NEW RESEARCH

A Novel Group Parenting Intervention for Emotional and Behavioral Difficulties in Young Autistic Children: Autism Spectrum Treatment and Resilience (ASTAR): A Randomized Controlled Trial

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Objective: To examine the feasibility and preliminary efficacy of a group behavioral parenting intervention for emotional and behavioral problems (EBPs) in young autistic children.

Method: This was a feasibility pilot randomized controlled trial comparing a 12-week group behavioral parenting intervention (Predictive Parenting) to an attention control (Psychoeducation). Parents of 62 autistic children 4 to 8 years of age were randomized to Predictive Parenting (n = 31) or Psychoeducation (n = 31). The primary outcome was a blinded observational measure of child behaviors that challenge. Secondary outcomes were observed child compliance and parenting behaviors; parent- and teacher-reported child EBPs; self-reported parenting practices, stress, self-efficacy, and well-being. Cost-effectiveness was also explored.

Results: Recruitment, retention, completion of measures, treatment fidelity, and parental satisfaction were high for both interventions. There was no group difference in primary outcome: mean log of rate 0.18 lower (*d*, 90% CI = −0.44 to 0.08) in Predictive Parenting. Differences in rates of child compliance (0.44, 90% CI = 0.11 to 0.77), facilitative parenting (0.63, 90% CI = 0.33 to 0.92) and parent-defined target symptom change (−0.59, 90% CI −0.17 to −1.00) favored Predictive Parenting. There were no differences on other measures. Predictive Parenting was more expensive than Psychoeducation, with a low probability of being more cost-effective.

Conclusion: Feasibility was demonstrated. There was no evidence from this pilot trial that Predictive Parenting resulted in reductions in child EBPs beyond those seen following Psychoeducation; in addition, the effect size was small, and it was more expensive. However, it showed superiority for child compliance and facilitative parenting with moderate effect sizes. Future, definitive studies should evaluate whether augmented or extended intervention would lead to larger improvements.

Clinical trial registration information: Autism Spectrum Treatment and Resilience (ASTAR); https://www.isrctn.com/ISRCTN91411078.

Key words: autism, emotional and behavioral problems, parenting, feasibility, randomized controlled trial

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Autism is characterized by difficulties in reciprocal social communication and the presence of restricted and repetitive behaviors and sensory anomalies.[1] Psychiatric disorders frequently co-occur with autism at higher rates than in the general population, with up to 80% to 90% of young autistic children displaying emotional or behavioral problems (EBPs).[2-4] Anxiety disorders, attention-deficit/hyperactivity disorder (ADHD), and oppositional defiant disorder are most common and tend to persist over time.[5] These co-occurring difficulties are associated with greater parental stress and poorer well-being.[6]

Behavioral parenting interventions (BPIs) based on operant conditioning and social learning theories are well-established psychosocial approaches for improving behavioral problems in non-autistic children.[7] There is evidence

for their effectiveness when delivered in both individual and group formats.[8,9] These interventions have been adapted for parents of young autistic children, and there is emerging evidence for their efficacy.[10-12] Meta-analysis of randomized controlled trials (RCTs) of BPIs to reduce disruptive child behavior found a moderate effect[13] and some evidence for improvements in child hyperactivity and parent stress.[14]

However, there are limitations in the extant literature. Only 1 RCT[13] involved anxiety management techniques, even though anxiety disorders are the most common co-occurring psychiatric diagnoses in autistic children[2-4] and disruptive behaviors are often described by parents as an observable manifestation of anxiety.[15] Most trials have evaluated individual BPIs, although groups are more scalable and provide a support network for parents[8,16] (see Williams *et al.*[17] for a recent exception). Primary outcomes have been parent-reported measures of child EBPs, which are unblinded to intervention allocation for parent-mediated interventions, and there is a need for blinded, objective measures of child outcomes. No trials in this area have estimated costs or explored cost-effectiveness.

Aims and Objectives

We conducted a pilot RCT to evaluate the feasibility and preliminary efficacy and cost-effectiveness of a novel, group-based BPI for young autistic children (Predictive Parenting), in comparison to an attention control (Psychoeducation), using a blinded observational measure of child behaviors that challenge (BTC) as the primary outcome.[18] Predictive Parenting consisted of 12 sessions with 6 to 8 parents or carers/caregivers and 2 individual consultations. This BPI provides strategies to manage both externalizing behavioral problems and anxiety.[19] Separate groups were run for parents of minimally verbal (MV) and verbal (V) children to tailor the content to the child's level of language and to facilitate group cohesion. As universal interventions are warranted given the high prevalence of co-occurring EBPs, we did not exclude children based on level of EBPs.

The aims of the study were as follows: (1) to examine feasibility in terms of recruitment, retention, completion of research measures, fidelity of implementation of the intervention, and parental satisfaction; (2) to provide an indication of preliminary efficacy on the primary and secondary outcomes; and (3) to provide preliminary estimates of the costs and cost-effectiveness of the intervention, to inform a larger trial.

METHOD

Trial design

The study was registered as ISRCTN91411078, and ethical approval was provided by the National Health Service (NHS) Camden and Kings Cross Research Ethics Committee (16/LO/1769). Parents/carers gave written informed consent. The study was a parallel 2-group, 2-site pilot RCT comparing Predictive Parenting to Psychoeducation. Parents of 62 children were randomized to Predictive Parenting (n = 31) versus Psychoeducation (n = 31). Because intervention group composition and content were adapted based on child verbal language (MV versus V), randomization was stratified by verbal ability as well as by site. Randomization was conducted on blocks of 10 to 18 families on a ratio of 1:1, resulting in groups of 5 to 9 families in each condition for any block. Baseline measures were collected up to 2 months before the planned randomization date and postintervention measures at approximately 18 to 24 weeks after randomization, once the 12-week intervention finished. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram and timeline are provided in Figure 1.

Participants

Inclusion Criteria. Inclusion criteria were as follows: parent/carer of child between 4.0 and 8.11 years of age, with a confirmed autism diagnosis; parent with sufficient spoken English to access the intervention; agreement to inform family doctor of involvement in the study.

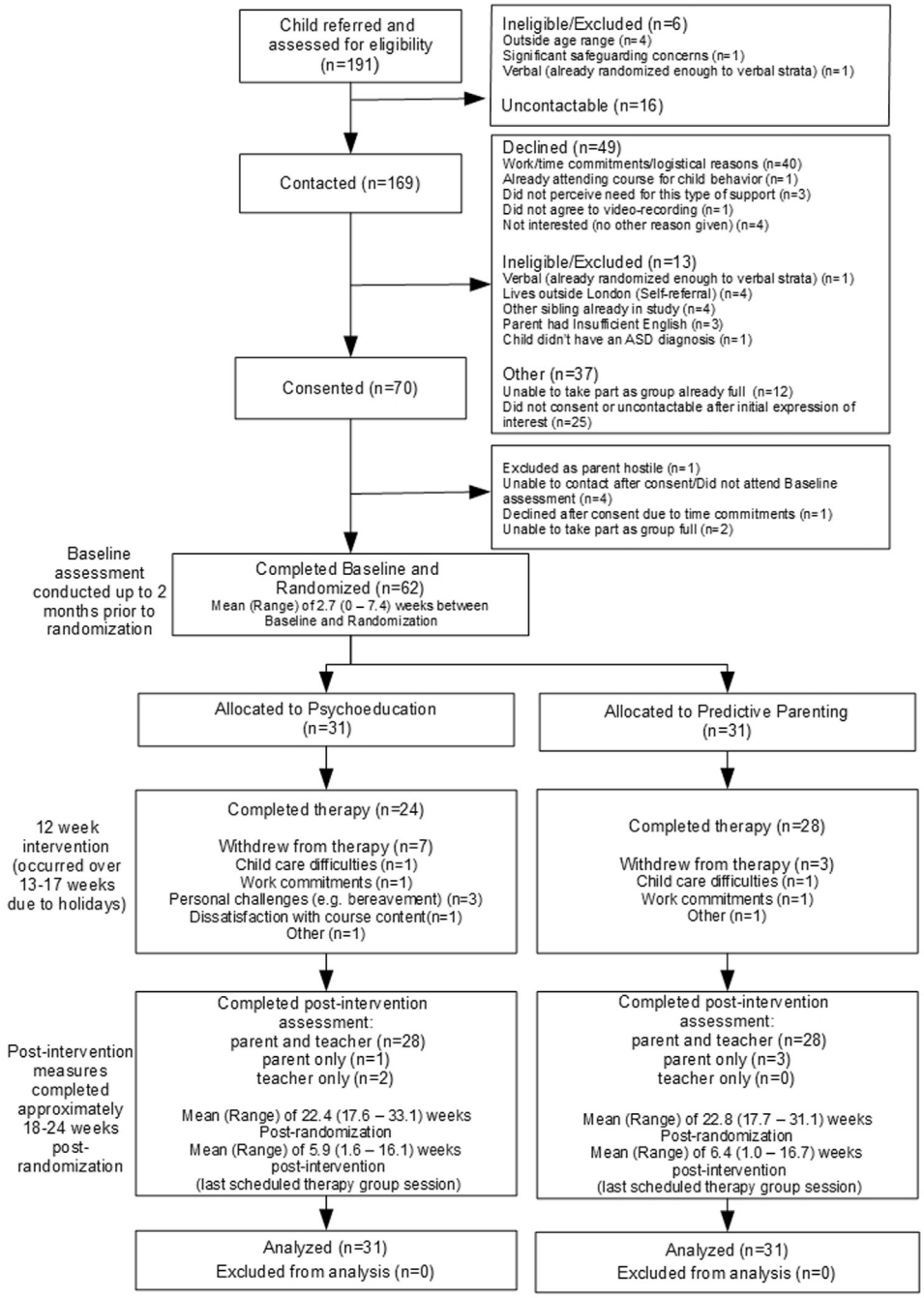
Exclusion Criteria. Exclusion criteria were as follows: current participation in another BPI; child with epileptic seizures more than weekly; parent or child with a severe hearing or visual impairment; active safeguarding concerns; current severe parental psychiatric disorder; and participation in the initial feasibility study.[18]

Procedure

Children were referred via local autism diagnostic teams, education professionals, support groups, or self-referral. After pre-screening for eligibility, informed consent was obtained, and baseline assessments were conducted. There were separate research and clinical teams based in different buildings with separate supervision structures. Researchers involved in conducting the assessments were blinded to intervention content and allocation, and, to reduce "training to task," therapists were blinded to details of the primary outcome.

Demographic information and child characterization measures obtained at baseline are shown in Table 1. These included an observational measure (Autism Diagnostic Observation Schedule–2nd edition [ADOS–2])[20] and parental report of autism severity (Social Communication Questionnaire–Lifetime version [SCQ-L]),[21] and parental report of adaptive skills (Adaptive Behavior Assessment System–3rd edition [ABAS–3]).[22] The ADOS–2 module was used as the verbal ability stratification factor (MV = module 1, defined as pre-verbal or using single words; V = module 2

FIGURE 1 CONSORT Diagram



or 3, defined as using phrases or fluent speech). Standard scores (mean = 10, SD = 3) on the ABAS-3 Communication domain reflected the following stratification factor: MV: 1.14 (0.44); V: 5.24 (2.36).

Interventions

Predictive Parenting. Predictive Parenting consisted of 12 weekly, 2-hour groups that extended parents' understanding of autism and co-occurring EBPs, and that included techniques to help parents anticipate, prevent, and respond to the child's disruptive behavior and anxiety.[19] It was developed from the clinical observation that autistic children struggle with unpredictability and anticipating change, and it integrates well-established behavioral parenting strategies within an autism-specific framework. Predictive Parenting included 3 over-arching themes: (1) learning to predict

TABLE 1 Characteristics of the Sample by Intervention Arm and Overall

	Predictive parenting (n = 31)		Psychoeducation (n = 31)		Total (N = 62)	
Sample characteristics	**n**	**%**	**n**	**%**	**n**	**%**
Child sex (male)	25	80.6	25	80.6	50	80.6
Site						
Croydon, UK	16	51.6	16	51.6	32	51.6
Bromley, UK	15	48.4	15	48.4	30	48.4
Child verbal ability						
Minimally verbal (ADOS–2 Module 1)	16	51.6	17	54.8	33	53.2
Verbal (ADOS–2 Module 2 or above)	15	48.4	14	45.2	29	46.8
Child ethnicity[a]						
White	16	51.6	17	54.8	33	53.2
Black/Black British	7	22.6	3	9.7	10	16.1
Asian/Asian British	4	12.9	4	12.9	8	12.9
Mixed/multiple ethnicities	4	12.9	6	19.4	10	16.1
Did not wish to answer	0	0.0	1	3.2	1	1.6
Parental education						
No formal qualification	2	6.5	5	16.1	7	11.3
General Certificate of Secondary Education (GCSEs), General Certificate of Education Advanced Level (A levels), or equivalent	3	9.7	10	32.3	13	21.0
Vocational qualifications (NVQ, City and Guilds or equivalent)	6	19.4	4	12.9	10	16.1
University degree	20	64.5	12	38.7	32	51.6
Parent/carer						
Mother	28	90.3	29	93.6	57	91.9
Father	3	9.7	0	0.0	3	4.9
Grandmother	0	0.0	2	6.5	2	3.2
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Child age, y	6.52	(1.22)	6.81	(1.06)	6.67	(1.15)
Autism severity						
ADOS–2 CSS total	7.29	(2.36)	7.71	(1.40)	7.50	(1.93)
Parent-reported SCQ-L total	25.13	(6.58)	21.74	(6.63)	23.44	(6.77)
Adaptive functioning						
ABAS–3 General Adaptive Composite (GAC) standard score	61.90	(12.98)	62.45	(12.63)	62.18	(12.70)

Note: [a]*White = English/Welsh/Scottish/Northern Irish/Irish/British/Other White ethnicity; Black/Black British = African/Caribbean/Other Black ethnicity; Asian/Asian British = Indian/Pakistani/Bangladeshi/Chinese/Other Asian ethnicity, Mixed/Multiple ethnicities = White and Black Caribbean/White and Black African/White and Asian/Other Mixed ethnicities.*

behavior more effectively; (2) making life for the child more predictable; and (3) helping the child cope with unpredictability. It also included content on promoting parental self-care and stress reduction (see Table S1, available online). Content was adapted based on child verbal ability. The group structure included a mixture of presentations

and didactic teaching with accompanying handouts and tools (eg, visual schedules, reward and emotion cards, etc), group coaching and practicing techniques, and parents supporting each other with strategies and review of homework tasks. If sessions were missed, parents were supported to catch up either by telephone or in person. In addition, two 45- to 60-minute individual sessions were conducted between sessions 2 and 4 and sessions 10 and 12, to support individualization and generalization of the strategies. The groups were held in local child and adolescent mental health services, libraries, or schools.

Psychoeducation ("Seven C's of ASD"). Psychoeducation also consisted of 12 weekly, 2-hour groups providing psychoeducation and social support, but no specific guidance on managing behavior or individual sessions. Content was adapted based on child verbal ability and delivered in the same community settings.

Intervention Adherence. The therapists delivering the interventions were 3 doctoral-level clinical psychologists experienced in working with autistic children, who led the development of the intervention manuals. Sessions were led by 2 therapists and supported by a pre-doctoral psychology assistant or a learning disability nurse. The team was consistent for the duration of each program (see Table S1, available online). A checklist was completed by therapists after each session, assessing intervention fidelity related to content (6 items of Predictive Parenting and 7 items of Psychoeducation) and group process (6 items), scored on a scale of 0 to 2 (0 = not covered; 1 = partially covered; 2 = fully covered). Mean ratings are reported. Parents provided satisfaction ratings via a self-report questionnaire completed after the intervention. Questions (scored on a scale of 1−4, with higher scores indicating greater satisfaction) asked about overall satisfaction with the intervention, the tailoring of content, and supportiveness, along with whether the parents would recommend the intervention to a friend, and, for Predictive Parenting, the effectiveness of the intervention on child behavior and emotions (see Table S2, available online). A global satisfaction score for both interventions was calculated by averaging the scores on the 4 items in common.

Measures

Feasibility. Feasibility was assessed in terms of recruitment, retention, completion of research measures, fidelity of implementation of the intervention, and parental satisfaction.

Child Outcomes. The primary outcome was the rate of child behaviors that challenge (BTC; eg, destructive behavior, aggression toward self and others, frustrated vocalizations, noncompliance, avoidance, and reassurance seeking). This was coded by researchers blinded to intervention allocation from video-recordings of researcher-child and parent-child interactions during an observation developed for the trial (the Observation Schedule for Children with Autism–Anxiety, Behavior and Parenting (OSCA–ABP[23]; see Supplement 1, available online, and list of tasks in Table S3, available online). Two researcher-led and 6 parent-led tasks are completed during the 18- to 22-minute observation. Tasks aim to simulate everyday challenges that autistic children may face and find difficult. As the length of the observation varied, the rate of child BTC per minute was calculated. To establish interrater reliability, all baseline videos were coded by 2 or 3 researchers, and 15 post-intervention videos were double coded (total n = 77 videos, resulting in 172 observations). The intraclass correlation coefficient (ICC) for the rate of child BTC was 0.83 (95% CI = 0.72−0.94).

Secondary outcomes included the rate of child compliance, facilitative parenting behaviors (eg, positive comments, clear commands, praise and supportive physical guidance), non-facilitative parenting behaviors (eg, negative comments, unclear commands, no opportunity to comply and physical handling) and the proportion of facilitative parenting behavior (compared to total of all facilitative and non-facilitative parenting behaviors) displayed during the OSCA–ABP (see Table S4, available online).

Other secondary outcomes included parent-reported child irritability and hyperactivity measured on the Aberrant Behavior Checklist (ABC)[24]; parent-reported child noncompliance measured on the Home Situations Questionnaire–Autism Spectrum Disorders (HSQ-ASD)[25]; parent-reported externalizing and internalizing behavior measured on the Assessment of Concerning Behaviors scale (ACB) [26]; parent-reported child anxiety measured using the Preschool Anxiety Scale–Revised (PASR)[27]; researcher-rated change in 1 or 2 parent-defined target problems;[28] and researcher-rated overall improvement in the child from baseline on the Clinical Global Impression − Improvement (CGI-I)[29] (both of the latter were rated at postintervention only). Teacher-reported child irritability and hyperactivity measured on ABC[24] and externalizing and internalizing behavior measured on the ACB[26] were also examined.

Parent Outcomes. Parent outcomes measures were the Autism Parenting Stress Index (APSI)[30] to assess parenting stress; the Child Adjustment and Parent Efficacy Scale − Developmental Disability (CAPES-DD)[31] Parent Efficacy subscale to assess parenting self-efficacy; the Short Warwick–Edinburgh Mental Wellbeing Scale

(SWEMWBS)[32] to measure parental well-being; and a short version of the Parenting Scale (PS)[33] to measure self-reported lax and overreactive parenting practices.

Economic Pilot Evaluation

Information on services used by children and parents was collected using a tailored Client Service Receipt Inventory (CSRI)[34] administered retrospectively at baseline and postintervention covering the previous 3-month periods. Service use data were multiplied by unit costs (2017–2018 prices) obtained from publicly available sources[35] or calculated from pay-scales and working hours (see Table S5, available online). Medications prescribed for children were costed from the British National Formulary.[36] Unpaid parent and carer support were costed at unit cost of a homecare worker.

Questionnaires completed by therapists tracked time spent on intervention-related activities (direct contact, arranging and preparing for groups, other administration) and travel expenses. Costs of both groups combined time-use data, mean salaries, and overhead costs using a micro-costing approach (see Table S6, available online).

Quality-adjusted life-years (QALYs) were calculated from parent reports of their own health-related quality of life (EQ-5D-5L)[37] and societal weights,[38] adjusting for time-elapse between data points and linear interpolation.

Adverse Events

Adverse events (AEs) were monitored and documented as they arose during intervention sessions and by the research team at postintervention, regardless of relationship to study intervention or research procedures. Hospitalization and bereavement in a family member residing in the home were considered to be serious adverse events (SAEs).

Statistical Analyses

Descriptive statistics were used to demonstrate the feasibility of the study protocol. As detailed in Supplement 1, available online, we had estimated the study design as providing 79% power for a d of 0.6 (2-tailed $\alpha = 0.05$). As a result of the range of baseline scores observed for the primary outcome, some very low, we analyzed the log-rate of behavior, for which power analysis suggested 80% power for a 15% reduction in rate, sufficient to be of clinical significance.

Analyses followed the Statistical Analysis Plan (SAP) available at ISRCTN91411078, registered prior to data-lock and unblinding. All analyses were carried out partially blinded and using the intention-to-treat population. Bivariate linear mixed models (jointly modeling the baseline and postintervention measures) were used within the generalized structural equation modelling framework in Stata (version 15.1) software and estimated using maximum likelihood. Allocation group, time (baseline or post-intervention), and site were included as covariates; a random intercept for therapy group was included. In the light of possible effect differences, the models were stratified by verbal ability (MV versus V) rather than dummy variable adjusted. The effect of allocation group at baseline was constrained to 0. Modeling this way yielded an analysis of covariance estimate of the intervention's preliminary efficacy, and allowed participants with non-missing baseline and/or postintervention observations of the measure to be included. The analysis model outcome included interactions terms for verbal ability strata with treatment and also time providing verbal ability stratum–specific estimates of the treatment effect size, which were then pooled. Separate interpretation of the verbal ability stratum–specific estimates was not prespecified in the SAP and are included in Supplement 1 (Table S7, available online) as exploratory. Analysis models for the secondary outcomes did not include these interactions, and therefore estimated overall treatment effects directly.

Raw score and residual plots were examined for non-normality, those measures with skew being log-transformed. This was the case for all the OSCA–ABP outcomes. To retain a simple proportional interpretation of effects, the constant added to avoid instances of logarithms of zero was chosen to be as small as possible while maintaining normality. For outcomes that were rated at postintervention only (CGI-I and parent-defined target symptoms), the *mixed* command in Stata was used with the same covariates (trial arm, verbal ability, and site) and a random intercept for therapy group.

For all outcomes except teacher reports, there were complete baseline data. For the teacher reports, there was a small amount of missing baseline data, and an indicator of baseline missingness was additionally included as a covariate.[39] No investigation of predictors of postintervention missingness was conducted, as the proportion was small and for all outcomes (except teacher outcomes and those measured only at postintervention) all participants were included in the model as a consequence of the bivariate modeling. Under an assumption of missing at random, estimates from the bivariate model will be unbiased. Standardized mean differences (d) use the pooled SD across arms measured at baseline, except where there was no baseline measure, in which case the pooled SD at postintervention was used. Standardized mean differences are given on the log-scale for log-transformed outcomes. Throughout, we have reported 90% CIs as suggested by the IDMC and described in the SAP to ensure that possible pilot effects are

not missed; however, conventional statistical significance was used ($p < .05$).

The primary economic pilot evaluation (cost-effectiveness analysis) compared incremental costs and outcomes over 12 weeks between trial arms from 3 perspectives: NHS and personal social service (NHS/PSS); public sector (NHS/PSS, education, and criminal justice services linked to the child's autism); and societal (public sector, out-of-pocket payments for autism-related services used by child, services used by other family members linked to child's autism, and unpaid care). Differences in mean costs, adjusted for baseline costs, verbal ability, and baseline child OSCA–ABP BTC rate and site, were analyzed using standard nonparametric bootstrapping (repeat re-sampling).[40] Preliminary cost-effectiveness was explored using the net-benefit approach with effectiveness measured on child BTC rates and parent QALYs. Cost-effectiveness acceptability curves were plotted. Sensitivity analyses investigated robustness, given uncertainty around some parameters and assumptions.

RESULTS

Feasibility

Recruitment. The majority of the 191 referrals came from child development centers (n = 80, 41.9%) or child and adolescent mental health services (n = 55, 28.8%). A total of 35 families (18.3%) referred themselves for the trial after seeing information circulated by local support groups. The remaining 21 referrals (11.0%) were from specialist education provision. Of those who were contactable, slightly less than half (n = 70/169, 41.4%) consented to take part, and of these individuals, 62 (88.6%) completed baseline assessments and were randomized.

Completion of Research Measures, Acceptability, and Retention. Completion of baseline assessment was high, with all families (100.0%) and greater than 90% of teachers completing assessments. High retention rates were achieved (90.3%−96.8%), with at least 1 outcome being available for all children (see Table S8, available online).

Intervention: Fidelity of Implementation and Parent Satisfaction. Intervention adherence was good, with mean (SD) attendance of 8.6 (3.3) and 8.4 (3.7) of 12 therapy group sessions, and 28 (90%) and 24 (78%) families still participating at the end of the final session in Predictive Parenting and Psychoeducation, respectively (see Figure 1 for reasons for withdrawal from therapy and SM for further information on attendance). Attendance in the individual Predictive Parenting sessions was high (mean = 1.68 sessions, range 0−2). Therapist-rated treatment fidelity was good, with mean (SD) scores (out of 2) of 1.93 (0.19) and 1.92 (0.14) for content and 1.90 (0.15) and 1.94 (0.14) for process items for Predictive Parenting and Psychoeducation, respectively. Parental satisfaction was high, with 91.3% and 81.8% "very satisfied" and 8.7% and 13.6% "satisfied" for Predictive Parenting (8 missing) and Psychoeducation (9 missing), respectively. The mean (SD) global satisfaction scores (out of 4) were 3.78 (0.29) and 3.76 (0.28) for Predictive Parenting and Psychoeducation. Parental reports of the effectiveness of Predictive Parenting on their child's behavior (mean = 3.74, SD = 0.45) and emotions (mean = 3.58, SD = 0.51) were high.

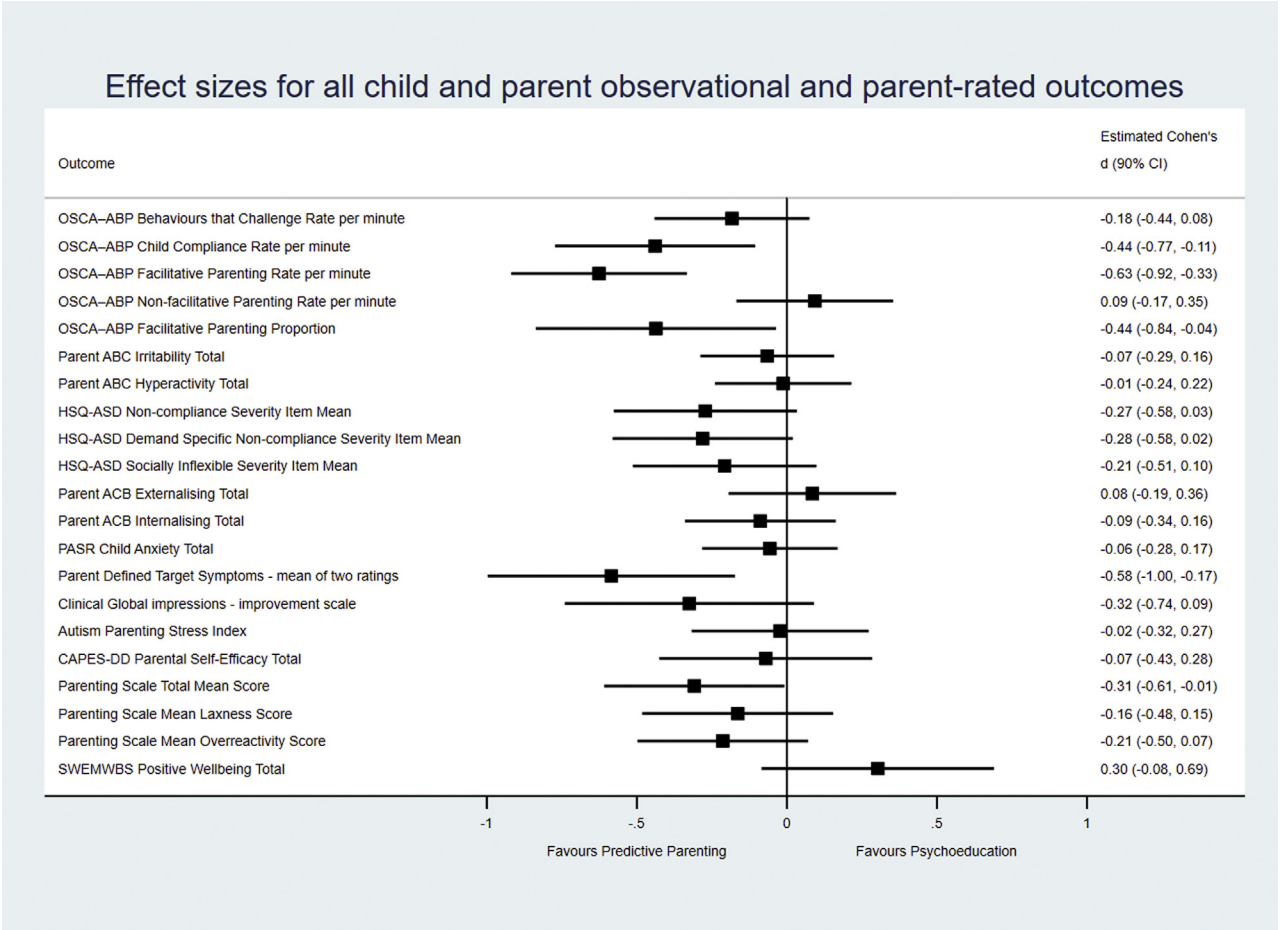
Pilot Outcomes

Figure 2 shows the Cohen's d effect sizes for all outcomes. Figure 3 shows observed baseline and postintervention OSCA–ABP scores. The model-estimated relationship for the primary outcome of child BTC in Figure 3A shows substantial declines in both groups, the additional change in Predictive Parenting compared to Psychoeducation was of modest size and nonsignificant (Cohen's $d = 0.18$, 90% CI = −0.44 to 0.08). A test of homogeneity of pilot treatment effect across verbal ability strata was nonsignificant ($p = .149$). There were group differences on the secondary observational measures in the relative rates of change in child compliance (Figure 3B, $d = 0.44$, 90% CI = 0.11−0.77) and facilitative parenting (Figure 3D, $d = 0.63$, 90% CI = 0.33−0.92) favoring Predictive Parenting, but no group difference for non-facilitative parenting (Figure 3C). There was an improvement in researcher-rated, parent-defined target problem measurement ($d = -0.59$, 90% CI = −0.17 to −1.00) favoring Predictive Parenting. Groups did not differ on parent- or teacher-reported child EBPs measures, or on measures of parenting, parent stress, self-efficacy, and well-being (Figure 2, Tables 2 and 3). Nontransformed OSCA–ABP rates are provided in Table S9, available online.

Exploratory, non-preregistered analyses by verbal ability strata suggested that there was a moderate difference for child BTC and child compliance in favor of Predictive Parenting among MV children, and a large difference in favor of Psychoeducation for facilitative parenting among V children. However, tests of the significance of these differences across strata were, in all cases, nonsignificant (for details see Table S7, available online).

Adverse Events. There were 47 adverse events (AEs) reported during the trial, of which 12 were SAEs. The AEs were similar across arms: 15 families reporting 24 events (Predictive Parenting) and 16 families reporting 23 events (Psychoeducation). The number of SAEs was also similar across arms: 3 families reporting 4 events (Predictive

FIGURE 2 Effect Sizes for Child and Parent Observational and Parent-Rated Outcomes



Parenting) and 5 families reporting 8 events (Psychoeducation), with all considered to be unrelated or unlikely to be related to the intervention. No AEs occurred in more than 10% of the sample (see Table S10, available online).

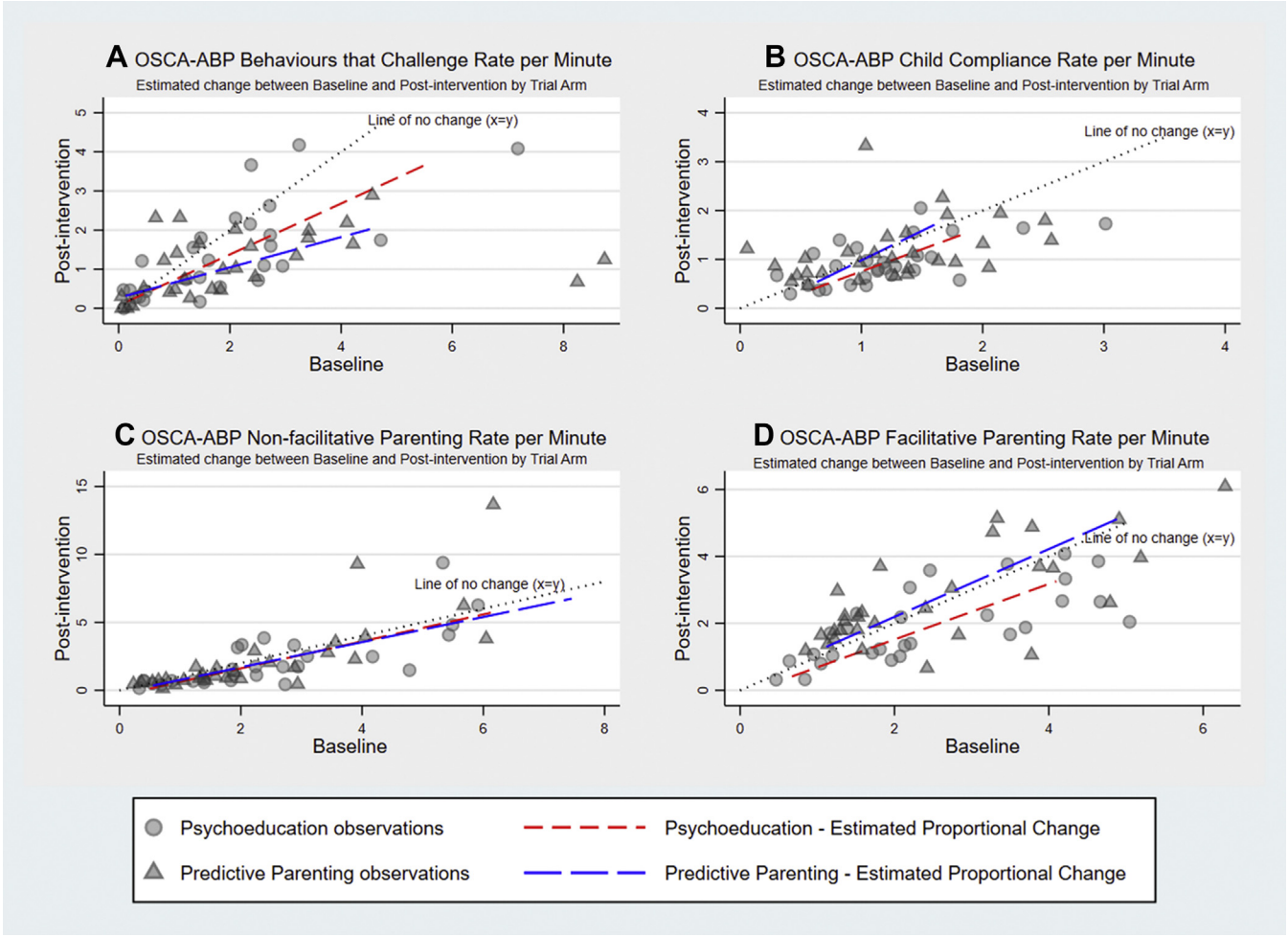
Pilot Cost-Effectiveness. In terms of intervention costs only, Predictive Parenting was £135 per participant more costly than Psychoeducation (90% CI = £74.67−£195.38) (Table 4). Without including intervention costs, NHS/PSS costs were £211 higher (90% CI = £68.12−£392.82) for Predictive Parenting than for Psychoeducation, and public sector costs were £577 higher (90% CI = £287.75−£918.39). There were no significant differences in societal costs (mean difference £481; 90% CI = −£285.74 to £1,581.96). QALY gains were not different between the interventions (mean difference = −0.019, 90% CI = −0.048 to 0.012).

When preliminary effectiveness was measured in terms of child BTC, the probability that Predictive Parenting would be viewed as cost-effective (from any study perspective) only exceeded 50% at willingness-to-pay values above £1,200 per point improvement in OSCA–ABP BTC rate (see Figure S1, available online). When measured in terms of parental QALY gains, the probability that Predictive Parenting would be viewed as cost-effective was very low, not exceeding 1% from any perspective, even at thresholds of £30,000 per QALY gain (see Figure S2, available online). Preliminary evidence suggests Psychoeducation is less expensive but possibly more cost-effective than Predictive Parenting. Sensitivity analyses explored different ways to measure unpaid care: reducing cost to 0, and applying the national minimum wage instead of the homecare worker cost. Neither altered the pilot cost-effectiveness interpretation.

DISCUSSION

The feasibility of implementing this pilot RCT of the 12-week behavioral Predictive Parenting group intervention versus an attention control Psychoeducation group was demonstrated. Recruitment into groups of 5 to 9 families stratified by child verbal ability was achievable but required

FIGURE 3 Baseline-to-Postintervention Plots for Primary and Secondary Blinded Observational Child and Parent Outcomes



Note: Within A–D, scores on the Observation Schedule for Children with Autism–Anxiety, Behavior and Parenting (OSCA-ABP) variable at baseline are plotted along the x-axis and scores at postintervention on the y-axis. Each triangle represents a participant in Predictive Parenting, and each circle represents a participant in Psychoeducation. The dotted gray line shows the line of no change; the blue dashed line shows the estimated proportional change for Predictive Parenting; the red line is the equivalent for Psychoeducation. For example, in A (top left) the Behaviors That Challenge (BTC), both lines show a reduction in BTC, but the proportional change for predictive parenting is larger than for psychoeducation as it is further away from the line of no change.

a substantial number of referrals, and dropout between referral and randomization was high. Of those who were involved, high rates of completion of measures by families indicated that once recruited, parents remained engaged in the study. Similarly, teacher completion of questionnaires was good, indicating that online collection of key outcomes in school settings was feasible within appropriate timeframes. Initial findings demonstrated that the therapists could implement the interventions as planned to high fidelity, and parental satisfaction was high.

However, in terms of preliminary efficacy, there were no group differences on the primary outcome, a blinded observational measure of child BTC, although in both groups, postintervention rates were lower than those at baseline. The reduction in observed child BTC in both groups is difficult to interpret in the absence of a treatment-as-usual (TAU) or waitlist control group. Reduction in child behavioral problems in both groups was also reported by Bearss *et al.*,[10] who similarly used an attention control design whereby the comparison group received psychoeducation, but these were greater for the BPI compared to psychoeducation (see also Bradshaw *et al.*[41]). We do not know the natural trajectory of child BTC on the OSCA–ABP in children who received no intervention and how this would compare with the reductions seen after parent-mediated interventions. There may be repetition effects from the observational presses and materials, the assessment location, and the research staff being more familiar to both

TABLE 2 Baseline and Postintervention Scores for the Blinded Primary and Secondary Outcomes

	Baseline				Postintervention					
	Predictive parenting		Psychoeducation		Predictive parenting		Psychoeducation			
Outcome measure	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	***d* (90% CI)[a]**	***p***
Primary observational outcome[b]										
Log OSCA–ABP child behaviors that challenge rate per minute	0.52	(0.94)	0.36	(0.86)	0.06	(0.76)	0.13	(0.82)	−0.18 (−0.44, 0.08)	.243
Secondary observational outcomes[b]										
Log OSCA–ABP child compliance rate per minute	0.49	(0.40)	0.49	(0.32)	0.46	(0.32)	0.32	(0.31)	0.44 (0.10, 0.77)	.030
Log OSCA–ABP facilitative parenting rate per minute	0.79	(0.57)	0.73	(0.63)	0.86	(0.54)	0.48	(0.67)	0.63 (0.33, 0.92)	<.001
Log OSCA–ABP non-facilitative parenting rate per minute	0.89	(0.60)	0.89	(0.58)	0.72	(0.74)	0.73	(0.69)	0.09 (−0.17, 0.35)	.557
Log OSCA–ABP facilitative parenting proportion	0.43	(0.10)	0.42	(0.08)	0.47	(0.12)	0.42	(0.11)	0.44 (0.04, 0.84)	.073
Teacher-reported secondary outcomes—child emotional and behavioral problems[c]										
ABC irritability total	7.43	(8.71)	7.47	(10.29)	8.89	(10.48)	9.00	(9.30)	0.05 (0.31, −0.20)	.729
ABC hyperactivity total	13.79	(10.43)	16.07	(12.45)	13.32	(13.21)	15.80	(12.15)	−0.04 (0.24, −0.31)	.820
ACB externalizing total	14.46	(9.10)	17.20	(11.93)	15.89	(11.34)	16.77	(9.95)	0.15 (0.42, −0.12)	.369
ACB internalizing total	13.46	(8.01)	14.73	(9.56)	14.70	(10.80)	15.03	(10.51)	0.09 (0.43, −0.26)	.676

Note: *Observation Schedule for Children with Autism–Anxiety, Behavior and Parenting (OSCA–ABP) rates are per minute and have been log transformed for analysis. The log transformations are reported here.*

[a]*Cohen's d is reported on the log scale for log-transformed variables. These values show the magnitude of the effect of Predictive Parenting in comparison to that of Psychoeducation.*

[b]*n = 31 and n = 29 at baseline and postintervention respectively for Predictive Parenting. For Psychoeducation, n = 31 and n = 28 for baseline and postintervention respectively.*

[c]*n = 28 at baseline and postintervention respectively for Predictive Parenting. For Psychoeducation, n = 30 for baseline and postintervention.*

TABLE 3 Baseline and Postintervention for the Unblinded Secondary Outcomes

	Baseline				Postintervention					
	Predictive Parenting (n = 31)		Psychoeducation (n = 31)		Predictive Parenting (n = 30)		Psychoeducation (n = 30)			
Outcome measure	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Cohen's *d* (90% CI)**	***p***
Parent-reported secondary outcomes—child emotional and behavioral problems										
ABC irritability total	18.13	(11.02)	14.39	(9.90)	15.3	(9.08)	12.71	(8.94)	−0.07 (−0.29, 0.16)	.630
ABC hyperactivity total	24.45	(13.73)	21.88	(12.87)	22.63	(12.34)	19.93	(11.3)	−0.01 (−0.24, 0.22)	.929
HSQ-ASD noncompliance severity	3.98	(2.04)	2.76	(1.77)	2.69	(1.65)	2.33	(1.53)	−0.27 (−0.58, 0.03)	.143
HSQ-ASD demand specific noncompliance severity	3.59	(2.20)	2.58	(1.86)	2.38	(1.45)	2.18	(1.6)	−0.28 (−0.58, 0.03)	.124
HSQ-ASD socially inflexible noncompliance severity	4.37	(2.36)	2.93	(1.93)	3.01	(2.11)	2.48	(1.59)	−0.21 (−0.51, 0.10)	.264
ACB externalizing total	23.81	(12.88)	21.65	(11.20)	23.27	(11.6)	20.21	(10.69)	0.09 (−0.19, 0.36)	.617
ACB internalizing total	22.84	(13.28)	22.1	(14.36)	21.2	(10.41)	20.39	(10.91)	−0.09 (−0.34, 0.16)	.562
PASR anxiety total	40.81	(22.92)	46.1	(22.89)	36.27	(20.69)	40.29	(22.56)	−0.06 (−0.28, 0.17)	.679
Improvement in parent-defined target symptoms[a,b,c]	—	—	—	—	4.09	(0.98)	4.64	(0.84)	−0.59 (−1.00, −0.17)	.020
CGI improvement[a]	—	—	—	—	3.33	(1.12)	3.72	(1.22)	−0.33 (−0.74, 0.09)	.198
Parent-reported secondary outcomes—parent outcomes										
APSI parenting stress total	24.52	(9.49)	21.74	(10.20)	21.33	(9.96)	19.79	(7.75)	−0.02 (−0.32, 0.27)	.901
CAPES-DD parental self-efficacy total	99.61	(33.92)	108.06	(29.24)	120.17	(30.59)	120.61	(24.35)	0.07 (−0.28, 0.43)	.744
SWEMWBS positive well-being total	21.13	(5.75)	23.94	(4.34)	21.8	(6.09)	25.21	(3.39)	−0.30 (−0.69, 0.08)	.198
PS mean	3.08	(0.72)	2.82	(0.90)	2.57	(0.75)	2.67	(0.84)	−0.31 (−0.61, −0.01)	.091
PS laxness mean	3.07	(0.83)	2.97	(1.15)	2.64	(0.85)	2.77	(1.08)	−0.16 (−0.48, 0.15)	.397
PS overreactivity mean	2.90	(1.02)	2.50	(0.98)	2.37	(0.98)	2.34	(0.88)	−0.21 (−0.50, 0.07)	.217

Note: [a]*These variables are improvement ratings and recorded at postintervention only.*
[b]*Mean of 2 ratings.*
[c]*Categorized as follows: externalizing problem (56.4%), internalizing problem (19.7%), or other (23.9%).*

TABLE 4 Costs and Outcomes Between Baseline and 12-Week Follow-up for Predictive Parenting and Psychoeducation

Costs (£, 2017–1818 prices) and outcomes	Predictive Parenting (n = 29) Mean (SD)	Psychoeducation (n = 28) Mean (SD)	Difference (90% CI)[d]
Intervention costs	431.27 (159.61)	295.81 (129.65)	135.27 (74.67 to 195.38)
NHS/PSS (child)[a]			
NHS/PSS	383.21 (552.76)	153.52 (192.79)	210.80 (68.12 to 392.82)
Total NHS/PSS costs (incl. intervention costs)	789.77 (567.96)	434.48 (231.66)	347.04 (186.55 to 539.17)
Public sector (child)[b]			
Public sector costs	1,028.51 (951.25)	432.27 (281.18)	576.57 (286.75 to 918.39)
Total public sector costs (incl. intervention)	1,393.42 (1,008.07)	700.19 (318.69)	668.88 (372.88 to 1,015.79)
Societal (child and parent)[c]			
Societal costs	2,845.16 (2,223.14)	2,015.99 (2,702.37)	364.01 (−402.97 to 1,512.99)
Total societal costs (incl. intervention)	3,092.87 (2,315.62)	2,181.74 (2,689.04)	480.84 (−285.74 to 1,581.96)
Outcomes:			
OSCA-ABP rate per minute at 12 weeks	1.13 (0.80)	1.33 (1.18)	−0.310 (−0.664 to 0.076)
Utility values (EQ5D-5L) at 12 weeks	0.782 (0.210)	0.878 (0.123)	−0.064 (−0.117 to 0.007)
QALY gain (baseline to 12 weeks)	0.385 (0.107)	0.427 (0.102)	−0.019 (−0.048 to 0.012)

Note: *incl. = including; NHS/PSS = National Health Service and personal social service; OSCA-ABP = Observation Schedule for Children with Autism–Anxiety, Behavior and Parenting.*

[a]*NHS/PSS perspective (health and social care services used by the child).*

[b]*Public sector perspective (NHS/PSS, education and criminal justice services) linked to the child's autism.*

[c]*Societal perspective (NHS/PSS services, education and criminal justice services used by the child, services used by other family members that are linked to the child's autism and unpaid care).*

[d]*Adjusted for baseline costs, trial arm, ADOS module (verbal vs minimally verbal), baseline OSCA-ABP, and site (Bromley or Croydon).*

the child and parent at postintervention, resulting in fewer child BTC.

The current feasibility pilot was powered to detect only moderate-to-large effects. However, the effect size on the child behaviors that challenge primary outcome was small ($d = -0.18$) and nonsignificant, but those for the secondary outcomes of child compliance and facilitative parenting were moderate ($d = 0.44$ and 0.63, respectively) and significant. Larger, better-powered trials of individual therapist–delivered BPIs have found significant reductions in child EBPs,[10,11] with Bearss *et al.*[10] reporting a moderate effect size (n = 180, $d = -0.62$) and Brookman-Frazee *et al.*[11] reporting small effects (n = 202, $d = -0.19$ and −0.28 across their 2 primary outcomes). However, these studies relied on unblinded parent report of primary outcomes. Both of these studies also had programs that extended ∼24 weeks, twice as long as the present intervention. In addition, baseline parent-reported ABC irritability and hyperactivity scores and, to a lesser extent, HSQ-ASD scores, were higher in Bearss *et al.*[10] compared to our sample, possibly indicating greater scope to demonstrate change on these measures. We did not exclude children based on level of EBPs, offering the intervention universally to parents of all eligible children with an autism diagnosis given the high prevalence of co-occurring EBPs,[2,3] but for some children baseline rates were low and for whom substantial absolute improvement would not be possible A pilot RCT of the Incredible Years Autism Spectrum and Language Delays 12-week group BPI reported no differences in parent-reported EBPs compared to TAU,[17] but a group-based format of the RUBI program has reported encouraging (uncontrolled) feasibility data.[42]

Predictive Parenting did show superiority over Psychoeducation for the observational measures of child compliance and facilitative parenting. When looking at the baseline and postintervention scores for both groups (Table 2), this effect was due to a maintenance of rates on both measures in the Predictive Parenting group, whereas both child compliance and facilitative parenting declined from baseline to postintervention for the Psychoeducation group. Again, in the absence of a TAU group, the interpretation of these group differences is not clear. It might be

that Predictive Parenting has a "protective effect" on both child and parent across time that is not apparent in those who received Psychoeducation and in whom both child compliance and facilitative parenting strategies reduced across the course of the pilot trial. The other measure that showed superiority for Predictive Parenting was the researcher-rated change in parent-defined target symptoms that has previously shown large effect sizes in psychopharmacological trials,[28] is widely used clinically,[43] and is a meaningful in regard to outcomes for families. However, although the researchers were blinded to group allocation, parents were not, and we used a researcher rating of change in problems over time rather than rating the severity separately at each timepoint, thereby limiting interpretation.

Although there were no group differences on the unblinded parent-report measures of child EBPs, with most having small effect sizes, there was a broadly consistent pattern across measures favoring Predictive Parenting (Figure 2). The Cohen's d effect size for the HSQ-ASD subscales were ~0.20, and in both groups there were modest reductions in HSQ-ASD scores from baseline to postintervention. Similarly, there were no group differences on parent self-report of parenting practices, but a similar pattern showed general favoring of Predictive Parenting. No differences were seen on blinded teacher-reported child EBPs. Change in child behavior in the school setting following a time-limited BPI might not be expected over this time period, and the timing of assessment of EBPs in the school context is an important design consideration for future RCTs.

In part due to including individual sessions, Predictive Parenting was more expensive to deliver than Psychoeducation, and was associated with higher NHS, social care, and other public sector costs. However, the cost differences were not expected, and should be examined in future studies. Predictive Parenting is probably less cost-effective than Psychoeducation in addressing child BTC and in generating parent QALY gains.

The present study has a number of strengths, which include the following: the autism-specific framework of Predictive Parenting that focused on managing both behavior and anxiety; therapy and research protocols that were developed with input from parents of autistic children and autistic adults[18]; the comparison to an active attention control condition; the group format designed to be scalable within the UK public health service context; and a blinded observational measure of primary and secondary child and parenting behaviors. However, it also has a number of limitations, as follows: its being a pilot RCT with a small sample size and hence modest power to detect group differences; the lack of an objective rating of intervention fidelity; the lack of a TAU group to track the natural trajectory of child and parent behaviors over time; and the fact that although the researchers who coded the observational measure were blinded to intervention allocation, they were not blinded to timepoint.

In conclusion, this pilot RCT demonstrated good feasibility of the intervention and research procedures. However, it was not powered to detect small-to-moderate intervention effect sizes and, combined with the use of an active attention control condition and the absence of a TAU group, firm conclusions about the potential efficacy of the Predictive Parenting program will require further research. Although there was some evidence for benefit on both child and parent secondary measures for Predictive Parenting with moderate effect sizes ($d = 0.44$ and $d = 0.63$, respectively for child compliance and facilitative parenting), there was no effect on the primary outcome—namely, child BTC—which was small in size ($d = 0.18$), although the 90% CIs included moderate effects (−0.44 to 0.08). Previous behavioral therapist−mediated and parent-mediated interventions that have reduced EBPs in young autistic children have been conducted over longer periods, have been individualized, and have also used preselected samples based on the presence or severity of child EBPs at baseline.[10,11] We do not know whether a more intensive or extended version of a group-based approach that may provide more time for parents to practice and to consolidate the behavioral techniques that they are learning would provide additional benefit, or whether pre-selection based on severity of child EBPs would have led to larger improvements. The observational outcome measures, including the primary outcome child BTC, were positively skewed, indicating that some children showed low rates of these at baseline. Future larger, better-powered definitive efficacy studies are required to further evaluate scalable BPIs such as Predictive Parenting, which, if proved to be effective at reducing EBPs, would bring considerable benefit to young autistic children and their families.

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