors). However, this program is not proposed as a comprehensive treatment program addressing the core deficits inherent in PDD. Rather, it is meant to be an adjunct to medication to improve child compliance and adaptive functioning and further decrease disruptive behaviors. Furthermore, this PT program is consistent with one of the overall aims of the RUPP Autism Network, which is to conduct studies that can guide clinical practice. Indeed, we are confident that this PT program can be delivered by competent therapists in clinical settings. Efficacy of this PT program at this level of intensity and the specific constellation of interventions chosen await the results of the currently ongoing RCT.

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