

Treatment of Preschoolers with Attention-Deficit/Hyperactivity Disorder

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Abstract This article reviews the current treatment literature for attention-deficit/hyperactivity disorder (ADHD) in preschoolers. Parent training studies show consistent behavioral improvements reported by teachers and observers as well as parents, with evidence of clinically significant improvement in ADHD symptoms for up to 2 years. Few other behavioral interventions have been evaluated, although data from a large psychosocial, multimodal intervention are forthcoming. There is evidence to support the benefit of immediate-release stimulant medication for up to 1 year; however, effects do not seem to be as large, and some of the side effects may be greater than for school-age children. With regard to nonstimulants such as atomoxetine, there are literally no controlled outcome data for children with ADHD who are younger than 5 years of age. Overall, a great deal remains to be learned about the safety and efficacy of pharmacotherapy in this age group. Fortunately, results of several large intervention studies will be available soon to better inform clinical practice.

Keywords ADHD · Preschool · Psychosocial · Parenting

Introduction

Attention-deficit/hyperactivity disorder (ADHD) in preschoolers has become established as a valid psychiatric disorder, with prevalence estimates ranging from 2% to 6% in community samples [1, 2]. Despite some differences in

symptom presentation in younger children, similar patterns of comorbidity and impairment have been identified [3]. In the largest clinical sample available, oppositional and aggressive behaviors co-occurred with ADHD at rates as high as 70%, communication disorders at rates greater than 20%, and anxiety disorders at rates of 14.5% [4]. Many areas of impairment have been identified among preschoolers with ADHD, including relationships with parents, siblings, peers, and teachers, as well as their ability to cooperate with family activities and behave appropriately in public, which requires limitations of activities outside the home [5]. Academically, preschoolers with ADHD perform more poorly on tests of pre-academic skills [6] and have identified deficits in working memory, planning, and delay of gratification [7]. A large community survey indicated that more than 40% had been suspended from a preschool or day care setting at least once, and 16% had been expelled (Egger, personal communication).

Evidence indicates that ADHD may be more severe and complicated in younger children and those with earlier-onset ADHD. Within a sample of clinically diagnosed children 3 to 5.5 years of age with ADHD, symptoms were rated by parents and teachers as more severe in younger children [4]. Earlier age at onset of ADHD (recalled by parents in annual increments from birth to 6 years of age) within a clinical sample of elementary school-age children was also associated with higher rates of parent-reported aggressive symptoms [8]. Diagnosis during the preschool years also predicts the development of other psychiatric disorders and creates significant risk for the development of secondary impairments such as school failure and peer difficulties during adolescence [9, 10]. Unfortunately, ADHD in preschoolers seems quite stable over time, with symptoms remaining to age 6 years in 50% of children identified at age 3, and in 48% at age 9 [11].

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Although specific data comparing preschoolers to school-age children with ADHD are lacking, there is reason to believe that impairment may actually be greater for preschoolers in some areas. For example, young children diagnosed with ADHD exhibit an increased risk of physical injury related to impulsive behaviors compared with similarly aged peers without disruptive behavior difficulties, with more reported accidents, unintentional injuries, and visits to emergency departments [12]. Specific examples from the largest preschool ADHD study to date include behaviors such as falling off furniture after excessive climbing, unbuckling restraints and standing up in cars and strollers, drinking poison, and falling or jumping out of windows [4]. Also, because there are fewer options for child care for preschoolers than school-age children, the high rates of suspension and expulsion noted above may create tremendous management burdens for parents and contribute to their high levels of parenting stress. Clearly, effective early interventions are needed to prevent the negative developmental trajectories seen in this high-risk population.

Current Status of Treatment Research

More than 10 years ago, the National Institutes of Health Consensus Development Conference on the Diagnosis and Treatment of ADHD called for investigations to identify better ADHD treatments for preschoolers due to alarming increases in the use of stimulant medications for children younger than 6 years of age [13]. In response, the past decade has seen increased research in this area. Results of the large Preschool ADHD Treatment Study (PATS) examining the safety and efficacy of methylphenidate in a large, cross-site sample of 3–5-year-olds in a double-blind, placebo-controlled trial followed by 10 months of open-label treatment are now available, and data from a two-site trial of the nonstimulant atomoxetine in 5- and 6-year-olds are forthcoming. In addition, ADHD-specific treatment guidelines recently have been developed by the Preschool Psychopharmacology Working Group [14], a cross-disciplinary initiative funded by the American Academy of Child and Adolescent Psychiatry, which published its recommendations a few years ago.

Increased empiric attention also has been paid to the evaluation of psychosocial treatments of ADHD in preschoolers, although the body of data from controlled trials with clinical samples is notably smaller than that for pharmacotherapy, as well as that for school-age children. A recent review of psychosocial treatments for ADHD in preschoolers identified only five ADHD-specific studies (four of which were published since 2000), although a much larger body of literature on the treatment of disruptive behavior defined more broadly is also relevant to consider

[15]. In addition, three large, federally funded trials of parent training and combination parent/child training with clinical samples of ADHD preschoolers are currently under way or have results under review (Webster-Stratton et al. [5-R01-MH067192-03], Abikoff [1-R01-MH074556-01], and Eyberg [5-R01-MH072780-02]). When published, these data should provide considerable guidance to clinicians in referring families for evidence-based psychosocial treatments.

The present article reviews existing research for both pharmacologic and psychosocial treatments for preschoolers with ADHD (parent training, classroom behavioral interventions, and multimodal treatments) and the above-referenced ongoing studies. Clinical implications are discussed, and recommendations for community practitioners provided. It should be noted that although assessment and diagnosis of preschool ADHD are not addressed here, careful and comprehensive evaluation is absolutely critical for determining the appropriate course of treatment. For evaluation guidelines, readers are referred to work by Egger and Angold [16] and Posner et al. [4] and a publication by the Task Force on Research Diagnostic Criteria: Infancy and Preschool [17].

Parent Training

Parent training is considered a well-established treatment for ADHD, according to guidelines from the American Psychiatric Association Presidential Task Force on Evidence-Based Practice [18]. The rationale for parent training for preschoolers is supported by data showing inconsistent and controlling management strategies, poor maternal coping, and decreased encouragement and paternal communication in this population [6]. Parent training is based on social learning principles and teaches parents to manage children's behavior by manipulating antecedents (eg, giving instructions and establishing rules) and consequences (eg, providing rewards and using timeouts).

Traditionally, parent-training programs such as that created by Barkley [19] have provided didactic instruction and modeling in a group or individual format, with adults engaging in role plays in session and practicing skills at home as “homework.” Other parent training programs (eg, Parent–Child Interaction Therapy [PCIT]) focus more directly on parent–child interactions in that therapists provide feedback to parents and coach them in using skills with their child in session [20]. These programs add developmental theory to social learning as a way to understand and change behavior, and focus heavily on the parent–child relationship. As will be described, some programs (eg, New Forest Parenting Package [NFPP]) have combined elements from both of these approaches [21].

The following ADHD-specific studies were previously reviewed by this author and colleagues [15•].

The earliest randomized study of parent training with 46 clinically diagnosed preschoolers [22] used treatment adapted from Forehand and McMahon's *Helping the Noncompliant Child* (HNC) [23] and Barkley's *Hyperactive Children* [19], including some didactic and some interactive components provided in groups. Compared with wait-list controls, treated children evidenced improved compliance with parental commands that was maintained for 3 months. In contrast, Barkley's 10-week parent training group program did not show any effects in a large, community-based, randomized trial of kindergarteners ($n=158$) rated as having above-average hyperactive-impulsive and conduct problems [24]. This was attributed to the low rates of parent participation in treatment (only 25% of parents attended at least half the sessions).

Using a variant of the traditional parent training approach in another community sample, the Triple P Positive Parenting Program [25] was evaluated with 87 economically disadvantaged 3- and 4-year-olds whose parents identified six or more *DSM-IV* symptoms of inattention or hyperactivity-impulsivity [26]. Triple P involves 10–12 individual parent training sessions in which children are invited to several sessions so that parents can practice their newly learned behavior management skills with them. In this study, parents were randomly assigned to a standard behavioral family intervention (BFI) group, an enhanced BFI group with partner support and coping skills training, or a wait-list control group. Results showed significant decreases in parent ratings of children's disruptive and ADHD behaviors for both groups and decreased observed negative child behaviors for enhanced BFI compared with the wait-list group, and treatment effects were maintained at 1-year follow-up.

Positive results also have been reported in studies of parent-child interaction therapies, namely the PCIT conducted by Eyberg et al. [20]. PCIT is considered a well-established treatment for children with conduct problem behavior, many of whom also demonstrate characteristics of ADHD. It involves 12–20 individual sessions focused on instruction and live coaching of the parent interacting with the child. In a recent literature review of PCIT, four studies were identified that included preschoolers meeting *DSM* criteria for ADHD, and two more studies included children 2–7 years of age with multiple disruptive behavior disorders [27].

Outcome data from these PCIT studies indicate sustained improvement in parent ratings of inattention and hyperactivity over 2 years, normalization of teacher ADHD symptom ratings up to 1 year, and improvement in time on-task on observational ratings [28–30]. Samples of clinic-referred children meeting criteria for ADHD and oppositional defiant disorder were less likely to meet *DSM* criteria after treatment

for these disorders, with up to one half remaining free of any disruptive behavior diagnosis at 2-year follow-up [28]. Moreover, improvements also have been observed in teacher ratings of social competence, hyperactivity, and time on-task behaviors following PCIT treatment [30].

Combining traditional parent training with some parent-child interaction elements, the NFPP is an 8-week, home-visiting treatment program developed in the United Kingdom that has been evaluated in two different community samples of 3-year-olds with elevated parent-reported ADHD symptoms [21]. In the first study, children were randomly assigned to NFPP ($n=30$), parent counseling and support ($n=29$), or a wait-list control group ($n=20$). Parent- and observer-rated ADHD symptoms were significantly reduced by NFPP compared with the other two groups after treatment and at 15-week follow-up, with 53% of children evidencing clinically significant improvement [31]. However, in the second study, which delivered NFPP by nonspecialist nurses rather than mental health therapists, no treatment benefits were apparent [32].

It also should be noted that current trials of PCIT, NFPP, and HNC for ADHD in preschoolers are under way. Eyberg et al. (unpublished data) are investigating the comparative efficacy of PCIT in different treatment formats (eg, group vs individual) in the presence and absence of comorbid oppositional defiant disorder for about 120 4–6-year-olds with ADHD. Abikoff et al. (unpublished data) are comparing NFPP, a home-based parenting intervention, to HNC, which is clinic based, in 180 3- and 4-year-olds. In addition to providing important efficacy data from large randomized controlled trials of promising parent training interventions in clinical samples, these studies will also provide information on the relative efficacy of different parent training approaches, which will be informative for practitioners.

Summary

Many different parent training interventions have been evaluated with both clinical and community preschool samples identified by varying criteria, with almost uniformly positive results and improvements perceived by teachers, observers, and parents. Building upon the large treatment efficacy literature for disruptive behavior in preschoolers, there is now evidence that parent training can yield clinically significant improvements in ADHD symptoms for up to 2 years and with clinically diagnosed preschoolers. It is anticipated that results of two large, federally funded trials will strengthen these findings considerably and inform selection of specific programs that may be the most effective. What remains unknown is whether efficacy rates may vary by age of the child (eg, 3 vs 5 years) or group versus individualized format (although

this is currently being investigated), which programs are most effective (although one comparative treatment study is ongoing), and which treatment components may be critical for achieving positive effects.

Classroom Behavioral Interventions

Classroom behavioral interventions have been found to improve school-related outcomes for at-risk youngsters and are considered evidence based for elementary school students with ADHD. Several single-case and small sample ($n < 5$) studies using behavioral interventions for preschoolers suggest potential benefit for ADHD-related behaviors. Results of these studies reflect increased on-task behavior and decreased disruptive behavior based upon observational methods and teacher ratings [33]. The Barkley et al. [24] multimodal intervention study also evaluated the unique benefits of a kindergarten classroom intervention including direct child instruction in anger management, social skills, and self-control as well as a variety of contingency management procedures such as token economies, response-cost systems, and a daily report card. Behavioral improvements were seen at the end of the school year; however, these benefits were not maintained at 2-year follow-up despite attempts to provide consultation to subsequent first-grade teachers [34]. Given the limited and variable research in this area, it is difficult to draw conclusions regarding efficacy. Clearly, more research is needed, particularly given the level of impairment that preschoolers with ADHD are reported to experience in classroom and day care settings.

Multimodal Psychosocial Interventions

Two multimodal interventions for preschool/kindergarten children with ADHD have been developed. As previously described, Barkley et al. [24] provided parent training in combination with classroom treatment that included behavior management plus direct skills training with children. Due to lack of participation in the parent training program, however, few conclusions can be drawn about the benefits of this combined treatment. The second multimodal intervention, the Incredible Years Program (IY) developed by Webster-Stratton [35], is considered well-established for children with oppositional defiant disorder by the National Registry of Evidence-based Programs and Practices [36]. About 30% of participants in four randomized trials of IY are estimated to have had ADHD, and preliminary evidence indicates that this treatment reduces ADHD-related symptoms as well as improving parenting, parent-child interactions, and other negative child behaviors at home and school [37–40].

IY includes parent-, teacher-, and child-targeted components that focus on strengthening young children's social and emotional competence. About 20 parent training sessions are provided in group format using videotape modeling and role plays in a more collaborative approach than traditional parent training. Parent involvement and support of children's school activities are also addressed. The teacher intervention uses similar training methods, targeting classroom management skills and attempting to promote children's prosocial behaviors. Child training (eg, "Dinosaur School") teaches emotional regulation, social skills, and problem-solving strategies in small groups (for clinic-referred children) or classroom settings (in a prevention model). Webster-Stratton et al. (unpublished data) recently completed a randomized controlled trial of the combined parent and small group child interventions with 99 4- to 6-year-olds with ADHD; results are currently under review and should be available soon.

Medication

Prescription guidelines from the US Food and Drug Administration indicate that stimulant medications should not be used in children younger than 6 years of age. However, off-label use has increased dramatically since the 1990s, when 34% of pediatricians and 15% of family practitioners reported prescribing stimulants to preschoolers with ADHD [41]. Data from two Medicaid samples and one managed care organization collected between 1991 and 1995 reflect a threefold increase in the number of 2–4-year-olds diagnosed with ADHD who were receiving methylphenidate [42], and from 2000 to 2003, Medco Health Solutions reported a 49% increase in the use of medications for ADHD in children younger than 5. Although most prescriptions written for preschoolers are stimulants, atypical antipsychotics, antidepressants, and alpha agonists are also being used. Even more concerning are data from the Michigan Medicaid system showing that 57% of children 3 years of age or younger with ADHD were treated with as many as 22 different medications in 30 different combinations and monitored less than every 3 months [43]. Understandably, many concerns have been raised about these practices, including ethical objections to using any medications for children this young, concerns about side effects, and the limited body of efficacy data.

An extensive body of data spanning several decades supports the safety and efficacy of stimulant medication in school-age children; however, few studies have included preschoolers. Prior to the National Institutes of Health-funded PATS, initiated in 2000 [44], there were only 11 publications of 10 controlled stimulant treatment studies, including less than 280 total participants, with many

methodologic limitations that affected interpretation of outcomes [45]. In particular, most of these studies were not placebo controlled, sample sizes were small, duration of the trials was short, and the diagnostic procedures and side effect reporting were highly variable. As described by Greenhill et al. [46], results were mixed, with six reporting good efficacy and safety, two failing to show benefit, and two reporting higher rates of adverse events, including sadness and social withdrawal.

Results of the PATS Study

To provide more reliable safety and efficacy data, the PATS study examined the effects of immediate-release methylphenidate in 165 children 3–5.5 years of age randomly assigned to placebo and 1 week each of 4 methylphenidate doses (1.25, 2.5, 5, and 7.5 mg) administered three times daily in a double-blind, placebo-controlled, crossover design. Significant improvements in ADHD symptoms were found during the initial trial, with an average dose of 14.2 ± 8 mg/d [46], optimized to within one SD of the mean on parent ratings. This is considerably lower than a similarly optimized dose for school-age children in the Multimodal Treatment Study of Children with ADHD (MTA) using the same medication (30.5 ± 14.2 mg/d). Only 21% were considered excellent responders (as defined by symptom normalization), with average effect sizes (0.4–0.8) that were notably smaller than those for MTA children (0.8–1.2), although this could be partially related to the lower doses used. A total of 30% of participants experienced moderate to severe side effects, including insomnia, appetite loss, emotional outbursts, repetitive thoughts/behaviors, and irritability; 11% discontinued [47]. Of note, efficacy was linearly related to comorbidities, with the best response seen in those with children with ADHD alone or in combination with oppositional defiant disorder, and no response seen in those with three or more comorbidities [48]. Overall, these data reflect significant clinical benefit at dose equivalents of 7.5, 15, and 22.5 mg/d of methylphenidate but lower short-term efficacy as well as tolerability compared with school-age children.

For 95 of the 140 children who entered the 10-month maintenance phase of PATS, stable improvement in ADHD symptoms was seen with continued improvement in global functioning (eg, social skills) over time [49]. However, parent and teacher symptom ratings fell within the normal range for only about one third of these children. One third ($n=45$) of those who entered maintenance discontinued due to adverse events ($n=7$), behavioral deterioration ($n=7$), switching to a long-acting stimulant ($n=7$), inadequate benefit ($n=3$), or other reasons. Common side effects included appetite loss, trouble sleeping, stomachaches, social withdrawal, and lethargy, with higher rates of

emotional side effects such as tearfulness or irritability than in school-age children. Preschoolers taking stimulants for 1 year also experienced significant growth suppression, with a 20% less than expected height gain (-1.38 cm/y) and 55% less than expected weight gain (-1.32 kg/y), although it should be noted that the sample upon which these data are based was found to be significantly larger than average as compared with Centers for Disease Control and Prevention norms [50]. For children who initially responded positively to methylphenidate, however, continued benefit was seen in more than 90% of the cases.

Nonstimulants

To date, there is only one published study of any non-stimulant in preschool-age children with ADHD. Kratochvil et al. [51] treated 22 5- and 6-year-olds with atomoxetine in open-label fashion for 8 weeks in combination with parent education in behavior management adapted from HNC provided at each pharmacotherapy visit. A significant decrease in ADHD symptoms was observed at a dose of 1.25 mg/kg, which is similar to the dosing for school-age children. Similar to adverse events seen with stimulants, mood lability, decreased appetite, and weight loss were common. Results of an 8-week, double-blind, placebo-controlled trial of atomoxetine by the same authors in 101 5- and 6-year-olds recruited across two sites are currently under review and should be available soon. Although 3- and 4-year-olds were not included, and any effects of the psychoeducational component cannot be separated out, this study will greatly increase the existing knowledge base and inform clinicians considering nonstimulant treatment for preschoolers with ADHD.

Summary

Despite significant advances made recently in our knowledge of medication use for preschoolers with ADHD, many important questions relevant for clinical practice remain. In particular, stimulant dosing parameters and tolerability issues need further examination, as do the effects of sustained-release formulations, which have now become the standard of care in the United States. In addition, there are literally no data on use of the nonstimulants such as atomoxetine in children younger than 5 years of age. Although there is evidence of benefit of stimulant medication for preschool-age children with ADHD, effects do not seem to be as large, and some of the side effects may be greater than for school-age children, including growth slowing. The long-term impact of medication use for preschoolers beyond 1 year is also unclear, although the follow-up to the PATS study should be able to address this in the near future.

Conclusions

As can be seen in Table 1, there are now data supporting the efficacy of both psychosocial and pharmacologic treatments for preschoolers at risk of or clinically diagnosed with ADHD. However, the impact of early treatment on the developmental trajectory of early-onset ADHD, the development of associated psychiatric conditions, and later functional outcomes is unknown. Just as preschoolers seem more vulnerable to adverse effects of medication, they also may be uniquely receptive to early interventions. Indeed, effect sizes for PCIT on ADHD symptoms in preschoolers (−1.6–1.88; Eyberg, unpublished data) are double those reported for traditional parent training interventions with school-age children (−0.87) [52], suggesting that this type of early intervention may be more powerful than those provided when children are older.

There is growing indication of the elasticity of young children's brains and evidence that several brain structures and cerebral metabolic rates peak in the first 3 years of life [53]. Inhibitory processes and emotional regulation that seem to play a key role in ADHD-related impairment are also developing rapidly during the preschool years, and negative behavior patterns often have not yet become ingrained. Thus, at least theoretically, early interventions have the potential to create lasting change in young children's neurodevelopmental functioning. This is certainly an area warranting further research.

The Preschool Psychopharmacology Working Group [14] has recommended that evidence-based parent training or other behavioral intervention should be the first-line intervention for preschoolers with ADHD, which is consistent

with the data reviewed here, as well as with parent preferences. For children with moderate to severe symptoms and functional impairment that persist after an adequate course of psychosocial treatment, a carefully monitored trial of methylphenidate (which has the largest body of efficacy data) is recommended. If extended-release formulations (for which no preschool data exist) are used to enhance ease of administration and compliance, consideration must be given to the availability of an optimally tolerated dose. In children who do not sufficiently improve with psychosocial treatments alone, the developmental and safety risks likely outweigh the risks of side effects of medication. Importantly, however, a discontinuation trial should be conducted after 6 months to reassess the disorder and the need for medication given that a proportion of children diagnosed at preschool age will not meet criteria in the future and may not require ongoing pharmacotherapy [54].

These guidelines also assume that the psychosocial treatments provided are evidence based, or at least behavioral in nature. Given that results of the three largest parenting trials are not yet available, community practitioners may be challenged to identify specific interventions that are effective. Moreover, these interventions all require considerable clinician training, and their availability outside of research grants is likely limited at this time. Thus, parents and prescribers may be at a loss to access them. Indeed, the limited data available on mental health service utilization for young children with ADHD identify a range of widely used interventions without empirical support, including play therapy, dietary interventions, “developmental therapies” (eg, occupational and physical therapy), and unspecified counseling or psychotherapy [55]. Given data from samples of school-age children with ADHD identifying

Table 1 Summary of extant treatment literature regarding ADHD in preschoolers

Treatment modality	Clinical ADHD sample?	Randomized controlled trial?	Short-term effects?	Long-term effects?
Parent training programs				
Barkley's (1981) model [24]	No	Yes	No	NA
PCIT [28–30]	No ^a	Yes	Yes	Yes
NFPP [31, 32]	No ^a	Yes	Yes ^b	Yes
Barkley's model+ <i>Helping the Noncompliant Child</i> [22]	Yes ^a	Yes	Yes	NA
Triple P: Positive Parenting Program [26]	No	Yes	Yes	Yes
Other psychosocial treatments				
Classroom management+child skills instruction [34]	No	Yes	Yes	No
Incredible Years parent+child skills instruction [37–40]	No ^a	Yes	Yes	Yes
Medication				
Methylphenidate immediate release [49•]	Yes	Yes	Yes	Yes
Atomoxetine [51]	Yes	No ^a	Yes	NA

^a Study ongoing or results under review.

^b Only with mental health professional delivering.

ADHD attention-deficit/hyperactivity disorder; NA not available; NFPP New Forest Parenting Package; PCIT Parent–Child Interaction Therapy

a trend toward decreased therapy visits and infrequent use of behavioral interventions such as parent training [56], it might be expected that evidence-based behavioral treatments for preschoolers with ADHD are similarly rare.

Increased availability of evidence-based, nonpharmacologic treatment is likely to require policy interventions, including adequate third party payment and coordination across service sectors, including primary care, mental health, and early-childhood programs such as Head Start. Given the increased enrollment of preschoolers into structured child care programs during the past decade and increased expectations for academic readiness, interventions that provide consultation or training to early child care educators may be particularly important [35]. Indeed, given the multiple cross-setting impairments seen in preschoolers with ADHD, a comprehensive treatment approach such as that provided by IY seems warranted. In addition, it appears that some direct intervention with parent–child interactions and emphasis on the parent–child relationship may be beneficial for young children. Finally, research identifying effective strategies for disseminating evidence-based ADHD care for preschoolers to real world settings in a comprehensive, coordinated manner is greatly needed.

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