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PARENT TRAINING FOR CHILDREN WITH PERVASIVE DEVELOPMENTAL DISORDERS: A MULTI-SITE FEASIBILITY TRIAL

Research Units on Pediatric Psychopharmacology [RUPP] Autism Network*,†

The primary purpose of this study was to evaluate the feasibility of a structured, manual-based parent training (PT) program designed to reduce noncompliant behavior and enhance adaptive behavior in children with Pervasive Developmental Disorders (PDD) who were taking medication for irritability, tantrums, aggression, and self-injury. Children ($N = 17$, mean age 7.7 ± 2.6 years) with PDD were enrolled in a 24-week structured PT protocol. Parental attendance to sessions (93%), satisfaction with the program (92%), and adherence to PT assignments (80%) were excellent. The program was adequately implemented with a mean treatment integrity rate of 94%. Parent-reported rates of noncompliance were reduced by 39%; irritability was reduced by 34%; and daily living skills were enhanced by 19%. Parenting stress was also reduced by 14%. However, these results must be interpreted with caution because the study did not include a control group. The study supports feasibility of the PT program, which will be used in an randomized clinical trials (RCT). Copyright © 2007 John Wiley & Sons, Ltd.

For the purposes of this report, Pervasive Developmental Disorders (PDD) refers to children diagnosed with a DSM-IV diagnosis of Autistic Disorder, Asperger's Disorder, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). A large percentage of children with PDD display significant disruptive behaviors (Gadow, Devincent, Pomeroy, & Azizian, 2004; National Research Council, 2001; Tonge & Einfeld, 2003; Lecavalier, 2006). These disruptive behaviors often interfere with family life and educational and community adjustment. Parent training for behavior management, or parent training (PT) has been applied for the

*Correspondence to: Eric M. Butter, Departments of Psychology and Pediatrics, The Ohio State University, Columbus Children's Hospital Autism Center, 187 West Schrock Road, Westerville, OH 43081, USA.
E-mail: buttere@chi.osu.edu
†Participants in the Research Units on Pediatric Psychopharmacology (RUPP) Autism Network include: Eric M. Butter, Ph.D., Michael G. Aman, Ph.D. (Principal Investigator), L. Eugene Arnold, M.Ed., MD, Kristy Hall, BA, James A. Mulick, Ph.D., Jill Hollway, M.A., and Luc Lecavalier, Ph.D., The Ohio State University, Columbus, OH; Lawrence Scahill, MSN,Ph.D. (Principal Investigator), Denis G. Sukhodolsky, Ph.D., Susan Williams, Ph.D., Kathleen Koenig, MSN, Karen Bearss, Ph.D., and Roumen Nikolov, M.D., Yale University, New Haven, CT; Christopher, McDougle, M.D. (Principal Investigator), Kimberly Stigler, M.D., Naomi Swiezy, Ph.D., Arlene Kohn, B.A., Joy Fairbanks, M.S., Megan Grothe, B.A., Indiana University School of Medicine, Indianapolis, IN; Benjamin L. Handen, Ph.D. and Cynthia R. Johnson, Ph.D., The University of Pittsburgh School of Medicine, Pittsburgh, PA; and, Ann Wagner, Ph.D., Benedetto Vitiello, M.D., and Louise Ritz, MBA, National Institute of Mental Health.

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treatment of disruptive behaviors in children with PDD (Harris, Handleman, Arnold, & Gordon, 2000; Lovaas & Smith, 2003; Romancyk, Lockshin, & Matey, 2000; National Research Council, 2001). PT involves direct instruction to parents on managing child behavior problems and teaching developmental skills (Harris, 1986; Schreibman & Koegel, 1996). The techniques taught in PT are based upon the extensive literature available from the fields of behavioral psychology and applied behavior analysis. Though few randomized clinical trials (RCTs) have been completed, structured PT programs and less formal PT activities have been a component of many comprehensive treatments for children with PDD (Lovaas, 1987; Smith, Groen, & Wynn, 2000; Maurice, Green, & Luce, 1996).

The current study reports the results of a feasibility investigation of a 24-week PT program, operationalized in a detailed manual and designed to complement pharmacotherapy of highly disruptive behavior, for parents of children with PDD. The PT program was developed as a structured program to facilitate uniform delivery in a multi-site study (Carroll & Nuro, 2002). For more detailed presentation of this PT program, see the companion paper (Johnson, Handen, Butter, Wagner, Mulick, et al., in this issue).

The PT program evaluated here was developed as a complementary treatment for an RCT comparing the effects of risperidone plus PT to the effects of risperidone alone in children with PDD accompanied by noncompliance, tantrums, aggression, and self-injury. Previous reports from the Research Units on Pediatric Psychopharmacology (RUPP) Autism Network (2002) and others (see Aman & Madrid, 1999; Arnold, Vitiello, McDougle, Scahill, Shah, Gonzalez, et al., 2003) showed that risperidone was well-tolerated and effective in reducing serious behavioral problems among children with autism. Risperidone was superior to placebo in reducing negative and disruptive behaviors (RUPP Autism Network, 2002). These gains were stable over 6 months of treatment, and behavior problems tended to return when medication was discontinued (RUPP Autism Network, 2005). However, effects on core symptoms of communication and social interaction or adaptive behavior were modest (RUPP Autism Network, 2002; McDougle et al., 2005; Williams, Scahill, Vitiello, Aman, Arnold, McDougle, et al., 2006).

An often-cited behavioral target of PT is child noncompliance (McMahon & Forehand, 2003; Kazdin, 2003; Moran & Whitman, 1991; Schopler & Reichler, 1971; Wells, Pelham, Kotkin, Hoza, & Abikoff et al., 2000). Noncompliance is even more prevalent among children with PDD than in other groups of children with developmental disabilities (Lemanek, Stone, & Fishel, 1993). Noncompliance, broadly defined as a lack of cooperation with parental requests and/or daily activities, is multiply determined in children with PDD. Such children may be noncompliant because of communication deficits, disinterest in acquiring new adaptive skills, distress related to interference with repetitive behaviors resistant to change,

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noncompliance also may enable children to escape from routine environmental demands. These patterns of noncompliance may be inadvertently sustained by caregivers' uncertain and inconsistent efforts to manage these behaviors. The PT intervention was designed to replace ineffective parenting strategies with techniques intended to create greater cooperative behavior in activities of everyday life.

The current study is based on the assumption that noncompliance interferes with daily living tasks such as dressing, eating, toileting, or other adaptive activities (Moran & Whitman, 1991; Newman, Needelman, Reinecke, & Robek, 2002). Indeed, children with PDD display lower-than-expected adaptive functioning for their intellectual level. This discrepancy is present in children with (Carter, Volkmar, Sparrow, Wang, Lord, Dawson, et al., 1998 and without mental retardation (Bolte & Poustka, 2002). Thus, the underlying assumption for this PT program for children with PDD is that noncompliance interferes with the regular performance of daily living skills. Of particular interest in this feasibility project was the improvement in compliance and adaptive behavior.

In designing the current study, we sought to evaluate the feasibility of a specially designed PT program (Johnson et al. in this issue) and, as a secondary aim, to provide initial open data on the efficacy of PT for reducing noncompliance and other unwanted behaviors while increasing adaptive behavior. Feasibility in this context includes four parameters: *treatment integrity*, which is *the demonstrated ability of the structured PT program to be implemented uniformly by different clinicians across different sites*, *parental adherence* as measured by parental active participation, *parental attendance* at PT sessions, and *parent satisfaction* with the program.

METHOD

Participants

This study was approved by the Institutional Review Boards of each university and parents of all participating children signed informed consents. Families were compensated for their time and traveling expenses for each assessment and treatment visit.

Seventeen children between the ages of four and 13 years who were on stable medication for significant behavior problems and had at least one parent available for training were enrolled over a nine-month period. To be eligible, children had to meet clinical DSM – IV criteria for Autistic Disorder, Asperger's Disorder, or PDD – NOS. Diagnostic assessment was conducted by experienced clinicians at each site by interview and direct observation. Diagnosis was corroborated by the Autism Diagnostic Interview: Revised (Lord, Rutter, & Le Couteur, 1994). Of the 17 children enrolled, 11 were diagnosed with Autistic Disorder, two with Asperger's Disorder, and three with Pervasive Developmental Disorder, Not Otherwise Specified. Six

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children were treated at the Ohio State University site, five at Indiana University, four at the University of Pittsburgh, and three at Yale University. Of the 17 children enrolled, 13 were also receiving special education services, while four children were enrolled in regular education public school classrooms.

In addition, participants were required to be clinically stable. Clinical stability was defined as having had the same medication dose for at least four weeks with no planned dosage changes for six months and a Clinical Global Impression – Severity (CGI; Guy, 1976) score at baseline of at least three (mild) but no greater than five (marked). This pattern of scores provided some assurance that children had received some benefit from medication, but some behavioral problems remained. Additionally, children with an IQ below 35 (or mental age of less than18 months) were excluded, based on the belief that these children might need more specialized intervention.

Procedures

Screening assessments included intelligence testing using either the Wechsler Intelligence Scale for Children: Third Edition, Mullen Scales of Early Learning, or Leiter International Performance Scale: Revised, depending on the child's cognitive functioning, and the Slosson Intelligence Test. Children and families who met the inclusion/exclusion criteria were invited for the baseline visit scheduled seven to 14 days after the screening visit. The baseline visit involved completion of standardized parent ratings, clinician measures, and a structured observation of parent-child interaction. During the 24-week study, parent(s) were seen weekly for 75 to 90 minute PT visits until Week 14 and then for a home visit (week 17) and booster sessions (weeks 18, 20, and 22). Also, an initial home visit was conducted between the week two and week three PT session.

Study assessments were completed under conditions mimicking as closely as possible the anticipated randomized trial. Repeated measures were collected at regular time points during the PT program (e.g., at baseline, weekly through week eight, monthly at weeks 12, 16, and 20, and at study end-point at week 24). Blinding procedures included maintaining separate offices for independent evaluators and PT therapists, providing childcare in discrete locations after evaluations when parents were involved in PT sessions, and monitoring traffic patterns in buildings to reduce chance contact between independent evaluators and the families.

Intervention

The rationale for the PT program, as well as qualifications, training, and supervision of PT therapists, are described in the companion paper (Johnson et al. in this issue). In brief, the PT package included 11 required sessions covering topics such

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as prevention strategies, schedules, reinforcement, planned ignoring, compliance training, functional communication training, teaching techniques (task analysis, chaining, and prompting), and generalization. Additionally, there were up to four optional sessions including time-out, contingency contracting, imitation training, and crisis management that could be implemented at the clinician's discretion. These optional sessions allowed some degree of individualized treatment to meet the needs of specific children. Booster sessions, using previously-introduced parent training strategies, were provided at Weeks 18, 20, and 22. These booster sessions were designed to deal with additional or lingering behavioral concerns.

PT sessions included a structured curriculum and clinician script, video vignettes depicting various skills to be taught to the parents, worksheets, and parent handouts. Given that PT involved direct instruction to parents in behavioral intervention strategies, children were required to participate in portions of up to eight sessions which allowed for direct observation of parent-child interactions demonstrating the interventions introduced in PT sessions. Otherwise, parents were encouraged to obtain childcare services to permit full participation of the parent in PT. If a parent was unable to obtain childcare, the child was allowed to play in a supervised setting at the clinic while the parent was involved in the PT program. PT therapists also conducted two home visits. The first home visit (between study week two and three) was designed for the therapist to observe family interactions in the home environment in order to guide PT interventions. The second home visit (between study week 16 and 17) was designed to evaluate the implementation of PT interventions and to provide additional guidance about previously-introduced interventions.

Efforts were made to tailor the PT program to the specific challenges and needs of families with a child with PDD. For example, videotapes depicted children engaging in behaviors typical of children with PDD; modules contained examples and techniques for children with a range of functioning including nonverbal children; descriptions of visual strategies (e.g., schedules, token reinforcement boards, picture communication) were used; a session emphasizing developing schedules and establishing routines was incorporated as a prevention strategy perhaps uniquely helpful for children with PDD; two sessions on generalization were included recognizing that children with PDD often have difficulty generalizing new learning; finally, an optional session on imitation training was developed as many children with PDD experience incomplete, inaccurate, or a lack of imitation skills.

Feasibility Measures

Parental Acceptance

Parental attendance at PT sessions is an essential indicator of parental acceptance of the PT program. Prior to the study we set a parental attendance rate of 67% as a

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minimum standard. Though no consensus of an appropriate attendance rate is reported in the literature, a target that indicated parents would have attended two-thirds of PT sessions is consistent with attendance rates actually reported and seemed reasonable to us. Parents also completed a satisfaction questionnaire at the end of the study. This questionnaire asked parents to rate various elements of the PT program such as number of sessions, length of sessions, and the usefulness of teaching tools such as video tape vignettes, in-session worksheets, and homework. The questionnaire also asked parents to rate the helpfulness of specific elements of the PT program, as well as their confidence in handling future behavior problems. Items were scored on either three or four points Likert scales, with higher scores reflecting greater levels of satisfaction with the PT program. Items were anchored with phrases such as 'just right' (three or four), 'ok' (two or three), and 'not helpful' (1). For items that were on a four point scale (e.g., number and length of sessions, difficulty of PT materials, usefulness of parent handouts) scores of one or two were anchored by additional phrases such as 'too easy', 'too difficult', 'too long', 'too short', 'too many' or 'too few' The score range was 16 to 52 with higher scores reflecting greater satisfaction.

Parental Adherence

The Parent Treatment Adherence scale is a clinician-rated measure keyed to the PT manual such that the items matched activities and homework assignments session-by-session. Clinicians rated the degree to which parents successfully completed session and homework assignments on a zero- to two-point scale, with higher scores indicating more successful implementation. Clinicians made ratings based upon parent report, review of homework data work sheets, parent's responses to videotape vignettes, and observation of parent-child interactions during sessions. Scores of 65% or higher represented an acceptable rate of parental adherence, based upon the rationale that the minimum standard should be greater than 50% but not so stringent as to characterize parents who participated in a substantial majority of the aspects of the PT as nonadherent. As a check on the therapists' ratings, the primary authors of the PT manual viewed 50% of videotaped PT sessions and independently rated parental adherence to treatment.

Treatment Integrity

Treatment integrity, defined as how faithfully the manualized treatment was implemented by the therapist, was evaluated by therapist's own ratings of how thoroughly each PT topic was covered. These ratings, which were completed immediately after each session, were scored on a zero- to two-point scale. Higher

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scores indicated greater integrity. A sample of treatment integrity ratings made by PT therapists were reviewed through videotape by the primary authors of the PT manual. Prior to the study, a threshold of 80% on clinician-rated treatment integrity was established. This benchmark was based on the rationale that while some small amount of flexibility should be permitted, the large majority of the manualized program needed to be implemented to represent a true test of the PT program. This integrity rating provided data regarding cross site consistency between PT therapists.

Efficacy Measures

Child Noncompliance

Child noncompliance with rules and parental requests was measured by the modified Home Situations Questionnaire (HSQ; Barkley, 1997). The HSQ is a 25-item parent-completed questionnaire about the presence and severity of child noncompliance across a variety of common daily situations. Parents indicated the presence of noncompliance and then rated the severity of the problem on a one- to nine-point scale. Scores were expressed as a mean score (total severity divided by 25 items) with higher scores indicating greater severity. For this study the HSQ was slightly modified from the original such that new items more appropriate to children with PDD were added (e.g. difficulty with transitions). The HSQ was collected at baseline and at weeks 2, 4, 6, 8, 12, 16, 20, and 24.

Behavioral Adjustment

The Aberrant Behavior Checklist (ABC; Aman, Singh, Stewart, & Field, 1985) was completed by the parent at baseline and weeks two, four, six, eight, 12, 16, 20, and 24. It is a 58-item, informant-based scale comprising five subscales: *Irritability* (includes agitation, aggression, and self-injurious behaviors, 15 items); *Lethargy* (includes social withdrawal, 16 items); *Stereotypic Behavior* (seven items); *Hyperactivity* (includes noncompliance, 16 items); and *Inappropriate Speech* (repetitive verbalizations, four items). The ABC is commonly used as a measure of treatment effects in developmentally disabled populations, reported in over 165 studies (Aman et al., 1985; Aman, Richmond, Stewart, Bell, & Kissel, 1987; Aman, 2005).

Global Improvement

Clinical Global Impressions – Improvement Scale (CGI – I) is a seven-point scale designed to measure overall change at a given time as compared to baseline (Guy, 1976). Scores range from one (Very Much Improved) through four (Unchanged) to

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seven (Very Much Worse). The CGI – I was rated by an independent clinical evaluator at weeks four, eight, 12, 16, 20 and 24 of the study based on interview with the parent and review of other ratings obtained at that evaluation visit. Scores of 'much improved' or 'very much improved' were used to define a positive response.

Adaptive Behavior

The Communication, Socialization, and Daily Living Scales of the Vineland Adaptive Behavior Scales-Survey Form (VABS-Survey; Sparrow, Balla, & Cicchetti, 1984a) were administered at baseline to characterize the independent functioning of subjects and the Vineland Adaptive Behavior Scales – Expanded Form, Daily Living Scales were administered at baseline, week 16, and week 24 to measure changes in personal care skills (VABS-DLS; Sparrow, Balla, & Cicchett, 1984b). The expanded form provided significantly more items and was expected to be more sensitive as a measure of change over time. The VABS was scored in the standard manner (i.e., a zero to two-point scale for most items, with higher scores indicating greater functioning), and age equivalent scores were used for analysis.

The Assessment of Basic Language and Learning Skills (ABLLS) is a criterion referenced assessment that provided a behaviorally oriented task analysis of a variety of developmental skills (Partington & Sundberg, 1998). The ABLLS assesses the component steps of an overall skill and the version that we used closely tracks progress in four developmental self-help domains: toileting, grooming, dressing, and eating. Typically the measure is rated by parents or teachers. For this study, we modified the ABLLS as a structured clinician interview with ratings of how independently the child performed daily living activities; higher scores represented greater independence. In addition to revising the four self-help domains, our group created a 'household chores' measure that assessed independence in activities such as cleaning up after oneself, preparing and organizing school materials, and using household electronics. The final modified measure included 108 items across the five subdomains. The scoring key ranged from zero ('unable or won't do') to three ('will do independently'). Total raw scores were used in analyses (possible range of zero to 324). The ABLLS was administered at baseline and at Weeks 16 and 24 of the study. Other than the cross-site discussions on the development of this modified version of the ABLLS, there was no formal check on the reliability and validity of the measure.

Parenting Stress

The Parenting Stress Index was collected at screen and at week 24 (PSI; Abidin, 1983). This 36-item, parent-completed questionnaire asks parents to rate, on a

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five-point scale from ‘strongly agree’ to ‘strongly disagree’, current stress associated with parenting.

Analytic Methods

Feasibility was determined by observing rates of parental attendance, parent satisfaction, parental adherence, and treatment integrity. These data are presented as percentages. Reliability of the therapists’ ratings of treatment integrity is also reported as percentages, corresponding to the rate of congruence between the therapist ratings and the expert behavioral clinicians ratings who reviewed the videotapes. Efficacy of PT was evaluated using repeated measures across five domains including compliance, behavioral adjustment, global improvement, adaptive behavior, and parenting stress. The HSQ and ABC repeated measures were analyzed using mixed-effects linear models in which subjects and site were the fixed effects and the outcome variable and time were the random effects. This approach followed the intent to treat convention and made use of all available data. The Vineland and ABLLS data were collected only three times during the study and, therefore, were analyzed using repeated measures analysis of variance. The within group effect sizes (d) were calculated using the following formula: mean score at 24 weeks minus the mean score at baseline divided by the pooled standard deviation. Data were analyzed using SPSS 14.0.

RESULTS

Table 1 provides characterization of the study participants (e.g., age, baseline IQ, adaptive behavior, aberrant behavior profiles, and annual household income). Race identification indicated that the sample was 88% Caucasian, 12% African-American, 6% Asian, and 12% Hispanic; the total is greater than 100% because 18% of the participants selected more than one race identification category. Additionally, the children came from largely intact families; 88% of the participants came from two parent households and all of the children lived in a parental home. Most of the children were in pre-school or kindergarten (76%), while 24% were enrolled in first through eighth grade. About two-thirds of the children (65%) were enrolled in a special education classroom, and 35% were enrolled in a regular education classroom.

Feasibility Outcomes

Parental Acceptance

First, feasibility of the PT protocol was established by observing the rates of parental attendance at PT sessions and parent satisfaction. Parents attended 93.1% of

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Table 1. Participant Characteristics (N = 17; 14 male, 3 female).

	Mean	*Standard deviation*
Age (years)	7.7	2.6
IQ (standard score)	55.9	22.3
Vineland adaptive behavior scales (standard scores)	—	—
Communication	50.6	18.3
Daily Living Skills	37.7	17.1
Socialization	52.3	10.9
Composite	43.2	13.7
Aberrant behavior checklist	—	—
Irritability	24.3	9.3
Stereotypic behavior	8.8	5.7
Lethargy/social withdrawal	9.5	8.2
Hyperactivity/noncompliance	27.4	9.5
Inappropriate speech	3.8	3.6
Annual household income	Percent	—
Less than $20,000	12%	—
$20,001 to $40,000	18%	—
$40,001 to $60,000	47%	—
$60,001 to $90,000	23%	—

the 11 mandatory PT sessions, which was substantially higher than the pre-study criterion of 67%. Three families (17.6%) exited prior to completion of the feasibility study. Subjects terminated because of medication changes ($n = 1$), medical problems ($n = 1$), or parent unavailability related to factors outside of the study ($n = 1$).

The Parent Satisfaction Questionnaire measured parent perceptions of helpfulness of different elements of the PT program and is reported in Table 2. The mean total parent satisfaction score was 91.6% of the possible maximum and was interpreted as a high level of satisfaction with PT. More specifically, parent satisfaction ratings for different elements of the PT program (e.g., number of sessions, length of sessions, difficulty of PT materials, videotape vignettes, and parent hand-outs) were high or moderate, but nonetheless slightly varied. All parents were at least moderately satisfied with the *content* of PT sessions. All parents indicated that target behaviors had improved and indicated that they had greater confidence in handling current behavior problems. Most parents (91%) reported more confidence in handling future behavior problems and 91% indicated that they would recommend the PT program to other parents. One parent would not recommend the PT program to others.

Parental Adherence

The mean parental adherence score for the 11 mandatory PT sessions was 80%. Thus, our pre-study minimum standard of 65% for parental adherence scores

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Table 2. Parent satisfaction ratings for different elements of the PT program.

Elements of PT sessions (1–3 or 1–4 rating as indicated)	*Mean ± SD*[1]	*% Highly satisfied*[2]	*% Moderately satisfied*[3]
Number of sessions (1–4 rating)	3.4 ± .5	36%	64%
Length of sessions (1–4 rating)	3.5 ± .5	46%	54%
Difficulty of PT materials (1–4 rating)	3.3 ± 1.2	64%	18%
Parent hand-outs (1–4 rating)	3.8 ± .4	82%	18%
Videotape vignettes (1–3 rating)	2.5 ± .5	46%	54%
Home visits (1–3 rating)	2.6 ± .7	64%	27%
PT sessions (1–3 rating)			
Behavior principles	2.9 ± .3	91%	9%
Prevention strategies	2.9 ± .3	82%	9%
Reinforcement	2.6 ± .5	82%	18%
Compliance training	2.8 ± .4	64%	36%
Teaching strategies	2.9 ± .3	91%	9%
Generalization	2.7 ± .5	91%	9%
Attributions about child behaviors (1–3 rating)			
Target behaviors improved	3.0 ± 0	100%	—
More confident in handling current behavior problems	3.0 ± 0	100%	—
More confident in handling future behavior problems	2.9 ± .3	91%	9%
Recommend PT to other parents	2.9 ± .3	91%	0%
Parent satisfaction total score	47.64 ± 4.01	(range of 16 to 52)	—

[1]higher scores reflected greater satisfaction.
[2]represents percentage of parents who indicated 'just right' or 'very helpful' for that PT element.
[3]represents percentage of parents who indicated 'ok' for that PT element.

(i.e. ratings of how well the parents implemented aspects of the PT program) was exceeded.

Treatment Integrity

The mean clinician treatment integrity score across sessions and therapists was 94.2%, with a range of 80.4% to 100%. Clinician ratings of treatment integrity for the 11 mandatory PT sessions were 95.7% congruent with reliability scoring as indicated by the video tape review. More specifically, experienced clinician ratings of treatment integrity across all sessions and all therapists ranged from 55% to 100%; three sessions were rated below the pre-study criterion of 80%. Further, the video tape review showed that mean individual therapist reliability scores across all sessions ranged from 91.7% to 97.3%. Thus, the PT therapist appeared to implement most, and in many cases all, of the critical elements of the standardized PT protocol and rated their own tendencies to follow the treatment manual accurately.

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Summary of Feasibility by PT Session

Table 3 presents data on parent attendance, parental adherence, treatment integrity, and clinician reliability ratings for each of the 11 mandatory PT sessions. Though attendance was high throughout the study, parental adherence was lower in the later sessions. Adherence for the Functional Communication session was particularly low (60.5%). Treatment integrity and clinician reliability remained high throughout the study. The session with the lowest treatment integrity rating was the Generalization/ Maintenance II session, perhaps reflecting the slightly looser structure of that particular session.

Efficacy Outcomes

Compliance

A mixed-effects linear model of HSQ scores indicated a significant downward trend across time ($F = 13.36$, $p = 0.01$), resulting in a 39.4% improvement in parent ratings of noncompliance (from 3.56 ± 1.05 at baseline to 2.17 ± 1.48 at week 24). This reduction in the HSQ score corresponded to the effect size $d = 1.11$. Figure 1 depicts the downward trend in HSQ scores, and suggests that nearly all gains were made by week 8.

Behavioral Adjustment

Analysis with a mixed-effects linear model indicated that the Irritability subscale of the ABC decreased significantly across time ($F = 6.89$, $p < 0.01$), resulting in a 33.8%

Table 3. Feasibility outcomes for each mandatory PT session.

	Parent Attendance	*Parent Adherence*	*Treatment Integrity*	*Clinician Reliability*
Behavioral principles	100%	94.7%	99.3%	97.5%
Prevention strategies	94.1%	85.3%	99.5%	100%
Schedules	100%	89.2%	80.4%	100%
Reinforcement	100%	89%	95.3%	91.3%
Compliance training	94.1%	78.0%	96.5%	92.7%
Planned ignoring	94.1%	73.1%	94.1%	96.4%
Functional communication	88.2%	60.5%	96.7%	88%
Teaching I	88.2%	80%	97.3%	100%
Teaching II	88.2%	77.6%	96%	93.3%
Generalization/maintenance I	88.2%	72%	95.5%	96.6%
Generalization/maintenance II	88.2%	80.1%	82.2%	96.6%
Total	93%	80%	94%	96%

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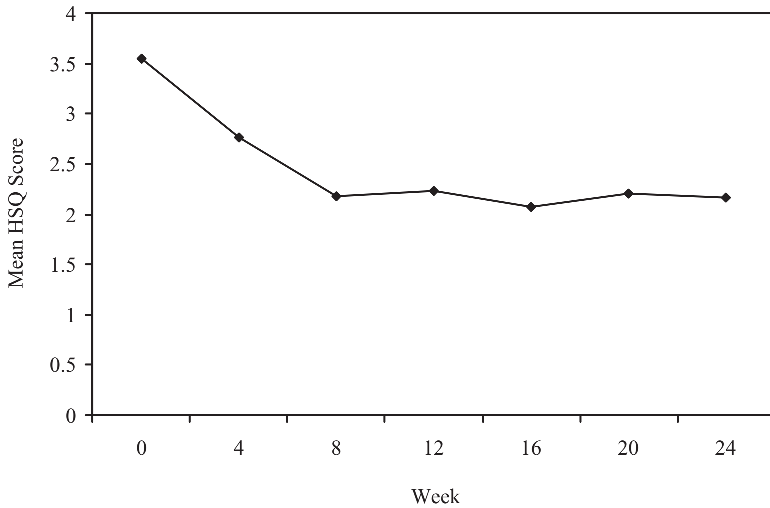

Figure 1. Mean scores on the Home Situations Questionnaire (HSQ) over the 24 week study period.

reduction (from 24.3 ± 9.3 at baseline to 16.1 ± 9.5 at 24 weeks, $d = 0.90$). The Hyperactivity/Noncompliance subscale showed a significant downward trend ($F = 4.51$, $p < 0.05$) and an overall 20.6% reduction (from 27.4 ± 9.5 at baseline to 21.7 ± 10.2 at 24 weeks, $d = 0.60$). These results are depicted in Figure 2. The three other Aberrant Behavior Checklist subscales (i.e., Lethargy/Social Withdrawal, Stereotypy, and Inappropriate Speech) did not show statistically significant changes over time.

Global Improvement

The response rate, defined as a CGI-I rating of 1 (very much improved) or two (much improved) was 53%, while 30% indicated minimal improvement, and 6% indicated no change. Data for one subject was missing.

Adaptive Behavior

Improvements in adaptive behavior were found on the Vineland Daily Living Skills (Vineland DLS) domain. Raw scores, standard scores, and age equivalent scores are presented in Table 4. These were analyzed using repeated measures ANCOVA. The mean age equivalent score increased significantly over time ($F = 14.6$, $p < 0.01$), representing an 18.7% increase in age equivalency (from 35.7 months to 42.4 months, $d = 0.34$). Raw score increases were also significant ($F = 11.72$, $p < 0.01$) with a 22.3% increase (from 119.9 to 146.7). The increase in standard scores was not

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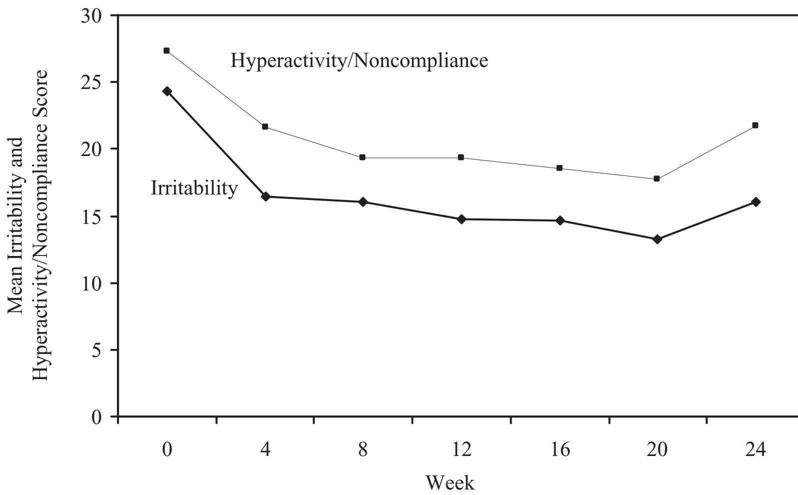

Figure 2. Mean scores on the ABC-irritability and hyperactivity/noncompliance subscales over the 24-week study period.

significant. Clearly, these children remained behind, but showed an increase in adaptive behavior greater than would be expected with the passage of time based on past performance extrapolated.

The ABLLS scores were analyzed using repeated measures ANCOVA. ABLLS scores significantly increased over the 24 week study period ($F = 11.04$, $p < 0.01$), with a 19.2% increase in adaptive skills (from 133.4 ± 64.2 at baseline to 159.0 ± 56.4 at 24 weeks, $d = 0.44$) (see Table 4). Because the ABLLS is not referenced to a normative sample, raw score increases represent gains in component steps of developmental tasks.

Table 4. Change in adaptive skills as measured by the Vineland adaptive behavior – daily living scale (Expanded Form) Raw score, standard scores and age equivalency scores and ABLLS raw scores.

	Baseline	*Week 16*	*Week 24*	*Percent*
	$M \pm SD$	$M \pm SD$	$M \pm SD$	*Change*
Vineland				
Raw score	119.9 ± 62.4	143.1 ± 66.9	146.7 ± 68.5	22.3%*
Standard score	38.3 ± 16.4	44.6 ± 17.2	45.2 ± 18.2	18%^{ns}
Age equivalency	35.7 ± 18.2	41.1 ± 18.9	42.4 ± 22.2	18.7%*
ABLLS				
Raw score	133.4 ± 64.2	156 ± 63.02	159 ± 56.4	19.2%**

*significant at $p < 0.01$.
**significant at $p < 0.001$.
^{ns}non-significant.

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Finally, the Parenting Stress Index was analyzed using repeated measures ANCOVA. Parenting stress was characterized by a decline in overall PSI scores across time ($F = 5.89$, $p < 0.05$), with a reduction in parenting stress of 13.9% (from 114.1 ± 18 at screen to 98.3 ± 17.7). The effect size was 0.92.

Exploratory Analyses

To examine the relationship between noncompliance and adaptive behavior, we calculated correlations between improvements on the HSQ at selected time points and adaptive behavior (change in the age equivalent score on the Vineland Daily Living Skills). This analysis showed $r = 0.17$ at week 8, $r = 0.32$ at week 16, and $r = 0.28$ at week 24. This pattern suggested greater correlation between improved compliance and improved adaptive behavior as PT progressed to week 16 and a subsequent plateau through week 24.

DISCUSSION

In this feasibility trial, the manual-based PT protocol yielded strong indicators of feasibility. Parents attended 93% of the core PT sessions; this compares favorably with the multi-site Multimodal Treatment Study of ADHD (MTA), which reported a 77.8% mean attendance for parent training (MTA Cooperative Group, 1999). Dropout rates in the current study were relatively low at 18%. Forehand, Middlebrook, Rogers, and Steffe (Forehand, Middlebrook, Rogers, & Steffe, 1983) reported good results from parent training with a 28% dropout rate. Parental adherence, at nearly 80%, compares favorably to PT adherence/compliance by parents reported in the literature (Baker, 1996; Newsom, 1998). Also, the parental adherence rate in this study, gauged by completed in-session assignments, brief parent-child observations, and homework, compares favorably to studies that used more stringent assessment, such as extended direct observations. Using more naturalistic and extended observations, recent studies reported adherence rates between 30% and 40% (Chaffin, Silovsky, Funderburk, Valle, Brestan, Balachova, et al., 2004).

Parents reported high levels of satisfaction. All parents indicated that their child's target behaviors improved and that they felt more confident in handling their child's behavior problems. Parents reported high satisfaction with most elements of the PT sessions. Also, parent-reported stress levels decreased significantly over the course of study, an additional benefit for the parents.

Treatment integrity rates were between 80% and 100%, verified by videotape review by experienced behavior therapists with a reliability rating of greater than

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90%. Thus, the PT protocol could be successfully implemented with several different clinicians at different research sites. There is a strong sentiment in the field that multi-site feasibility studies are an important step toward developing empirically-supported psychosocial treatments (Lord Wagner, Rogers, Szatmari, Aman, in press Smith et al., in press). These data indicate that the structured, manual-based PT program is feasible for a multi-site clinical trial.

Although the outcome data must be viewed with caution due to the lack of a control group, these data suggest that the manualized PT program may be an effective psychosocial treatment for children with PDD taking a moderately-effective medication for irritability and disruptive behaviors. PT did appear to enhance treatment effects; meaningful reductions of noncompliance and irritability were observed, and these were the symptoms targeted by ongoing medication in most cases. Most of the treatment effect for noncompliance was evident two-thirds of the way through the PT sessions (indicated by a stabilization of HSQ scores after week eight). This is most easily explained by the content of PT modules over time. Up through week eight, PT session content focused on reducing uncooperative and disruptive behaviors and increasing overall compliance. Thus, a treatment effect for noncompliance would be observed when noncompliance was the focus of treatment.

Though reduction of noncompliance as measured by the HSQ remained stable throughout the study period, reduction of irritability and hyperactivity/noncompliance as measured by the ABC did not maintain until the end of the 24 week period, rising slightly between weeks 20 and 24. A likely explanation is the decrease of PT therapist time with the parent by this point in the PT program. Parents may not have been able to maintain the same level of application of techniques learned without the weekly therapist support. An alternative explanation might be that parents' perceptions of child behavior changed when they were not receiving weekly therapist support. Nevertheless, the current findings from this PT program are comparable to reports of more intensive parent training programs in reducing problematic behaviors (Smith et al., 2000; Eikeseth, Smith, Jahr, & Eldevik, 2002).

PT appeared to be related to growth in adaptive behavior and functional skill development. Results of two independent measures of adaptive behavior showed positive gains. Based upon report of the adaptive behavior index and increases in age equivalency for the Daily Living Scales of the Vineland Adaptive Behavior Scales-Expanded Form, the rate of growth in independent functioning of personal care skills increased beyond expected levels and beyond the passage of time. On average, children whose adaptive behavior acquisition was significantly below age expectations were scored as showing an increased age equivalency of 7 months in a 6-month period. In contrast, many reports in the literature show no gains or losses in adaptive behavior among children with autism (Carter et al., 1998; Smith et al., 2000) or a slower rate of acquisition of adaptive behavior skills compared to typically

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developing children (Schatz & Hamdan-Allen, 1995). On the ABLLS, a measure of specific skill development, an even greater effect size was observed.

PT also appeared to have a positive effect on parenting stress, and this could be related to several other outcomes already described. It is possible that increases in child compliance, improved adaptive behavior, and parenting effectiveness helped to mitigate parenting stress. Noncompliance and disruptive behaviors have been predictive of higher levels of parenting stress among parents of children with developmental disabilities (Baker, Blacher, Crnic, & Edelbrock, 2002). Lower levels of adaptive behavior (Weiss, Sullivan, & Diamond, 2003) and greater functional impairment in children with PDD (Tobing & Glenwick, 2002) also have been linked to higher amounts of parenting stress. Thus, a decrease in parenting stress when child compliance and adaptive behaviors have increased is not surprising. Also, positive parental attributions and optimism have been linked to parental adjustment (Baker, Blacher, & Olsson, 2005). In this regard, parents in this study may have gained a greater sense of mastery and optimism in their roles as parents, which could lead to a reduction in stress. The finding that 91% of the parents in this study felt more confident in their ability to handle future behavior problems is a likely indicator of optimism in their parenting role.

Limitations

Limitations in this feasibility trial included the following. The parent satisfaction questionnaire was developed for this study and has not been used previously. Similarly, modifications were made to the HSQ and the ABLLS which limits interpretation of our findings and complicates any comparison to other studies that have used these measures. Although validated through videotape review, parental adherence scores were based primarily on parent report, as well as the PT therapist's and videotape reviewer's evaluation of that report. Though some parent observations were made as part of the parental adherence measures, a comprehensive, direct observation measure of acquired parenting skills was not reported here, limiting our ability more reliably to validate parental mastery of the PT program. The PT program offered several limitations as well. Though there was a wide age range of children (4 to 13 years) enrolled in this study, the PT program did not differ by age ranges. However, therapists were free to adapt PT scripts, examples, and homework assignments for age or developmental considerations, varying communication skills, and expected abilities. A future study could look at modifying the PT program for older versus younger children or different developmental levels based on communication skills (e.g., verbal versus nonverbal).

The most significant limitation was the lack of a control group for comparison of the efficacy outcomes, although we feel the feasibility determination goal was

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achieved. Without such a control group, it is not clear how to interpret the statistically significant pre-post effect sizes. There is a notorious placebo effect for new autism treatments, partially arising from the desperation of the parents who are hoping for improvement and often provide the data for assessment (Metz, Mulick, & Butter, 2004). However, given the plan to apply this PT program in a larger multi-site trial, the primary goal of the study was to show feasibility, not efficacy. One other aspect of feasibility beyond treatment integrity and parental adherence is demonstrating that the outcome measures detect change and that there is sufficient variability within the population to warrant their inclusion in a controlled trial. The direction of this change was in the expected positive direction. Additionally, the effect on the ABC Irritability subscale was large ($d = 0.90$) when PT was added to medication. This finding exceeded the 8-week effect size ($d = 0.44$) for placebo in the previous randomized trial (RUPP Autism Network, 2002), inspiring some confidence that the noted improvement is more than nonspecific placebo effect. Interpreted within this context, the outcome measures are sensitive to change and the PT program may have contributed to these changes. A controlled trial using these outcome measures and this PT program is a necessary, and likely useful, next step.

Efficacy of this PT program awaits further study in the RUPP Autism Network's on-going RCT.

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