Original Investigation

Effect of Parent Training vs Parent Education on Behavioral Problems in Children With Autism Spectrum Disorder
A Randomized Clinical Trial

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IMPORTANCE Disruptive behavior is common in children with autism spectrum disorder. Behavioral interventions are used to treat disruptive behavior but have not been evaluated in large-scale randomized trials.

OBJECTIVE To evaluate the efficacy of parent training for children with autism spectrum disorder and disruptive behavior.

DESIGN, SETTING, AND PARTICIPANTS This 24-week randomized trial compared parent training (n = 89) to parent education (n = 91) at 6 centers (Emory University, Indiana University, Ohio State University, University of Pittsburgh, University of Rochester, Yale University). We screened 267 children; 180 children (aged 3-7 years) with autism spectrum disorder and disruptive behaviors were randomly assigned (86% white, 88% male) between September 2010 and February 2014.

INTERVENTIONS Parent training (11 core, 2 optional sessions; 2 telephone boosters; 2 home visits) provided specific strategies to manage disruptive behavior. Parent education (12 core sessions, 1 home visit) provided information about autism but no behavior management strategies.

MAIN OUTCOMES AND MEASURES Parents rated disruptive behavior and noncompliance on co-primary outcomes: the Aberrant Behavior Checklist–Irritability subscale (range, 0-45) and the Home Situations Questionnaire–Autism Spectrum Disorder (range, 0-9). On both measures, higher scores indicate greater severity and a 25% reduction indicates clinical improvement. A clinician blind to treatment assignment rated the Improvement scale of the Clinical Global Impression (range, 1-7), a secondary outcome, with a positive response less than 3.

RESULTS At week 24, the Aberrant Behavior Checklist–Irritability subscale declined 47.7% in parent training (from 23.7 to 12.4) compared with 31.8% for parent education (23.9 to 16.3) (treatment effect, −3.9; 95% CI, −6.2 to −1.7; $P < .001$, standardized effect size = 0.62). The Home Situations Questionnaire–Autism Spectrum Disorder declined 55% (from 4.0 to 1.8) compared with 34.2% in parent education (3.8 to 2.5) (treatment effect, −0.7; 95% CI, −1.1 to −0.3; $P < .001$, standardized effect size = 0.45). Neither measure met the prespecified minimal clinically important difference. The proportions with a positive response on the Clinical Global Impression–Improvement scale were 68.5% for parent training vs 39.6% for parent education ($P < .001$).

CONCLUSIONS AND RELEVANCE For children with autism spectrum disorder, a 24-week parent training program was superior to parent education for reducing disruptive behavior on parent-reported outcomes, although the clinical significance of the improvement is unclear. The rate of positive response judged by a blinded clinician was greater for parent training vs parent education.

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Autism spectrum disorder (ASD) is a chronic neurodevelopmental condition of early childhood onset characterized by social communication deficits, restricted interests, and repetitive behaviors.[1] Autism spectrum disorder affects an estimated 6 per 1000 children worldwide and is a major public health challenge.[2]

In addition to the defining features, as many as 50% of children with ASD exhibit behavioral problems, including tantrums, noncompliance, aggression, and self-injury.[3,4] These behaviors interfere with performance of daily living skills, limit the child's ability to benefit from educational and habilitative services, and may increase social isolation.[5,6] Uncertainty on how to manage these behavioral problems may also amplify caregiver stress.[7,8]

Parent training is an empirically supported intervention for children with disruptive behavior uncomplicated by ASD.[9] Parent training provides parents with specific techniques to manage behavioral problems in children. Despite growing interest in parent training for children with ASD and pilot studies supporting its use, it has not been evaluated in large-scale randomized trials.[10-13] Because it is a time-limited intervention that could be implemented in a range of settings, including clinics and schools, demonstrating the efficacy of parent training in ASD could have important public health implications.

ABC-I *Aberrant Behavior Checklist–Irritability subscale*

ASD *autism spectrum disorder*

CGI-I *Clinical Global Impression–Improvement scale*

HSQ-ASD *Home Situations Questionnaire–Autism Spectrum Disorder*

We developed a parent training manual and conducted a series of studies showing that this program is acceptable to parents, can be reliably delivered by trained therapists, and confers additional benefit when used in combination with medication.[14,15] The current study is, to our knowledge, the first large-scale randomized trial designed to test the efficacy of parent training for young children with ASD and disruptive behavioral problems.

Methods

This was a multicenter, 24-week, randomized clinical trial involving 180 children aged 3 to 7 years with ASD and moderate or greater behavioral problems. At baseline, eligible children were randomized to receive either parent training or parent education (**Figure 1**). At week 24, an independent evaluator who was blind to treatment assignment classified the treatment response of each participant as positive or not. Children in parent education who did not show a positive response at week 24 exited the study, and their parents were offered parent training. The protocol also permitted parents of participants who showed a positive response to parent education to cross over to parent training. All other participants and families were invited to return for assessment at weeks 36 and 48 to evaluate longer-term outcomes.

The study was conducted at 6 sites: Emory University, Indiana University, Ohio State University, University of Pittsburgh, University of Rochester, and Yale University. Coordinating center activities, data management, and analysis were performed at Emory and Yale.

The trial was approved by the institutional review boards at each site. Written informed consent was obtained from a parent or legal guardian. Parents received compensation for each assessment and therapy visit to cover travel costs. An independent data and safety monitoring board reviewed study results, enrollment, and procedures every 6 months during the trial.

The study was designed to evaluate whether parent training would be superior to parent education for reducing behavioral problems such as tantrums, noncompliance, aggression, and self-injury in children with ASD.

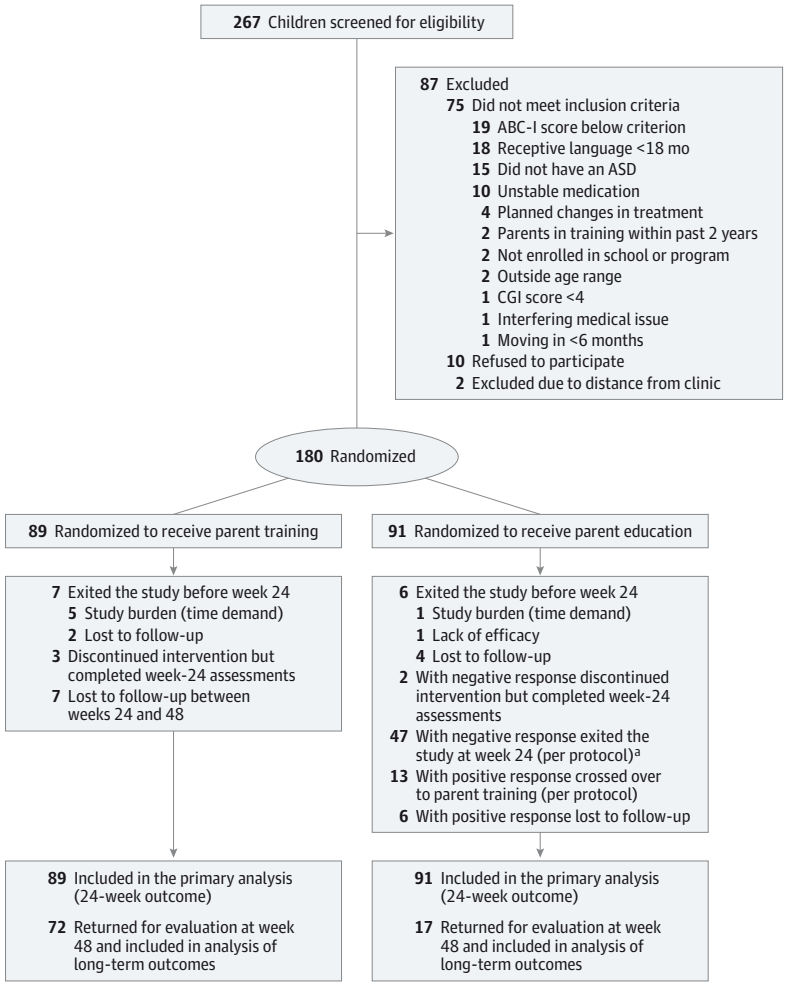
Participants

The pretreatment evaluation was conducted by an experienced team at each site. Eligible participants were children with an ASD (*Diagnostic and Statistical Manual of Mental Disorders* [Fourth Edition, Text Revision] [*DSM-IV-TR*] diagnosis of autistic disorder, pervasive developmental disorder-not otherwise specified, or Asperger disorder)[16] based on clinical assessment supported by the Autism Diagnostic Observation Schedule and Autism Diagnostic Interview-Revised completed by clinicians trained to reliability. Participants had to have moderate or greater behavioral problems as measured by a pretreatment score of 15 or greater on the parent-rated Aberrant Behavior Checklist-Irritability subscale (ABC-I) (reviewed by a research coordinator and tallied by computer)[17] and a rating of moderate or higher (≥4) on the Clinical Global Impression-Severity (CGI-S) by an independent evaluator. To assign the CGI-S score, the independent evaluators were trained to consider disruptive behavior, the child's overall clinical presentation, and the effect of the child's behavior on the family (for training and supervision methods, see eMethods 1 in the Supplement).

Children receiving stable medication or remedial or behavioral interventions were eligible if there were no planned changes in existing interventions for the duration of the trial. Children with receptive language less than 18 months on the Mullen Receptive Language scale, not enrolled in a school program, or living in a household without an English-speaking caregiver were excluded. Other exclusion criteria were a *DSM-IV-TR* diagnosis of Rett disorder or childhood disintegrative disorder, presence of a known serious medical condition in the child that would interfere with participation, or current psychiatric disorder requiring alternative treatment. Concomitant psychiatric disorders were assessed by clinical interview aided by the parent-rated Early Child Symptom Inventory.[18] Children whose parents participated in a structured parent training program in the past 2 years were also excluded.

Data on child race/ethnicity were obtained by parent questionnaire at the screening visit. These data were collected to characterize the sample and to explore possible moderators of treatment in future analyses. The parent-rated Vineland II was used to assess adaptive functioning at baseline.[19]

Figure 1. Flow of Patients Through Trial of Parent Training vs Parent Education in Autism Spectrum Disorder



ABC-I indicates Aberrant Behavior Checklist–Irritability subscale; ASD, autism spectrum disorder; CGI-I, Clinical Global Impression–Improvement scale.

[a] Response was rated by an independent evaluator using the CGI-I. Scores of much improved or very much improved were used to define positive response; all other scores indicated negative response.

Treatments

Parent Training

Parent training was delivered individually to the parents in 11 core sessions of 60 to 90 minutes' duration, up to 2 optional sessions, 1 home visit, and up to 6 parent-child coaching sessions over 16 weeks. Parent training also included 1 home visit and 2 telephone booster sessions between weeks 16 and 24. Spreading the parent training sessions over 16 weeks provided scheduling flexibility and fostered opportunity for the full dose of parent training.

To promote treatment fidelity, the parent training manual included verbatim scripts and instructions for therapists. The first session taught parents to identify the function of a behavior by analyzing its antecedents (events occurring before the behavior) and consequences (events following the behavior). Subsequent sessions presented strategies for preventing disruptive behavior (eg, visual schedules for routine events), positive reinforcement for appropriate behavior, planned ignoring of inappropriate behavior, and techniques to promote compliance. In the last few sessions, the therapist instructed parents on teaching new skills (eg, communication or daily living skills) and how to maintain improvements over time. This sequence was intended to reduce the child's disruptive behaviors and foster skill acquisition. The treatment sessions used direct instruction, video examples, practice activities, and rehearsal (role play) with feedback to promote parental skill acquisition. In homework assignments between sessions, parents applied new techniques to specific behaviors (for parent training session content, see eTable 1 in the Supplement).

Parent Education Program

To control for time and attention, parent education included 12 sessions of 60 to 90 minutes and 1 home visit over 24 weeks. Sessions covered useful information on young children with ASD, including the essentials of evaluation, developmental changes in ASD, educational planning, advocacy, and current treatment options. The selection of parent education as an active comparator was intended to determine whether information alone would improve behavioral problems in the child. To promote treatment fidelity, the parent education manual also included detailed therapist scripts and parent handouts at each session. Parent education did not include any instruction on behavior management (for parent education session content, see eTable 2 in the Supplement).

After systematic training and certification, therapists with master's level or more education implemented the interventions according to the treatment manuals. Therapists participated in weekly supervision at each site and monthly cross-site teleconferences to ensure integrity of study interventions. Using a checklist specifying the required elements of each session, independent raters scored treatment integrity on a 10% sample of randomly selected, video-recorded parent training and parent education sessions (therapist training and supervision are described in eMethods 2 in the Supplement).

Randomization and Blinding

The data center randomly assigned eligible children to treatment in a 1:1 ratio using permuted blocks allowing for concealment of allocation prior to enrollment. Randomization was done within site and further stratified by educational intensity to ensure an equal number of participants in high-intensity school programs across treatment groups. High-intensity service was defined as 15 hours or more per week of 1:1 or 1:2 specialized instruction for ASD. Parents and therapists were aware of the assigned treatment condition. Independent evaluators were blinded to treatment assignment. To protect the treatment blinding, we maintained separate study binders for therapists and independent evaluators. Parents were instructed to avoid discussing the treatment during assessments with independent evaluators.

Outcome Measures

Children were assessed every 4 weeks through the 24-week trial and after treatment at weeks 36 and 48. The first primary outcome measure was the parent-rated ABC-I.[17] The second primary outcome measure was the per-item mean score on the parent-rated Home Situations Questionnaire–Autism Spectrum Disorder (HSQ-ASD).[20] A secondary outcome was the Improvement item of the clinician-rated CGI (CGI-I). By convention, we present results on the other ABC subscales, but these subscales were not hypothesized to show changes with parent training.

The ABC[17] is a 58-item, parent-rated measure that includes 5 subscales: Irritability (includes tantrums, aggression, and self-injurious behaviors, 15 items); Social Withdrawal (includes 16 items); Stereotypy (7 items); Hyperactivity (includes hyperactivity and noncompliance, 16 items); and Inappropriate Speech (repetitive vocalizations, 4 items).[17,21] Each item is rated 0 to 3 with higher scores indicating greater severity. On the ABC-I subscale (range, 0-45), a 25% reduction from baseline is commonly used to indicate clinically meaningful improvement.[14,22]

The HSQ-ASD is a 24-item parent-rated measure of noncompliant behavior in children with ASD.[20] The scale yields per-item mean scores of 0 to 9 (higher scores indicating greater noncompliance) for the total score and on each of two 12-item subscales (Demand-specific, Socially Inflexible) (Michael Aman, PhD, and Monali Chowdhury, PhD, Ohio State University, written communication, November 10, 2014). Based on data from a prior study, a 25% decrease reflects meaningful improvement.[14]

The CGI-I[23] is a 7-point scale designed to measure overall improvement from baseline. This measure has been used in several clinical trials in ASD.[22,24] Scores range from 1 (very much improved) through 4 (unchanged) to 7 (very much worse). Scores of much improved or very much improved were used to define positive response; all other scores indicated negative response. The independent evaluator, who was blind to treatment assignment, rated the CGI-I monthly during the randomized trial and after treatment at weeks 36 and 48. At baseline, the independent evaluators asked parents to identify the child's 2 most pressing problems. From this discussion, the independent evaluator documented a brief narrative describing the frequency (eg, tantrums per day), duration, and intensity (actual appearance of the behavior) of episodes and effect of the behavior on the family. The baseline narrative was reviewed and revised in subsequent visits and used in combination with all other available information to score the CGI-I.

The protocol included 2 additional secondary outcomes. The Vineland II is a multidimensional measure requiring a detailed analytic approach; the results will be presented in a separate report. The Standardized Observational Analogue Procedure (SOAP) is a brief, semistructured laboratory observation of parent-child interactions. Since development of the protocol, questions have been raised about the ecological validity of the SOAP and whether it is representative of a child's behavior.[25] The SOAP will be presented in a separate report.

Adverse Events

Adverse events were monitored and documented at each assessment visit whether considered related to study treatments or not. At each assessment visit, the independent evaluator asked about recent health concerns, use of medical services, concomitant medications, and change in ongoing medications. An adverse event review form also guided inquiry on the child's sleep, appetite, and bowel habits. Reports of new adverse events or worsening of previously reported events were rated mild (present, but not a problem), moderate (present, posing a problem or intervention required to prevent a problem), or severe (present, posing a problem and needing intervention). Hospitalization was documented as a serious adverse event.

Statistical Analyses

The sample size calculation was based on an effect size of 0.5 (parent training superior to parent education) as the treatment effect that we would consider meaningful for the ABC-I and the HSQ-ASD.[26] Based on predictions of mean baseline scores, standard deviations, and change from baseline in each group, the study sought to detect a minimal clinically important difference between groups of 5 points on the ABC-I and 0.9 on the HSQ-ASD. A sample size of 90 per group was needed to provide 80% power to detect this difference at a 2-sided significance level of .05 and attrition of 10%. Outcome data are presented as least squares means from mixed-effects linear models (also called random regression models[27]) on the 2 primary outcome measures (ABC-I, HSQ-ASD). The models included fixed effects for treatment (2 levels), time (4, 8, 12, 16,

Table 1. Baseline Demographic and Clinical Characteristics by Treatment Group

	No. (%)	
	Parent Training (n = 89)	Parent Education (n = 91)
Study center		
Emory/Yale University[a]	17 (19.1)	18 (19.8)
Indiana University	14 (15.7)	14 (15.4)
Ohio State University	19 (21.4)	20 (22.0)
University of Pittsburgh	19 (21.4)	18 (19.8)
University of Rochester	20 (22.5)	21 (23.1)
Child demographics		
Age, mean (SD), y	4.8 (1.2)	4.7 (1.1)
Males	79 (88.8)	79 (86.8)
IQ		
<70	13 (14.6)	16 (17.6)
≥70	66 (74.2)	68 (74.7)
Missing[b]	10 (11.2)	7 (7.7)
Race		
White	78 (87.6)	78 (85.7)
Black	9 (10.1)	6 (6.6)
Asian/Pacific Islander	2 (2.3)	6 (6.6)
Other	0	1 (1.1)
Ethnicity		
Hispanic	13 (14.6)	13 (14.3)
Non-Hispanic	76 (85.4)	78 (85.7)
DSM-IV-TR diagnosis		
Autistic disorder	60 (67.4)	65 (71.4)
PDD-NOS	27 (30.3)	23 (25.3)
Asperger disorder	2 (2.3)	3 (3.3)
School program		
Regular class	36 (40.0)	46 (50.5)
Special education class	38 (42.7)	32 (35.2)
Special education school	13 (14.6)	10 (11.0)
Home instruction	2 (2.2)	3 (3.3)
Taking medication		
Melatonin	9 (10.1)	9 (9.9)
Psychotropic	4 (4.5)	1 (1.1)
Melatonin and psychotropic[c]	4 (4.5)	4 (4.4)
≥2 Psychotropics	4 (4.5)	1 (1.1)
Parent demographics		
2-Parent family	77 (86.5)	81 (89.0)
Maternal education		
Advanced degree	29 (32.6)	23 (25.3)
College degree	22 (24.7)	37 (40.7)
Some college	28 (31.5)	26 (28.6)
High school graduate	9 (10.1)	5 (5.5)
Some high school	1 (1.1)	0
Baseline clinical scores		
CGI-Severity		
Moderately ill	32 (36.0)	32 (35.2)
Markedly ill	41 (46.1)	49 (53.9)
Severely ill	16 (18.0)	10 (11.0)
Aberrant Behavior Checklist, mean (SD)		
Irritability	23.7 (6.4)	23.9 (6.2)
Social withdrawal	13.2 (8.4)	12.6 (8.0)
Stereotypy	6.2 (4.8)	6.6 (5.1)
Hyperactivity	29.5 (9.8)	31.4 (8.7)
Inappropriate speech	5.3 (3.1)	6.1 (3.2)
HSQ-ASD, mean (SD)		
Demand-specific	3.6 (1.7)	3.2 (1.7)
Socially inflexible	4.3 (1.7)	4.3 (1.7)
Total	4.0 (1.6)	3.8 (1.5)
Vineland II adaptive scales, mean (SD)[d]		
Communication	80.4 (15.1)	82.2 (15.6)
Daily living skills	76.7 (12.7)	79.5 (14.3)
Socialization	70.5 (11.3)	73.5 (10.5)
Adaptive behavior composite	73.5 (10.9)	76.7 (11.8)

Abbreviations: CGI, Clinical Global Impression; *DSM-IV-TR*, *Diagnostic and Statistical Manual of Mental Disorders* [Fourth Edition, Text Revision]; HSQ-ASD, Home Situations Questionnaire–Autism Spectrum Disorder; PDD-NOS, pervasive developmental disorder–not otherwise specified.

[a] Principal investigator and therapy supervisor moved from Yale to Emory during study.

[b] The 17 children missing IQ data were untestable. Fifteen of 17 completed the Mullen Receptive Language (RL) scale to confirm RL >18 months. The remaining 2 children were deemed eligible by study case panel.

[c] Five of 8 children were taking ≥2 psychotropic drugs.

[d] The Vineland II asks parents to score the child's adaptive skills on a 0-2 scale, with higher scores reflecting better adaptive function. Based on age and sex, raw scores are expressed as standard scores (population mean [SD] of 100 [15]) in communication, socialization, daily living skills, and an adaptive behavior composite domain.

20, and 24 weeks), site, educational intensity, and time × treatment interaction. Treatment × education intensity interactions were not significant for any outcome variables and were excluded from models presented.

Each child's response during the trial was modeled by regressing the ABC-I or HSQ-ASD score against time. The intercept and slope of the regression were allowed to vary randomly between participants through inclusion of random effects. The average slope of the regression line (ie, clinical response) over time was compared between the treatment groups and tested for statistical significance. With the 2 primary end points, a fixed-sequence testing strategy was used to minimize type I error inflation whereby ABC-I would be tested at a 2-sided 5% significance level, and if it was significant, HSQ-ASD would also be tested at a 2-sided 5% significance level. If ABC-I was not significant, testing of the HSQ-ASD would proceed at a 2-sided 2.5% significance level. The mixed model provides unbiased estimates of treatment effects under the assumption that missing data are missing at random and are independent of response given observable data. Prior to analyses for efficacy, we examined the missing data by comparing

the frequency, reasons, pattern and time to dropout, and missing values across treatment groups.

Least squares means at week 24 were adjusted for baseline. Effect sizes were estimated by taking the difference in the least squares means at week 24 and dividing by the pooled standard deviation at baseline for the entire study sample. The proportion of positive responses on the CGI-I was compared at week 24 by χ^2. Comparisons of adverse event rates were made with χ^2 and Fisher exact tests as needed. Long-term outcomes on the ABC-I and HSQ-ASD included within-group paired *t* tests comparing baseline with weeks 24, 36, and 48 for 3 separate groups: participants in parent training classified as much improved or very much improved on the CGI-I at week 24 by the independent evaluator; parent training participants who did not meet positive response criterion; and participants in parent education classified as much improved or very much improved at week 24, who did not elect to cross over to parent training. We also computed the rate of positive response on the CGI-I at weeks 36 and 48 for these same 3 groups. All analyses were conducted using SAS/STAT software, version 9.3 of the SAS System for Windows.

Results

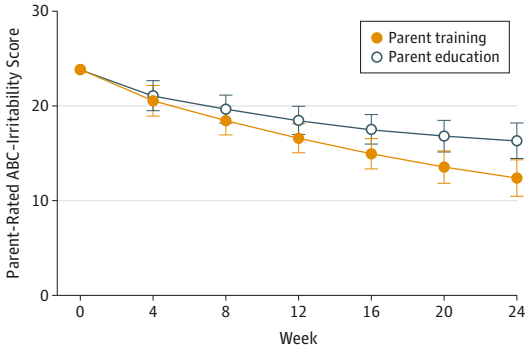
Between September 2010 and February 2014, 180 children were randomly assigned to 24 weeks of parent training or parent education. Of 267 children screened, 75 were ineligible, 10 declined participation, and 2 were excluded because of concern about travel distance and the family's ability to attend regular visits (Figure 1). Enrollment across sites was similar (**Table 1**). Participants (158 boys, 22 girls) ranged in age from 3 years to 6 years, 11 months (mean [SD] age, 4.7 [1.1] years). The study groups appeared similar at baseline except for maternal college education (Table 1).

Of the 23 participants enrolled in high-intensity school programs at baseline, 4 children (n = 1 parent training; n = 3 parent education) switched to low-intensity programs during the 24-week trial. Three children in parent training and 3 in parent education moved from low- to high-intensity programs during the trial. At baseline, 36 of 180 children (20%) were taking stable psychotropic medication. During the 24-week trial, 10 of 36 participants had a reported dose change (increase, decrease, stop); 5 children started a new medication after randomization. There were no differences in medication use or changes between parent training and parent education.

Primary Outcome

At week 24, parent training showed a 47.7% decline in the ABC-I (from 23.7 to 12.4) compared with a 31.8% decrease (23.9 to 16.3) for parent education (treatment effect, −3.9; 95% CI, −6.2 to −1.7; $P < .001$, standardized effect size = 0.62). **Figure 2** shows that both treatment groups improved over time and the gradual separation of parent training from parent education on the monthly parent-rated ABC-I. In parent training, there was a 55.0% decline in the HSQ-ASD total score (4.0 at baseline to 1.8 at week 24) compared with a 34.2% decrease (3.8 to 2.5) for parent education (treatment effect, −0.7; 95% CI, −1.1 to −0.3; $P < .001$, standardized effect size = 0.45). **Table 2** presents baseline, week 12, and week 24 scores and effect sizes for all ABC and HSQ-ASD subscales.

Figure 2. Least Squares Means and 95% CI for Parent-Rated ABC-Irritability at Baseline Through Week 24



No. of participants							
Parent training	89	86	82	81	79	79	82
Parent education	91	85	84	83	79	83	85

ABC indicates Aberrant Behavior Checklist.

On the CGI-I, 68.5% (61/89) of participants in parent training were rated much improved or very much improved compared with 39.6% (36/91) in parent education ($P < .001$) (**Figure 3**). The number needed to treat was 4 (68.5% − 39.6% = 28.9%; 1/28.9 = 3.5 rounded up to 4).

Treatment Fidelity and Attrition

Parent training and parent education were delivered by 23 therapists across 6 sites. Caseloads ranged from 1 to 21 cases (mean [SD], 7.7 [7.3] cases). Treatment fidelity was excellent with mean (SD) ratings of 96.7% (8.3) for parent training and 97.2% (6.4) for parent education (fidelity median and mode were 100% for both interventions). Attrition in parent training was 11.2% (10/89; 3/10 parents discontinued treatment but completed assessments) vs 8.8% for parent education (8/91; 2/8 discontinued treatment but completed assessments). Parents attended 92% (901/979) of core parent training sessions compared with 93% (1016/1092) in parent education.

Adverse Events

There were 925 adverse events (mild, 389; moderate, 461; severe, 72; serious, 3) reported during the 24-week trial. In the parent education group, 1 child was hospitalized for 2 days with pneumonia; another child was hospitalized for 2 days following seizures. In parent training, 1 child had a 2-day hospitalization for dehydration with severe vomiting. **Table 3** lists the adverse events that occurred in 5% or more of participants in either treatment group. There were no significant group differences.

Long-term Outcomes

Table 4 presents unadjusted ABC-I and HSQ-ASD total mean scores for baseline and weeks 24 and 48 for 3 groups in long-term follow-up. Per protocol, children who did not meet positive response criterion to parent education and those classified with positive response to parent education who crossed

Table 2. Baseline, Week 12, and Week 24 Scores on Key Outcome Measures[a]

	Mean Score (95% CI)			
	Parent Training (n = 89)	Parent Education (n = 91)	Group Difference	Effect Size[b]
Aberrant Behavior Checklist				
Irritability[c]				
Baseline	23.7 (22.3 to 25.0)	23.9 (22.6 to 25.2)		
Week 12	16.6 (15.1 to 18.1)	18.5 (17.0 to 20.0)	−1.9 (−3.4 to −0.4)	
Week 24	12.4 (10.5 to 14.3)	16.3 (14.4 to 18.2)	−3.9 (−6.2 to −1.7)	0.62
Social withdrawal				
Baseline	13.2 (11.4 to 14.9)	12.6 (10.9 to 14.2)		
Week 12	8.1 (7.0 to 9.2)	8.8 (7.7 to 9.8)	−0.7 (−1.8 to 0.4)	
Week 24	6.1 (4.7 to 7.4)	7.1 (5.7 to 8.4)	−1.0 (−2.6 to 0.6)	0.12
Stereotypic behavior				
Baseline	6.1 (5.1 to 7.1)	6.6 (5.5 to 7.6)		
Week 12	5.1 (4.5 to 5.7)	5.1 (4.5 to 5.7)	0.0 (−0.6 to 0.6)	
Week 24	4.2 (3.5 to 5.0)	4.1 (3.3 to 4.8)	0.1 (−0.7 to 1.0)	−0.02
Hyperactivity				
Baseline	29.5 (27.4 to 31.6)	31.4 (29.6 to 33.2)		
Week 12	23.2 (21.3 to 25.1)	25.3 (23.4 to 27.1)	−2.1 (−4.0 to −0.2)	
Week 24	18.8 (16.4 to 21.1)	22.8 (20.5 to 25.1)	−4.0 (−6.8 to −1.3)	0.43
Inappropriate speech				
Baseline	5.3 (4.7 to 6.0)	6.1 (5.4 to 6.7)		
Week 12	4.8 (4.3 to 5.3)	5.2 (4.7 to 5.7)	−0.4 (−0.9 to 0.1)	
Week 24	4.0 (3.4 to 4.7)	4.8 (4.2 to 5.4)	−0.7 (−1.4 to 0.0)	0.22
Home Situations Questionnaire[d]				
Demand-specific				
Baseline	3.6 (3.2 to 4.0)	3.2 (2.8 to 3.5)		
Week 12	2.1 (1.9 to 2.4)	2.6 (2.3 to 2.9)	−0.5 (−0.8 to −0.2)	
Week 24	1.5 (1.2 to 1.9)	2.1 (1.7 to 2.4)	−0.5 (−0.9 to 0.0)	0.29
Socially inflexible				
Baseline	4.3 (4.0 to 4.7)	4.3 (3.9 to 4.7)		
Week 12	2.9 (2.6 to 3.3)	3.5 (3.0 to 3.7)	−0.4 (−0.8 to −0.1)	
Week 24	2.2 (1.8 to 2.6)	2.9 (2.5 to 3.4)	−0.8 (−1.2 to −0.3)	0.47
Total				
Baseline	4.0 (3.7 to 4.3)	3.8 (3.4 to 4.1)		
Week 12	2.6 (2.3 to 2.9)	3.0 (2.7 to 3.3)	−0.4 (−0.7 to −0.1)	
Week 24	1.8 (1.5 to 2.2)	2.5 (2.2 to 2.9)	−0.7 (−1.1 to −0.3)	0.45

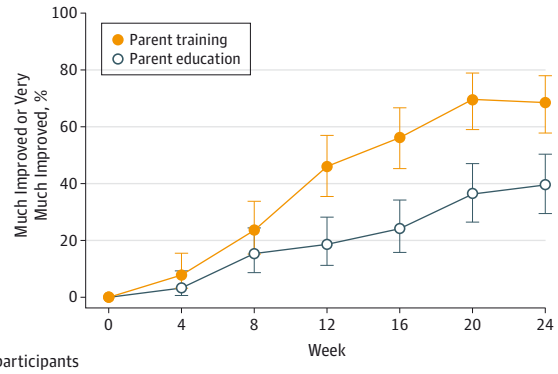
[a] Data are presented as raw mean scores at baseline and least squares mean values for week 12 and 24 with 95% CIs for each assessment point. Group differences with 95% CIs are also presented.

[b] The least squares means at 12 and 24 weeks were adjusted for baseline. Effect sizes were calculated by taking the difference in the least squares means at week 24 and dividing by the pooled standard deviation at baseline.

[c] Range for Aberrant Behavior Checklist–Irritability = 0 to 45.

[d] Range for Home Situations Questionnaire-Total and each subscale = 0 to 9.

Figure 3. Percentage and 95% CI of Children With a Rating of Much Improved or Very Much Improved on the Clinical Global Impressions–Improvement Scale During the 24-Week Trial



No. of participants							
Parent training	89	86	82	81	78	79	80
Parent education	91	86	84	83	79	82	85

over to parent training are not included. For children showing positive response to parent training at week 24, the retention rate at week 48 was 90% (55/61). The paired *t* tests indicate continued benefit on the ABC-I and the HSQ-ASD from baseline to week 48 for these 55 participants. As shown in Table 4, 21 children who did not achieve positive response to parent training were evaluated at week 24 (7 participants dropped out before week 24). Seventeen of 21 (81%) returned at week 48. In this group, the mean scores on the ABC-I and the HSQ-ASD total were lower at week 48 compared with baseline, but showed an upward trend from week 24. The available participants who showed a positive response to parent education (n = 23) maintained benefit to week 48 (week 36 data for all groups in follow-up are presented in eTable 3 in the Supplement).

On the CGI-I, all 61 children rated as much improved or very much improved at week 24 were included in the denominator at week 48. Of these, 79% (48/61) of participants main-

tained positive response at week 48. Among the total number of children who did not show a positive response to parent training at week 24 (n = 28), 9 (32%) were rated much improved or very much improved on the CGI-I at week 48 by the blinded rater. Of the 23 children showing positive response to parent education at week 24, 16 (70%) maintained positive response at week 48 (for week 36 CGI-I data, see eTable 4 in the Supplement).

Discussion

This study tested the efficacy of parent training vs parent education (an active comparator) in 180 children with ASD and moderate or greater behavioral problems. Although both treatments led to improvements, parent training was superior to parent education on parent ratings of disruptive and noncompliant behavior and a measure of overall improvement rated by a blinded clinician. Disruptive and noncompliant behaviors complicate the management of ASD and may blend with the core features of ASD. For example, children with ASD who engage in repetitive behavior may react with tantrums, aggression, or self-injury when interrupted by daily demands. Moreover, the social and functional communication deficits in children with ASD may increase the likelihood of tantrums in response to routine demands. Outbursts that include aggression or self-injury present additional challenges to parents and create uncertainty on how to manage these behaviors. Given these challenges, parents of children with ASD could benefit from parent training or parent education to manage behavioral problems. Future analyses may identify child and family characteristics that predict success with parent training or parent education. The cost-effectiveness of the 2 interventions also needs to be investigated.

Neither primary outcome met the minimal clinically important difference between groups, raising questions about the clinical significance of the observed improvement. For the ABC-I, the observed difference of 3.9 points was below the predicted 5 points. For the HSQ-ASD, the observed difference was 0.7, below the predicted 0.9. One possible explanation for these smaller-than-anticipated differences between groups is the larger-than-predicted improvement in the parent education group. Although parent education did not provide guidance on how to manage behavioral problems, retention was high and

Table 3. Adverse Events by Treatment Group Reported in 5% or More of Study Participants

Adverse Event	No. (%)		*P* Value
	Parent Training (n = 89)	Parent Education (n = 91)	
Cough	51 (57.3)	51 (56.0)	.88
Rhinitis	50 (56.2)	52 (57.1)	.99
Diarrhea	33 (37.1)	27 (29.7)	.34
Vomiting	29 (32.6)	26 (28.6)	.63
Skin rash/eczema	24 (27.0)	28 (30.8)	.62
Fever	23 (25.8)	30 (33.0)	.33
Trouble falling asleep	23 (25.8)	26 (28.6)	.74
Drowsiness/sedation	23 (25.8)	23 (25.3)	.99
Daytime fatigue	22 (24.7)	35 (38.5)	.06
Constipation	20 (22.5)	13 (14.3)	.18
Interrupted sleep	15 (16.9)	17 (18.7)	.85
Upper respiratory problem	14 (15.7)	12 (13.2)	.68
Appetite increase	13 (14.6)	20 (22.0)	.25
Earache	11 (12.4)	17 (18.7)	.30
Nausea	7 (7.9)	5 (5.5)	.56
Decreased appetite	6 (6.7)	11 (12.1)	.31
Sinusitis	5 (5.6)	2 (2.2)	.28
Abdominal discomfort	4 (4.5)	7 (7.7)	.54
Nasal congestion	4 (4.5)	7 (7.7)	.54
Wheezing	3 (3.4)	6 (6.6)	.50

Table 4. Unadjusted Mean Values and 95% CI at Baseline, Week 24, and Week 48 on Primary Outcome Measures for Protocol-Defined Groups[a]

	Baseline		Week 24			Week 48		
	No.	Mean (95% CI)	No.	Mean (95% CI)	*P* Value[b]	No.	Mean (95% CI)	*P* Value[b]
Positive response to parent training[c]								
ABC-Irritability	61	23.5 (21.8-25.1)	61	10.3 (8.8-11.8)	<.001	55	11.3 (9.5-13.1)	<.001
HSQ-Total	61	3.8 (3.4-4.2)	61	1.3 (1.1-1.6)	<.001	55	1.5 (1.2-1.8)	<.001
Negative response to parent training[d]								
ABC-Irritability	28	24.1 (21.7-26.6)	21	16.3 (13.4-19.2)	<.001	17	19.4 (15.7-23.0)	
HSQ-Total	28	4.4 (3.7-5.0)	21	3.2 (2.5-3.9)	<.001	17	3.2 (2.4-4.1)	.001
Positive response to parent education								
ABC-Irritability	23	24.9 (21.8-28.1)	23	9.6 (7.4-11.9)	<.001	17	9.2 (5.9-12.4)	<.001
HSQ-Total	23	3.9 (3.1-4.6)	23	1.3 (0.9-1.8)	<.001	17	0.9 (0.6-1.2)	<.001

Abbreviations: ABC, Aberrant Behavior Checklist; HSQ, Home Situations Questionnaire.

[a] Participants who did not show a positive response to parent education were allowed to cross over to parent training and were not included in the follow-up analyses; 13 of 36 participants who showed a positive response to parent education at week 24 elected (per protocol) to cross over to parent training and were not included in the follow-up analyses.

[b] Based on paired *t* tests comparing baseline to week 24 and baseline to week 48.

[c] Positive response = much improved or very much improved on the Clinical Global Impression–Improvement rated by a blinded clinician.

[d] Negative response = all other ratings on the Clinical Global Impression–Improvement.

there was a 39.6% positive response rate on the CGI-I. It may be that giving parents a better understanding of ASD and treatment options provided an indirect pathway for improvement in the child's disruptive behavior.

However, the results may still be considered clinically significant. The mean score on the ABC-I at week 24 in the parent education group of 16.3 remained in the moderate range and above the criterion score for study entry. By contrast, at week 24 the mean score on the ABC-I in the parent training of 12.3 was in the mild range. Indeed, this score is lower than the mean score reported in a large sample of young children with ASD not selected for behavioral problems.[21]

Of the 61 participants rated much improved or very much improved on the CGI-I in parent training at week 24, 55 (90%) returned at week 48. The mean scores on the ABC-I and HSQ-ASD remained significantly better than baseline at week 48 and showed essentially no change from week 24 to week 48. Similarly, 79% of these participants (48/61) maintained positive response at week 48. Of the 23 participants with a positive response to parent education in follow-up, 16 (70%) maintained the positive response on the CGI-I and had continued improvement on the ABC-I and HSQ-ASD.

To our knowledge, this is the largest randomized trial of any behavioral intervention for children with ASD. The results of this multisite study provide empirical support for wider implementation of this structured, relatively brief parent training intervention for young children with ASD. Strengths of the study include random assignment to parent training or an active comparator (parent education), blinded clinician assessment of the secondary outcome, and long-term follow-up. The multisite application of parent training demonstrates that it can be reliably delivered by multiple therapists.

Limitations of the study include the reliance on ratings from parents, who were not blind to treatment assignment. Although the CGI-I was administered by a blinded clinician, it also relied on discussions with parents. The low attrition, however, indicates that parents were engaged in both study treatments and does not suggest a systematic bias in favor of parent training. In addition, the absolute differences between treatment groups on the primary outcomes were not large and did not meet the prespecified minimal clinically important difference. The results of this study reflect benefits of parent training under optimal conditions: well-trained therapists and independent evaluators in a selected sample. Further study is needed to evaluate the wider implementation of parent training in clinical and educational settings.

Conclusions

For children with ASD, a 24-week parent training program was superior to parent education for reducing disruptive behavior on parent-reported outcomes, although the clinical significance of the improvement is unclear. The rate of positive response judged by a blinded clinician was greater for parent training vs parent education.

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