Efficacy of Osmotic-Release Oral System (OROS) Methylphenidate for Mothers With Attention-Deficit/Hyperactivity Disorder (ADHD): Preliminary Report of Effects on ADHD Symptoms and Parenting

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Objective: A preliminary study to examine the efficacy of osmotic-release oral system (OROS) methylphenidate for attention-deficit/hyperactivity disorder (ADHD) symptoms and parenting behaviors in mothers with ADHD who had children with ADHD.

Method: Participants included 23 mother-child dyads in which both were diagnosed with DSM-IV ADHD. Mothers underwent a 5-week, double-blind titration (placebo, 36 mg/day, 54 mg/day, 72 mg/day, 90 mg/day) to an optimal dose of OROS methylphenidate, followed by random assignment to 2 weeks of placebo or their maximally effective dose. Primary outcome measures included maternal ADHD symptoms (Conners' Adult ADHD Rating Scale) and parenting (Alabama Parenting Questionnaire). Secondary outcomes included side effects ratings. Data were collected from December 2004 until August 2006.

Results: During Phase 1, mothers reported significant decreases in inattention ($p < .001$) and hyperactivity/impulsivity ($p < .01$) with increases in OROS methylphenidate dose. As dose increased, significant reductions in inconsistent discipline ($p < .01$) and corporal punishment use ($p < .005$) were also demonstrated. During Phase 2, small effects on inattention ($d = 0.46$) and hyperactivity/impulsivity ($d = 0.38$) were found for those randomly assigned to medication versus placebo. In addition, medium to large medication effects were found on maternal involvement ($d = 0.52$), poor monitoring/supervision ($d = 0.70$), and inconsistent discipline ($d = 0.71$), with small effects on corporal punishment ($d = 0.42$). During both phases, few adverse effects were noted.

Conclusions: OROS methylphenidate was well tolerated and was associated with significant improvement in maternal ADHD symptoms and parenting. Variable effects on parenting suggest that behavioral interventions may be necessary to address impairments in parenting among adults with ADHD.

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Although attention-deficit/hyperactivity disorder (ADHD) once was considered a disorder of childhood, ADHD persists into adulthood in 50% to 60% of cases.[1] Heritability estimates range from 60% to 90%, with most estimates exceeding 80%.[2] Family studies suggest both that parents with ADHD are more likely to have offspring who are diagnosed with ADHD[3,4] and that children with ADHD are more likely to have parents with ADHD.[5] In particular, mothers of ADHD offspring are at 24-times increased risk for ADHD compared to mothers of nondisordered children.[5]

Parental psychopathology and maladaptive parenting behavior have been theorized to serve as important environmental risk factors for adverse developmental outcomes in children with ADHD.[6] High levels of harsh and inconsistent parenting and low levels of warmth, involvement, and supervision have predicted later conduct problems across a number of studies with varied populations.[7,8] In a recent prospective longitudinal study of children with ADHD, we found that both maternal psychopathology and early positive parenting independently predicted the developmental course of conduct problems over a period of 8 years.[9]

Research on parenting among adults with ADHD suggests that they are more often permissive and overreactive; less positive, involved, and consistent; poorer at planning and monitoring their children; and less effective at problem-solving child-rearing issues than non-ADHD parents.[10–13] Moreover, Sonuga-Barke and colleagues[14] found that maternal ADHD predicted attenuated response to behavioral parent training for children with ADHD. It is likely that parental ADHD also affects child pharmacotherapy, particularly the reliable administration of medication. Thus, parental ADHD appears to result not only in impairments in the affected adult's functioning but also in parents' ability to effectively administer evidence-based pharmacologic and psychosocial treatments for their children with ADHD.

At present, pharmacotherapy with stimulants is the most thoroughly studied treatment for adult ADHD. A 2004 review[15] noted that 6 studies of methylphenidate and 2 of amphetamines had been conducted with ADHD adults. These trials suggested robust effects of stimulants, with response rate varying as a function of rater, rating scale, and dosing. An average effect size of 0.9 has been reported, with effects as high as 1.3 when dosing is optimized and above 1 mg/kg/day.[15] A recent report[16] on osmotic-release oral system (OROS) methylphenidate in adults reported a 66% response rate, with response defined as a score of 1 or 2 on the Clinical Global Impressions-Improvement scale and a 30% reduction in ADHD symptoms, in the active medication condition compared with a 39% response rate in the placebo condition. Dosing in this study averaged 0.99 mg/kg/day.[16] In a similar double-blind trial[17] of short-acting methylphenidate, medicated participants demonstrated a 76% response rate (average dose = 1.1 mg/kg/day) compared with 19% for those receiving placebo.[17] Trials using mixed amphetamine salts and dextroamphetamine to treat adults with ADHD have also supported their efficacy.[18–20] More recently, the long-term efficacy, safety, and tolerability of atomoxetine, a nonstimulant, in treating adult ADHD has also been demonstrated in a number of clinical trials.[21–23]

Despite evidence that adult ADHD is associated with impairments in parenting and the established efficacy of pharmacotherapy in treating adult ADHD, only 1 uncontrolled case report examined the effects of stimulant treatment for parental ADHD on parenting.[24] This report describes a mother whose own ADHD interfered with her implementation of behavioral strategies with her son who had ADHD. A randomized, controlled trial of methylphenidate for the mother resulted in improvements in the mother's ADHD symptoms, her ability to consistently apply behavioral techniques, and her child's behavior. However, to date, no well-controlled studies have examined stimulant effects on parenting.

This study is the first to examine dose-related effects of methylphenidate, or any other adult ADHD medication, on parenting behaviors that have been shown to be deficient in mothers with ADHD. We hypothesized that increasing doses of OROS methylphenidate would improve both maternal ADHD symptoms and parenting relative to placebo. Further, we hypothesized that discontinuation of medication would result in increases in ADHD symptoms and maladaptive parenting.

This study is also the first adult ADHD pharmacotherapy study to utilize collateral reports of ADHD symptoms to both diagnose adult ADHD and evaluate medication effects in this population. Corroboration of symptoms from secondary sources (e.g., parents, spouses) is recommended in adult ADHD assessment, given concerns about the validity of reports from adults with ADHD,[25] but is not standard practice in adult pharmacotherapy trials.

METHOD

Participants

Participants included 23 mothers and their 6- to 12-year-old children recruited from treatment providers in the Washington, D.C., metropolitan area, including families who had previously been seen at the University of Maryland ADHD Program (College Park) and Children's National Medical Center Hyperactivity & Learning Problems Clinic (Washington, D.C.). Interested mothers completed a brief telephone screen in which their suitability for the study was assessed using the Conners' Adult ADHD Rating Scale, Self-Report Screening Version (CAARS-S:SV).[26,27] T-scores on the ADHD Index had to fall a minimum of ≥ 1.5 standard deviations above the mean for the participant's age and gender to proceed to the diagnostic assessment.

Written approval was obtained from the institutional review boards at the University of Maryland and Children's National Medical Center before study initiation. At the initial assessment, participants provided written informed consent after procedures had been fully explained; children aged 7 and older provided written assent.

Mothers were required to meet *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition (DSM-IV) criteria for ADHD according to assessment methods outlined by McGough and Barkley.[25] These recommendations specify that (1) at least 4 or 5 symptoms of ADHD currently be present, with evidence from self, collateral informants, or objective sources (report cards, discipline records) that full ADHD criteria were met prior to age 12 years; (2) there should be evidence of functional impairment in at least 1 setting (e.g., work, childcare, domestic tasks, social relationships, financial management, driving) currently and evidence from self, collateral informants, or objective sources of impairment in at least 2 settings (i.e., at home, at school, and/or with peers) during childhood; and (3) clinicians carefully assess for the

presence of other psychiatric conditions that may co-occur with or better account for what appear to be ADHD symptoms (e.g., depression, anxiety).

On the basis of these guidelines, mothers in the current study were administered the Structured Clinical Interview for DSM-IV (SCID)[28] to assess other psychiatric disorders, supplemented with the Schedule for Affective Disorders for School-Aged Children (K-SADS) ADHD module modified for current and lifetime self-report by adults.[3,29,30] Past and current collateral reports of ADHD symptoms were obtained from individuals who lived with or were in close contact with participants during the period in question. Past collateral informants (N = 20) included 13 parents and 7 older siblings; current collateral informants (N = 23) included 20 spouses/significant others, 2 parents, and 1 best friend. Collateral reports were obtained during telephone interviews using the modified K-SADS. Whenever possible, these data were supplemented with report cards and/or discipline records from childhood. Symptoms were counted if they were endorsed by the participant or collateral informant on the K-SADS, documented in past school records, or observed during the assessment. All cases were reviewed with the first author and the University of Maryland research team to ensure diagnostic accuracy.

Mothers were excluded on the basis of any current Axis I disorder other than ADHD, Beck Depression Inventory-II[31] scores consistently above 16 (N = 5), severe tics or Tourette's syndrome, a history of seizures or abnormal electroencephalogram, high blood pressure, narrowing/blockage of the gastrointestinal tract, current pregnancy or breast feeding, positive urine drug screen at intake, or concomitant psychotropic medication use. Participants receiving psychosocial interventions were required to suspend treatment during this study to the extent possible.

Children were included if they met DSM-IV criteria for ADHD, were between the ages of 6 and 12 years (mean = 8.74 years, SD = 1.71 years), and had no prior diagnosis of pervasive developmental disorder or mental retardation. Fifty-seven percent (N = 13) of the children were male. Child ADHD was evaluated using well-validated parent and teacher rating scales and parent interviews, including the Disruptive Behavior Disorders checklist,[32] the IOWA Conners' Rating Scale,[33,34] and K-SADS.[35,36] Symptoms were considered present if endorsed by either parent or teacher on these measures. Impairment was evaluated with parent and teacher forms of the Impairment Rating Scale.[37] Eighty-seven percent (N = 20) of the children met DSM-IV criteria for ADHD combined type and 13% (N = 3) met criteria for the predominantly inattentive type. Sixty-five percent (N = 15) had comorbid oppositional-defiant disorder, and 13% (N = 3) had conduct disorder. Sixty-one percent (N = 14) received stable medication doses throughout the study: 10 children were treated with methylphenidate, 3 with mixed amphetamine salts, and 1 with atomoxetine.

Procedure

This study took place in 2 phases. During Phase 1, medication was titrated over a period of 5 weeks to each participant's maximally effective dose of OROS methylphenidate. ADHD symptoms, parenting behaviors, and side effects were measured weekly via participant and current collateral informant ratings. Participants began the titration with a placebo dose. Dose was increased weekly from placebo to OROS methylphenidate 36 mg/day, 54 mg/day, 72 mg/day, up to a maximum dose of 90 mg/day until the following criteria were met: (1) 30% reduction in CAARS scores, (2) Clinical Global Impressions-Severity of Illness (CGI-S)[38,39] scale indicated "normal/not ill" (score of 1) or "borderline ill" (score of 2), and the medication was well tolerated. If these criteria were achieved at a dose less than 90 mg, the current dose was maintained until the end of Phase 1.

During Phase 2, mothers were randomly assigned to placebo or their maximally effective dose (based on the Phase 1 titration) for a period of 2 weeks. Outcome measures were again completed at the end of Phase 2. Study physicians, research staff, and participants were blind to medication dose throughout the study.

Efficacy Measures

ADHD symptoms. ADHD symptoms were measured by self-report and current collateral forms of the CAARS.[26,27] The CAARS assesses the core features of ADHD and symptoms appropriate for adults. The CAARS has excellent psychometric properties, provides age- and gender-based norms, and is sensitive to changes in severity of adult ADHD symptoms resulting from treatment.

Study physicians completed the CGI-S weekly. The CGI-S requires the clinician to rate the severity of the patient's illness at the time of assessment on a 7-point Likert scale (1 = normal/not ill; 7 = extremely ill).

Parenting. Participants and current collateral informants completed weekly measures of parenting. The Alabama Parenting Questionnaire (APQ)[40] is a well-validated,[41] 42-item measure that assesses on a 5-point scale (1 = never to 5 = always) the frequency with which the respondent uses (or observes) the following: corporal punishment (e.g., "You spank your child with your hand when he/she has done something wrong"; "You hit your child with a belt, switch, or other object when he/she has done something wrong"), inconsistent discipline (e.g., "You let your child out of a punishment early"; "You threaten to punish your child and then do not actually punish him/her"), poor monitoring/supervision (e.g., "You don't check that your child comes home at the time he/she was supposed to"; "You get so busy that you forget where

Figure 1. Disposition of Participants

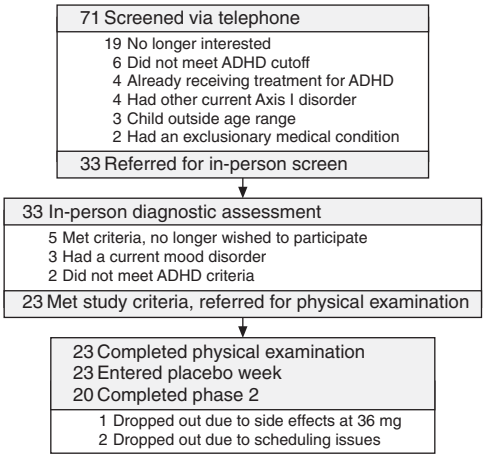

Table 1. Demographic and Baseline Characteristics of Mothers (N = 23)

Characteristic	Value[a]
Age, y	39.78 ± 5.53
Race/ethnicity, N (%)	
White	21 (91.3)
Asian	1 (4.3)
Hispanic	1 (4.3)
ADHD diagnosis, N (%)	
Combined type	13 (56.5)
Inattentive type	8 (34.8)
Hyperactive/impulsive type	2 (8.7)
Self-reported ADHD symptom score (CAARS)[b]	
Inattention	76.09 ± 11.31
Hyperactivity/impulsivity	59.45 ± 10.97
ADHD Index	64.45 ± 8.05
Clinical Global Impressions-Severity of Illness score	4.30 ± 0.64
Collateral reported ADHD symptom score (CAARS)[b]	
Inattention	56.80 ± 12.76
Hyperactivity/impulsivity	52.20 ± 14.27
ADHD Index	55.25 ± 13.98
Parenting scores	
APQ involvement	38.17 ± 4.45
APQ positive parenting	23.82 ± 3.23
APQ poor monitoring/supervision	13.43 ± 3.10
APQ inconsistent discipline	14.65 ± 4.27
APQ corporal punishment	3.96 ± 1.19
Parenting Stress Index	125.38 ± 16.44
Child behavior scores: IOWA Conners' Rating Scale	
Inattentive/overactive	8.91 ± 2.45
Oppositional/defiant	5.82 ± 3.79
Composite	13.68 ± 4.72
Severity	1.86 ± 0.73

[a]Data are given as mean ± SD except where otherwise indicated.
[b]Rating from Phase 1 placebo.
Abbreviations: ADHD = attention-deficit/hyperactivity disorder, APQ = Alabama Parenting Questionnaire, CAARS = Conners' Adult ADHD Rating Scale.

your child is and what he/she is doing"), involvement (e.g., "You help your child with his/her homework"; "You play games or do other fun things with your child"), and positive parenting (e.g., "You praise your child if he/she is behaving well"; "You reward or give something to your child for obeying you or behaving well"). In all cases in which parents endorsed using corporal punishment, the research team carefully evaluated the need for mandated child abuse reporting. In no case was this deemed necessary.

Side effects. Participants completed the Pittsburgh Side Effect Rating Scale[42] weekly to monitor common side effects associated with stimulant therapy. This scale has been used in numerous clinical trials and is sensitive to stimulant side effects. During weekly study visits, weight (kg), blood pressure, and heart rate were monitored. The Beck Depression Inventory-II,[31] a well-validated, 21-item self-report scale assessing depressive symptomatology, was used to evaluate mood-related side effects that may result from stimulant therapy.

RESULTS

The disposition of participants following screening and assessment is outlined in Figure 1. Twenty-three participants were eligible and proceeded to the physical examination. Participant characteristics are presented in Table 1.

Phase 1: Titration

Of 23 adult participants enrolled in the study, 20 (87%) completed Phase 1 of the protocol. Two were lost to follow-up (following weeks 3 and 4) and 1 withdrew during week 3 because of increased blood pressure and heart palpitations while taking 36 mg of OROS methylphenidate (a follow-up electrocardiogram showed normal sinus rhythm with no conduction abnormalities). During titration, 75% of participants (15 of 20) were titrated to a maximum dose of 90 mg; the remaining 25% (5 of 20) were titrated to 72 mg. The mean dose for participants at the end of titration was 83.7 mg—or a mean ± SD of 1.26 ± 0.25 mg/kg.

Linear mixed-model repeated-measures analyses of variance were conducted to evaluate dose effects during the titration phase, followed with contrasts evaluating the effects of each dose compared to placebo. Prior to these analyses, baseline and placebo doses were compared. No differences emerged.

Effect size (d) provides an estimate of the magnitude of within-subjects dose effects and was calculated by subtracting the mean score of a given outcome measure on each medication dose from the mean score on placebo and dividing the difference by the pooled standard deviation. An effect size of 0.2 is considered small, 0.5 medium, and 0.8 large.[43]

ADHD symptoms and impairment. Correlations between self-report and collateral scores on CAARS subscales were examined. For inattention, correlations

Table 2. Phase 1: Double-Blind Titration Effects on Maternal ADHD Symptoms and Parenting by Dose of OROS Methylphenidate[a]

Outcome Measure	Placebo (N = 23)	36 mg (N = 22)	54 mg (N = 21)	72 mg (N = 20)	90 mg (N = 15)	Optimal Dose (N = 22)	t Statistic for Placebo vs Optimal Dose (N = 22), df = 21
ADHD symptom scores							
CAARS self-report[b]							
Inattention	73.91 (11.11)	69.49 (12.66)	58.83 (15.52)***	60.80 (14.95)***	60.87 (18.84)***	61.50 (17.14)	–3.98***
Hyperactivity/ impulsivity	57.39 (10.75)	57.04 (12.23)	53.81 (14.42)	50.14 (14.69)***	48.54 (16.61)**	50.95 (15.53)	–2.95**
ADHD Index	61.65 (10.28)	59.63 (9.93)	55.94 (11.53)**	54.97 (13.63)**	54.24 (17.32)	56.73 (15.68)	–1.64
CGI-S	4.09 (0.73)	3.80 (0.58)*	3.71 (0.72)*	3.40 (0.89)*	3.27 (1.28)*	3.18 (1.11)	–4.33***
Parenting scores: APQ							
Involvement	37.98 (4.43)	38.00 (4.43)	37.83 (4.46)	38.86 (4.34)	40.01 (5.35)	39.20 (5.10)	–0.86
Positive parenting	23.54 (3.22)	23.88 (2.78)	24.07 (3.56)	24.17 (3.71)	24.18 (4.19)	24.23 (4.10)	1.458
Poor monitoring/ supervision	12.44 (2.29)	12.81 (2.21)	13.08 (3.25)	12.53 (3.59)	11.86 (2.53)	11.93 (2.71)	–0.98
Inconsistent discipline	14.15 (3.64)	13.67 (2.21)	13.28 (3.28)	12.46 (3.53)**	12.05 (3.26)**	12.60 (3.51)	–3.297**
Corporal punishment	4.00 (1.17)	3.72 (1.07)	3.59 (1.07)*	3.50 (0.93)**	3.20 (0.62)***	3.34 (0.78)	–3.748***

[a]Data are given as mean (SD).
[b]Clinical cutoff for all CAARS scores is a T-score of 65 (i.e., scores ≥ 65 are in the clinical range).
Abbreviations: ADHD = attention-deficit/hyperactivity disorder, APQ = Alabama Parenting Questionnaire, CAARS = Conners' Adult ADHD Rating Scale, CGI-S = Clinical Global Impressions-Severity of Illness scale, OROS = osmotic-release oral system.
*p < .05, **p < .01, ***p < .001.

ranged from 0.24 on placebo to 0.46 on 72 mg. For hyperactivity/impulsivity, correlations ranged from 0.24 on placebo to 0.45 on 36 mg. On the ADHD Index, correlations ranged from 0.01 on placebo to 0.39 on 54 mg.

Results of Phase 1 analyses are presented in Table 2. Treatment with OROS methylphenidate was associated with a statistically significant reduction in self-reported CAARS inattention ($F = 8.94$, $df = 4,27$; $p < .0001$), hyperactivity/impulsivity ($F = 5.54$, $df = 4,16$; $p < .01$), and ADHD Index scores ($F = 3.42$, $df = 4,19$; $p < .05$). Pairwise comparisons revealed that inattention was significantly reduced on 54-mg ($p < .0001$, $d = 1.14$), 72-mg ($p < .0001$, $d = 1.02$), and 90-mg ($p < .005$, $d = 0.62$) doses relative to placebo. However, significant reductions in hyperactivity/impulsivity were reported only at 72 mg ($p < .001$, $d = 0.56$) and 90 mg ($p < .01$, $d = 0.35$) in comparison to placebo. Reductions in self-reported CAARS ADHD Index scores were also demonstrated ($F = 3.42$, $df = 4,19$; $p < .05$), with significant reductions in ADHD Index scores on 54-mg ($p < .01$) and 72-mg ($p < .01$) doses compared to placebo. Results showed a significant reduction in physician-rated CGI-S scores as a function of medication ($F = 8.14$, $df = 4,23$; $p < .0001$), in which scores at all doses (36 mg, $d = 0.16$; 54 mg, $d = 0.51$; 72 mg, $d = 0.54$; 90 mg, $d = 0.15$) were significantly lower than placebo. Finally, inattention ($d = 0.86$), hyperactivity/impulsivity ($d = 0.48$), and CGI-S ($d = 0.97$) scores were significantly reduced on optimal dose relative to placebo (Table 2).

Collateral ratings also indicated dose effects on inattention ($F = 3.161$, $df = 4,20$; $p < .05$) and hyperactivity/impulsivity ($F = 2.841$, $df = 4,29$; $p < .05$). Inattention was significantly reduced on 54 mg ($p < .01$, $d = 0.33$), 72 mg ($p < .05$, $d = 0.32$), and 90 mg ($p < .005$, $d = 0.32$) relative to placebo; hyperactivity/impulsivity was significantly reduced at 72 mg ($p < .05$, $d = 0.20$) and 90 mg ($p < .01$, $d = 0.37$) compared to placebo.

When examining clinically meaningful change, the percentage of participants who were normalized (i.e., CAARS T-scores below 65, the clinical cut point) were examined at each dose. Results suggested that for self-reported inattention, the proportion of participants who were normalized increased from 26% (6 of 23) of those receiving placebo to 67% (10 of 15) of those receiving 90 mg. Collateral ratings of inattention demonstrated an increase in the proportion of participants below the clinical cutoff, from 70% (14 of 20) of those receiving placebo to 92% (12 of 13) of those receiving 90 mg. Likewise, self-report and collateral reports of hyperactivity/impulsivity demonstrated an improvement in the proportion of participants who were normalized with increasing doses of medication, such that 80% of participants (12 of 15) and 92% of participants (12 of 13), respectively, had scores below the clinical cutoff while receiving 90 mg. These results suggest that the majority of participants were normalized on both inattention and hyperactivity/impulsivity as dose increased, according to multiple informants. At the end of the titration (i.e., when participants met their optimal doses), more than one half of the participants demonstrated improvement in ADHD severity, with 25% (5 of 20) reporting CGI-S scores of 1 or 2, indicating "normal/not ill" or "borderline ill."

Parenting. Correlations between self-report and collateral scores on the APQ subscales were examined. For corporal punishment, correlations ranged from 0.30 to 0.43; for inconsistent discipline, from 0.06 to 0.23; for poor monitoring/supervision, from 0.07 to 0.21; for

Table 3. Treatment-Related Side Effects at Baseline and During Phase 1 Titration of OROS Methylphenidate[a]

Side Effect	Baseline (N = 23)	Placebo (N = 23)	36 mg (N = 22)	54 mg (N = 21)	72 mg (N = 20)	90 mg (N = 15)
Tics	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Buccal	2 (8.6)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13.3)
Picking skin	3 (13.0)	2 (8.6)	1 (4.5)	1 (4.7)	0 (0)	3 (20.0)
Worried	1 (4.3)	1 (4.3)	1 (4.5)	1 (4.7)	3 (15.0)	1 (6.7)
Dull/listless	2 (8.6)	1 (4.3)	0 (0)	0 (0)	0 (0)	2 (13.3)
Headache	1 (4.3)	1 (4.3)	0 (0)	1 (4.7)	0 (0)	1 (6.7)
Stomachache	1 (4.3)	2 (8.6)	0 (0)	0 (0)	1 (5.0)	1 (6.7)
Irritable	3 (13.0)	1 (4.3)	2 (9.1)	0 (0)	3 (15.0)	3 (20.0)
Tearful	0 (0)	0 (0)	0 (0)	0 (0)	1 (5.0)	0 (0)
Withdrawn	0 (0)	0 (0)	0 (0)	0 (0)	1 (5.0)	0 (0)
Hallucinations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Appetite loss	0 (0)	1 (4.3)	0 (0)	0 (0)	2 (10.0)	0 (0)
Sleep trouble	2 (8.6)	0 (0)	3 (13.6)	2 (9.5)	1 (5.0)	2 (13.3)
Heart rate, beats/min	74.22 ± 9.14	72.22 ± 10.71	77.77 ± 13.59	78.48 ± 14.01	78.64 ± 8.79	80.53 ± 9.88
Systolic blood pressure, mm Hg	119.96 ± 10.99	118.87 ± 10.75	119.14 ± 10.05	106.95 ± 31.58	119.55 ± 11.41	124.21 ± 14.04
Diastolic blood pressure, mm Hg	75.83 ± 14.37	73.11 ± 9.84	73.93 ± 11.65	72.57 ± 10.89	75.19 ± 10.14	75.71 ± 12.07
Weight, kg	74.49 ± 12.66	74.89 ± 12.81	73.61 ± 12.76	73.39 ± 13.18*	73.08 ± 12.95***	73.39 ± 14.24**

[a]Data are given as mean ± SD or as N (%) of subjects rated as moderate or severe.
*p < .05, **p < .01, ***p < .001 (in comparison to baseline).
Abbreviation: OROS = osmotic-release oral system.

Table 4. Effect of Child Medication Status on Maternal ADHD Symptoms and Parenting in Phase 1 of Study

Measure	Placebo[a]	Optimal Dose of OROS Methylphenidate[a]	Effect Size
Maternal ADHD symptom scores			
CAARS inattention[b]			
Child on medication	73.00 (11.48)	58.71 (15.21)	1.06
Child not on medication	75.75 (11.72)	66.38 (20.21)	0.57
CAARS hyperactivity/impulsivity[b]			
Child on medication	55.71 (10.51)	49.57 (15.21)	0.47
Child not on medication	60.63 (11.82)	53.38 (12.07)	0.61
Parenting scores: APQ			
Involvement			
Child on medication	37.18 (3.69)	38.79 (5.10)	0.36
Child not on medication	38.25 (4.83)	39.94 (5.36)	0.33
Positive parenting			
Child on medication	22.82 (2.91)	23.64 (3.92)	0.24
Child not on medication	24.75 (3.77)	25.25 (4.46)	0.12
Poor monitoring/supervision			
Child on medication	12.43 (2.17)	11.25 (1.87)	0.58
Child not on medication	12.75 (2.60)	13.13 (3.60)	–0.12
Inconsistent discipline			
Child on medication	13.75 (2.87)	11.07 (2.91)	0.92
Child not on medication	15.88 (3.60)	15.25 (2.92)	0.19
Corporal punishment			
Child on medication	3.64 (0.84)	3.07 (0.26)	0.92
Child not on medication	4.75 (1.39)	3.81 (1.13)	0.74

[a]Data are given as mean (SD).
[b]T-scores are presented.
Abbreviations: ADHD = attention-deficit/hyperactivity disorder, APQ = Alabama Parenting Questionnaire, CAARS = Conners' Adult ADHD Rating Scale, OROS = osmotic-release oral system.

involvement, from 0.04 to 0.53; and for positive parenting, from 0.02 to 0.32.

A significant dose effect was found on APQ inconsistent discipline ($F = 4.587$, $df = 4,17$; $p < .01$), suggesting that participants were more consistent disciplinarians with increasing OROS methylphenidate doses. Mothers were more consistent on 72-mg and 90-mg doses (both p values < .01; d = 0.37 and 0.10, respectively) compared to placebo. Mothers also reported a significant decrease in use of corporal punishment as dose increased ($F = 4.534$, $df = 4,38$; $p < .005$), with differences noted at 54 mg ($p < .05$, $d = 0.34$), 72 mg ($p < .01$, $d = 0.45$), and 90 mg ($p < .0001$, $d = 0.71$) relative to placebo. Finally, when placebo and optimal dose were compared, inconsistent discipline (d = 0.43) and corporal punishment (d = 0.66) were improved on optimal dose compared to placebo. Medication did not appear to affect maternal involvement, positive parenting, or poor monitoring/supervision. Collateral reports of parenting did not indicate dose effects on maternal parenting behavior.

Side effects. Participants reported few side effects during titration (Table 3). There were no serious adverse events or reports of suicidality, psychotic symptoms, or mania. Results did not show any significant change at any dose in heart rate or systolic or diastolic blood pressure compared to baseline. However, a significant dose effect on weight was found ($F = 21.91$, $df = 5,65$; $p < .0001$). Pairwise comparisons suggested significant weight loss from baseline to 54 mg ($p < .05$), 72 mg ($p < .001$), and 90 mg ($p < .01$). Weight loss from baseline to 90 mg ranged from 0 to 6.90 kg, with a mean ± SD loss of 2.31 ± 1.62 kg.

Child medication status. Given that child treatment with medication could potentially affect these findings, we explored the magnitude of medication effects on maternal ADHD and parenting during Phase 1 as a function of child medication status (Table 4). With the exception of CAARS hyperactivity/impulsivity, effects on maternal ADHD symptoms and parenting appeared at least slightly larger for mothers of children who were medicated relative to those who were not.

Phase 2: Randomized Discontinuation

During Phase 2, twenty participants were randomly assigned to 2 weeks of either placebo (N = 11) or their maximally effective dose (N = 9). Of those randomly assigned to their maximally effective dose, 1 participant (11%) received 54 mg, 3 (33%) received 72 mg, and 5 (56%) received 90 mg. Table 5 presents data at week 7 (end of Phase 2 randomization) for participants randomly assigned to placebo or optimal dose. It was expected that those randomly assigned to placebo would experience worsening of symptoms and parenting behavior from week 5 to 7, while those randomly assigned to their maximally effective dose would not evidence change.

Estimates of effect size (Cohen d) are emphasized in Phase 2, given the limited power to detect statistically significant differences. Effect size was calculated as the difference between the 2 treatment conditions (i.e., those randomly assigned to placebo compared to those randomly assigned to their maximally effective dose) on a given outcome measure divided by the pooled standard deviation and therefore reflects the magnitude of differences between these 2 groups at week 7 (Table 5).

ADHD symptoms. Random assignment to OROS methylphenidate was associated with reductions in self-reports of inattention (d = 0.48) and ADHD Index (d = 0.38) scores of small magnitude in comparison with random assignment to placebo.

Parenting. During Phase 2, treatment with OROS methylphenidate was associated with effects of medium magnitude on self-reported parental involvement (d = 0.52), poor monitoring/supervision (d = 0.70), and inconsistent discipline (d = 0.71) and with small effects on corporal punishment (d = 0.42) when compared to treatment with placebo. On each of these scales, methylphenidate-treated participants reported more adaptive parenting than did those receiving placebo.

Table 5. Phase 2: Randomization (OROS methylphenidate or placebo) Effects on Maternal ADHD Symptoms and Parenting at the End of the Study (N = 20)

Outcome Measure	Week 7 (end of study)[a]	Effect Size
Adult ADHD symptom scores		
CAARS self-report[b]		
Inattention		
OROS methylphenidate	57.78 (15.75)	0.48
Placebo	65.55 (16.31)	
Hyperactivity/impulsivity		
OROS methylphenidate	49.33 (17.06)	0.06
Placebo	48.27 (17.32)	
ADHD Index		
OROS methylphenidate	54.44 (12.82)	0.38
Placebo	60.27 (18.07)	
CGI-S		
OROS methylphenidate	3.11 (1.17)	0.15
Placebo	3.30 (1.34)	
Parenting scores: APQ		
Involvement		
OROS methylphenidate	40.67 (5.07)	0.52
Placebo	38.00 (5.14)	
Positive parenting		
OROS methylphenidate	24.22 (3.73)	0.15
Placebo	24.82 (4.09)	
Poor monitoring/supervision		
OROS methylphenidate	11.44 (2.30)	0.70
Placebo	13.27 (2.90)	
Inconsistent discipline		
OROS methylphenidate	12.00 (3.28)	0.71
Placebo	14.63 (4.15)	
Corporal punishment		
OROS methylphenidate	3.33 (0.50)	0.42
Placebo	3.64 (0.92)	

[a]Data are given as mean (SD).
[b]Clinical cutoff for all CAARS scores is a T-score of 65 (i.e., scores ≥ 65 are in the clinical range).
Abbreviations: ADHD = attention-deficit/hyperactivity disorder, APQ = Alabama Parenting Questionnaire, CAARS = Conners' Adult ADHD Rating Scale, CGI-S = Clinical Global Impressions-Severity of Illness scale, OROS = osmotic-release oral system.

DISCUSSION

This study, like several recent studies, indicates that stimulant medication is effective in reducing adult ADHD symptoms.[15–17] However, this is the first study targeting an underrepresented and unique population: mothers of children with ADHD who themselves were diagnosed with ADHD. Mothers of children with ADHD experience heightened parenting stress and risk for psychopathology,[6] particularly ADHD,[5] which may pose unique challenges in the parenting role. Therefore, in this study we sought to determine the feasibility of studying this important clinical population and to evaluate medication effects not only on adult ADHD symptoms but also on parenting, from the perspective of multiple informants.

During the titration phase, increasing doses of OROS methylphenidate from 0.5 to 1.3 mg/kg were associated with moderate reductions in ADHD symptoms, as reported by both participants and collateral informants. Improvements in inattention were noted on 54-mg, 72-mg, and 90-mg doses, while significant improvement in hyperactivity/impulsivity was found only at 72 mg and 90 mg. This finding is consistent with a study of OROS methylphenidate for children and adolescents indicating that effectively treating hyperactivity requires higher doses than treating inattention.[44] Also, larger improvements in inattention relative to hyperactivity/impulsivity may reflect the fact that baseline levels of inattention within our sample indicated greater impairment and therefore allowed more room for change compared to hyperactivity/impulsivity, which was less of a problem in our sample of adult women.

Decreases in inconsistent discipline and corporal punishment use at doses at or above 54 mg suggest that medication for ADHD mothers may result in improvements in parenting and family interaction after only a few weeks of treatment. We thought that these results may have been minimized by the fact that 61% of the

children were medicated, which has been found to reduce negativity in parent-child interactions. We attempted to explore this possibility by examining the magnitude of maternal treatment effects as a function of child medication status. Contrary to expectation, we found that mothers of children who were medicated reported similar or, in some cases, *larger* medication effects on their adult ADHD symptoms and parenting. Although exploratory in nature, these findings may reflect complementary effects of parent and child medication or a genetic propensity to positive stimulant response. Future studies could more carefully examine whether medicating both parent and child is superior to medicating either parent or child or neither. Future studies might also test for pharmacogenetic predictors of stimulant response within families.

It is important to note that participants reported improvements in parenting on higher doses of medication, whereas collateral informants did not. Correlations between participants and collateral informants in the current study were modest, with the strongest correlations found on the involvement and corporal punishment scales. These scales may be the most obvious to observers, as compared to inconsistent discipline or parental monitoring/supervision, which require the observer to have extensive opportunity to observe the participants' parenting. Indeed, examination of the extent to which collateral informants observed the participants' parenting might elucidate why we failed to detect significant medication effects on the basis of collateral reports of parenting. Likewise, the amount of contact the participants had with their children while maternal medication was active is another important consideration in interpreting our parenting results. One might expect that mothers who were with their children during the day while their medication peaked compared to situations in which the mother was working or the child was in school or day care would evidence stronger medication effects on parenting. Unfortunately, these data were not systematically collected in the present study.

It is also possible that participants' reports of improvement in parenting while actively medicated reflected their *perceptions* of improvements in parenting, rather than true changes. Improvements in maternal perceptions of parenting self-efficacy are nevertheless important; however, future studies should also utilize observational measures of parenting and/or have children report on their mothers' parenting to determine if improvements extend beyond maternal perceptions to true changes in parenting. It would also be interesting to determine whether children (or spouses) could accurately guess whether the participants were medicated, as a further indication of noticeable differences in their interactions.

Despite using higher fixed doses than those typically used with ADHD youth, tolerability of doses up to 90 mg/day was excellent in this small, preliminary study. Only 1 participant withdrew due to poor tolerability while receiving the lowest active dose, 36 mg/day. Only weight loss varied significantly with increasing dose, which is generally considered less concerning in adults than in children. These reports of side effects also appear to be somewhat lower than in other recent adult methylphenidate studies.[17] Since the majority of children (61%) were concurrently treated with stimulant medication, our sample might have been predisposed toward a positive stimulant response. Future research is needed to examine whether previous child or adult experience with stimulants moderates response.

During Phase 2, maternal inattention symptoms returned in those receiving placebo compared to those receiving their maximally effective stimulant dose. Similarly, a worsening in parenting of small to medium magnitude was noted in terms of involvement, poor monitoring/supervision, inconsistent discipline, and corporal punishment for mothers randomly assigned to placebo relative to those randomly assigned to active medication. These effects were smaller in magnitude than those seen in Phase 1, which may, in part, reflect expectation effects. Unfortunately, the small sample size precluded our ability to detect statistical significance during Phase 2; however, these results are promising in suggesting that medicating ADHD mothers may improve parenting behaviors that are established risk factors for the development of conduct disorder (e.g., inconsistent discipline, corporal punishment).[7,8,45]

This preliminary study sets the stage for larger, randomized, controlled trials to replicate these preliminary findings regarding stimulant effects on parenting. Future studies should evaluate parents and children over a longer follow-up period, as 7 weeks may be too short a period within which to observe meaningful changes in longstanding patterns of negative parent-child interactions. Future studies should also measure parenting at multiple time points during the day, for example, during afterschool hours when medication effects are at their peak, as well as in the evening, when stimulant rebound may negatively impact mothers' parenting behavior. Finally, further examination of stimulant effects on parenting directed toward non-ADHD offspring would provide a clearer examination of this question (i.e., by minimizing "child effects").

This study provides a model for comprehensive assessment of adult ADHD. Unlike childhood ADHD, adult ADHD assessment is in an earlier stage of development. Experts recommend the collection of self-reports and collateral reports of adult ADHD symptoms.[25] Yet, collateral reports have rarely been utilized in adult ADHD pharmacology studies. In this study, there was relatively low concordance between self-report and collateral reports of ADHD symptoms, which is not uncommon in the clinical literature. Consistent with prior research, participants

reported more ADHD symptoms than did collateral informants and reported greater change in symptoms as a result of medication.[46] Contrary to expectations, ADHD adults may have a greater awareness of their ADHD symptoms, which may be less apparent to outside observers than childhood symptoms. In adult ADHD, the persistent and impairing symptoms tend to be those of inattention, which may be more difficult for collateral informants to detect. Yet, the fact that both informants independently indicated clinically significant improvement in maternal ADHD symptoms with increasing stimulant doses is notable, in that it suggests that true change occurred and that findings were not simply a function of participants' improved self-perceptions while taking medication. Future research should continue to explore the best methods of evaluating medication effects in adults with ADHD, with particular attention to the incremental benefit (versus cost) of obtaining collateral reports.

In this small preliminary study, we sought to examine medication effects in ADHD mothers without current comorbid disorders so that we could evaluate medication effects on parenting in isolation. As such, those currently experiencing comorbid depression and/or those treated with psychotropic medications were excluded. The exclusion of several potential participants for these reasons suggested that we may have excluded a clinically meaningful subset of mothers with ADHD and depression. Indeed, mood disorders exist in approximately 40% of mothers of ADHD youth and commonly co-occur in adults with ADHD.[5] As such, our exclusion of participants with current comorbid disorders may limit the generalizability of these findings to real-world clinical settings.

The major limitations of this preliminary study are the small sample size and numerous comparisons made. Also, it is often difficult to maintain participant blind in discontinuation studies such as this, given that participants who have previously experienced drug effects are more likely to be aware if they are being actively medicated or not. For these reasons, future randomized controlled trials of stimulant treatment for ADHD parents are recommended that utilize larger, more inclusive samples, including fathers as well as mothers. Such studies should examine the possibility that stimulant rebound may occur in the evening, which could potentially worsen parenting in stimulant-treated mothers. In addition, future studies should systematically examine the impact of sequencing behavioral and pharmacologic treatments for parents and offspring with ADHD. It is possible that medicating parents with ADHD may improve parenting and child outcomes following behavioral parent training.

Despite these limitations, the present study clearly demonstrated the feasibility of treating mothers and evaluating effects on the family and detected significant effects on multiple, clinically relevant measures from the perspective of multiple informants. This study extends existing adult ADHD pharmacotherapy research by examining outcomes related to parenting behavior within a unique clinical population. Our findings are promising in that we found treatment effects that extended beyond the mothers' symptoms to their use of corporal punishment, involvement/supervision, parental monitoring, and consistency in discipline after just a brief medication trial. Given that these maladaptive parenting behaviors are established risk factors for the development and persistence of conduct disorder,[7,8] these preliminary findings may have important clinical implications.

Finally, it is unlikely that a brief trial of stimulant medication is sufficient to fully address parenting difficulties that mothers with ADHD experience. Although we did find medication effects on parenting behavior, these effects were smaller in magnitude and more variable than effects on maternal ADHD symptoms. This finding is consistent with other reports of the superiority of medication in reducing core symptoms of ADHD, with greater effects on domains of impairment coming from combined behavioral-pharmacologic treatment.[47] It is therefore likely that behavioral parent training is needed in conjunction with parent medication to effectively treat parenting deficits in these families. Future multimodal treatment studies should examine whether stimulant medication enhances the effects of behavioral parent training for mothers with ADHD. Future studies should also examine whether parent medication impacts parental compliance with child medication administration.

Drug names: atomoxetine (Strattera), dextroamphetamine (Dexedrine, Dextrostat, and others), methylphenidate (Methylin, Ritalin, and others), mixed amphetamine salts (Adderall), osmotic-release oral system methylphenidate (Concerta).

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