



# Effects of two doses of methylphenidate on simulator driving performance in adults with attention deficit hyperactivity disorder

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## Abstract

**Introduction:** Numerous studies have documented an increased frequency of vehicular crashes, traffic citations, driving performance deficits, and driving-related cognitive impairments in teens and adults with attention deficit hyperactivity disorder. **Method:** The present study evaluated the effects of two single, acute doses of methylphenidate (10 and 20 mg) and a placebo on the driving performance of 53 adults with ADHD (mean age=37 years, range=18–65) using a virtual reality driving simulator, examiner and self-ratings of simulator performance, and a continuous performance test (CPT) to evaluate attention and inhibition. A double-blind, drug-placebo, within-subjects crossover design was used in which all participants were tested at baseline and then experienced all three drug conditions. **Results:** A significant beneficial effect for the high dose of medication was observed on impulsiveness on CPT, variability of steering in the standard driving course, and driving speed during the obstacle course. A beneficial effect of the low dose of medication also was evident on turn signal use during the standard driving course. An apparent practice effect was noted on some of the simulator measures between the baseline and subsequent testing sessions that may have interacted with and thereby obscured drug effects on those measures. **Conclusions:** The results, when placed in the context of prior studies of stimulants on driving performance, continue to recommend their clinical use as one means of reducing the driving risks in ADHD teens and adults. **Impact on industry:** Given the significantly higher risk of adverse driving outcomes associated with ADHD, industry needs to better screen for ADHD among employees who drive as part of employment so as to improve safety and reduce costs. Use of stimulants to treat the adult ADHD driver may reduce safety risks.

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## 1. Introduction

Attention-Deficit Hyperactivity Disorder (ADHD) is a well-researched developmental disorder characterized by deficits in sustained attention or persistence, resistance to distraction, voluntary motor inhibition, and the regulation of activity level relative to same-aged peers (American Psychiatric Association, 1994; Barkley, 1998). Originating

in early childhood, ADHD is a relatively persistent condition with up to 80% of diagnosed children continuing to meet diagnostic criteria in adolescence (Barkley, 1998; Barkley, Fischer, Edelbrock, & Smallish, 1990; Weiss & Hechtman, 1993) and up to 67% will continue to have clinically significant symptoms of the disorder into adulthood (Barkley, Fischer, Smallish, & Fletcher, 2002; Weiss & Hechtman, 1993). In one of the first longitudinal investigations of hyperactive children followed to adulthood, Weiss, Hechtman, Perlman, Hopkins, and Wener (1979) found that as adolescents and as young adults, individuals with this disorder were more likely to be involved in traffic

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accidents as drivers than their normal peers. They were also more likely to incur greater damage to their vehicles relative to normal controls (Hechtman, Weiss, Perlman, & Tuck, 1981).

That ADHD, or hyperactivity, should predispose toward greater driving risks and adverse outcomes should not be surprising. Adult psychiatric patients have a one-to six-fold increase in risk for auto accidents relative to normal control groups (Kastrup, DuPont, Bille, & Lund, 1978; Noyes, 1985). The highest rates for adverse outcomes are associated with the following risk factors: males, conduct and antisocial symptoms, excessive risk-taking, inattention, and substance abuse disorders (especially alcohol; Boyd & Huffman, 1984; Brown, Sanders, & Schonberg, 1986; Finn & Bragg, 1986; Shaffer, Towns, & Schmidt, 1974; Tsuang, Boor, & Fleming, 1985). Many of these are likely to occur to a greater extent among ADHD teens and young adults, suggesting that they may have the highest rates of negative driving outcomes, particularly if they are male.

Subsequent studies supported these inferences about ADHD and greater driving risks. One involved a 3–5 year follow-up survey of normal adolescents and those with ADHD (Barkley, Guevremont, Anastopoulos, DuPaul, & Shelton, 1993). The survey asked parents about a variety of negative driving outcomes their teens may have experienced in the interim follow-up period since their teens began driving. The teens and young adults with ADHD were: (a) more likely to have driven an automobile illegally prior to the time they became eligible as licensed drivers; (b) less likely to be employing sound driving habits in their current driving performance, as reported by their parents; (c) more likely to have had their licenses suspended or revoked; (d) more likely to have received repeated traffic citations, most notably for speeding; and (e) nearly four times more likely to have had an accident while they were the driver of a vehicle. While the degree of current ADHD symptoms was significantly associated with driving risks, some risks were further associated with the degree of oppositional and conduct problems.

A later study of 171 adults diagnosed with ADHD and 30 adults seen in this same clinic not diagnosed with ADHD (predominantly anxiety or mood disorders) found similar results (Murphy & Barkley, 1996a). The adults with ADHD were more than three times as likely to have had automobile accidents, to have more such accidents ( $p < .06$ ), and had more traffic citations for speeding than did the psychiatric control group. Barkley, Murphy, and Kwasnik (1996) compared 25 young adults with ADHD to 23 young adults from the community. More of the ADHD young adults had received speeding tickets, had their licenses suspended or revoked, and had been involved in a crash as the driver than in the control group. The young adults with ADHD rated themselves as employing poorer driving habits while operating their own motor vehicles and were rated by others as doing so

compared to the control group. The ADHD group showed significantly more erratic control of a vehicle using a driving simulator and had more scrapes and crashes in this test.

Barkley, Murphy, DuPaul, and Bush (2002) compared large samples of ADHD ( $N=105$ ) and community control teens and young adults ( $N=64$ ) on a multi-method multi-source battery of driving measures. More young adults with ADHD had driven illegally prior to being licensed than the control group, just as they had found in prior studies. Both self reports and DMV records found more of the ADHD group to have been cited for traffic offenses, to have received speeding tickets, and to have had their licenses suspended or revoked in their relatively brief driving careers to date (approximately 4.5 years). Not only had a disproportionate number of the ADHD group experienced these adverse driving outcomes, but our quantitative measures showed that they had experienced them far more often than the control group. These negative outcomes were established not only through self-report but were confirmed in our review of their official DMV records. The ADHD group also was involved in more vehicular crashes, more crashes in which they were at fault, and more destructive crashes than was the control group. On tests of basic psychological abilities necessary for driving, the ADHD group was found to have slower and more variable reaction times and to make more errors in tasks when rule reversals were in effect. The simulated driving task revealed more erratic control of the vehicle and more errors in responding under rule-reversed contingencies by the ADHD than control group. Tests of driving knowledge and rapid decision-making found deficits in three out of four domains. These results argue strongly for intervention to improve the deficits identified in driving performance and reduce the risk for these adverse outcomes.

Among the commonly employed treatments for ADHD, stimulant medication offers the greatest likelihood of improving or normalizing the driving performance of ADHD teens and adults and thereby reducing their risks for various adverse outcomes (e.g., citations, crashes, license revocations, accident-related property damage, morbidity, and mortality). A treatment is needed that alters the individual's driving behavior when that individual is operating a motor vehicle and typically at times when no caregiver may be nearby to apply any intervention. Medication is the only treatment of which we are aware that meets these requirements and therefore may have some hope of improving the driving performance and risks of those with ADHD. As noted earlier, previous research has demonstrated that ADHD is associated with impaired motor inhibition, reaction time, visual-motor coordination, decision-making, and rule-governed behavior. Such deficits in basic psychological processes have routinely been found to improve with medication (Barkley, DuPaul, & Connor, 1999; Rapport & Kelly, 1993; Swanson, McBurnett, Christian, and Wigal, 1995). Yet the efficacy of stimulants

for improving driving performance in those with ADHD has only recently been studied, and only with very small clinical samples.

Three studies have directly investigated the effects of methylphenidate on driving performance in ADHD samples. Cox and colleagues (Cox, Merkel, Hill, Kovatchev, & Seward, 2000) used a virtual reality-driving simulator and tested participants 90 minutes after ingesting either placebo or immediate release methylphenidate (10 mg). During the placebo condition the ADHD drivers' overall Impaired Driving Score was significantly worse than controls, as was their self-appraisal of driving performance. However, during the methylphenidate condition driving performance significantly improved among the ADHD drivers, while slightly worsening for the control subjects. There was no difference between the ADHD and control drivers following ingestion of methylphenidate in terms of the objective Impaired Driving Score, or subjects' self-appraisal of driving performance.

In a subsequent study, Cox and colleagues (Cox, Humphrey, Merkel, Penberthy, & Kovatchev, in press) tested 12 male teenagers clinically diagnosed with ADHD (ages 16–19) while they drove their own car on two occasions: (a) no medication and (b) methylphenidate (Concerta<sup>®</sup>) in a randomized, repeated measure, cross-over, single-blind design. The two testings were conducted the same time of day under similar weather/road conditions. An examiner, blind to medication conditions, completed a checklist every two minutes noting inattentive and impulsive driving errors. The teens drove a 16-mile road course consisting of rural, highway and city driving approved by the Virginia DMV as a good test of driving competence. All teens were given a single dose of Concerta<sup>®</sup> either the same as their prescribed dose or a dose equivalent to their current medication regimen if not already taking Concerta<sup>®</sup>. Observations of on-road inattentive driving errors were significantly reduced on methylphenidate, with such improvements correlating with medication dosage ( $r=0.60$ ,  $p<.001$ ).

The next study (Cox, Merkel, Penberthy, Kovatchev, & Hankins, 2004) compared immediate release Ritalin<sup>®</sup> taken three times a day to an equivalent dose of Concerta<sup>®</sup> taken once daily, using the virtual reality driving simulator at 2 p.m., 5 p.m., 8 p.m., and 11 p.m. the same day. Again, a randomized, repeated measures, cross-over, single blind design was employed, evaluating six male teenagers clinically diagnosed with ADHD. Overall, Concerta<sup>®</sup> led to significantly lower Impaired Driving Scores ( $p<.001$ ) and significantly less inter-subject driving variance ( $p<.01$ ). Specifically, Concerta<sup>®</sup> and Ritalin<sup>®</sup> were associated with equivalent driving performance at 2 p.m. and 5 p.m., but while driving performance continued at a similar level through the 8 p.m. and 11 p.m. testings on Concerta<sup>®</sup>, driving performance on Ritalin<sup>®</sup> was five standard deviations worse than Concerta<sup>®</sup> at both the 8 p.m. and 11 p.m. testings.

The present study sought to further test the value of stimulant medication for improving the driving performance of ADHD teens and adults by examining the impact of two doses of methylphenidate (MPH-Ritalin<sup>®</sup>: 10 and 20 mg) on driving behavior and performance using a virtual reality driving simulator and using a considerably larger sample of adults. We hypothesized that MPH would produce significant improvements in: (a) several basic psychological abilities that are a prerequisite for driving (attention and inhibition), (b) driving performance while operating a driving simulator, and (c) self and examiner ratings of such performance.

## 2. Methods

### 2.1. Design

The design comprised a within subjects reversal design in which all participants experienced all drug and placebo conditions in a randomized, counter-balanced order. Drug conditions were placebo (P), a single low dose (L) of 10mg of methylphenidate (MPH, Ritalin<sup>®</sup>), and a single higher dose (H) of 20mg of MPH. Participants were typically tested at intervals of 7-14 days. There were 56 ADHD participants originally assigned to six possible orders. Two participants dropped out before completing all phases of the study and a mechanical failure of the simulator resulted in two participants having no baseline data. This left 52 participants having complete data. The following number of participants were left in each drug condition sequence: (1) PLH=7; (2) HPL=10; (3) LHP=9; (4) PHL=8; (5) HLP=9, and (6) LPH=9.

### 2.2. Participants

This study initially recruited 56 adults clinically diagnosed with ADHD. All participants met the following entry criteria: (a) chronological age between 18 years and 65 years; (b) composite IQ greater than 80 on the Shipley Institute of Living Test (Shipley, 1946); (c) corrected or uncorrected visual acuity of no worse than 20/30 based on a brief screening using a Snelling chart; (d) a valid state driver's license; and (e) no evidence of deafness, blindness, severe language delay, cerebral palsy, epilepsy, autism, or psychosis as established through clinical diagnostic interview and medical history. Forty-six percent of participants used some form of corrective vision device (glasses, contact lenses, etc.).

Participants were recruited from consecutive referrals to a clinic specializing in adult ADHD at a New England medical school. They were required to have received an expert clinical diagnosis of ADHD established not only by meeting the DSM-IV diagnostic criteria (American Psychiatric Association, 1994) but also the judgment of an expert clinician (Dr. Murphy). The DSM criteria were amended

such that the criterion for onset of symptoms was set at 12 rather than 7 years of age. This adjustment was based on the fact that no evidence exists to show that the DSM criterion of age 7 years distinguishes valid from invalid cases (Barkley & Biederman, 1997). The DSM-IV field trial also found that use of this criterion diminished the reliability of clinical diagnosis (Applegate et al., 1997). Moreover, the imposition of age 7 years for onset of symptoms in adults would create great difficulty considering the narrow time-frame in childhood on which to base their retrospective reports and their own limited cognitive development and self-awareness within that time frame. Participants therefore were asked to consider their childhood behavior between 5 and 12 years of age in answering questions about the onset of symptoms, as recommended by Barkley and Biederman.

The diagnosis of ADHD was determined through a structured clinical diagnostic interview with the participant. This structured interview was created for use in a prior study of adults with ADHD (Barkley et al., 2002). It contained the DSM-IV diagnostic criteria for ADHD to be reviewed twice with the participant—once for current symptoms and impairments and a second time for recall of childhood symptoms and impairment. This interview was conducted by a licensed clinical psychologist with 10 years of clinical experience evaluating teens and adults with ADHD (K.M.). In a previous project, the inter-judge agreement of this expert clinician was evaluated against that of a second expert (R.B.) who reviewed audiotapes of this interview and who was blind to the participant's original diagnosis. Agreement was 92%. Determination of final diagnosis was based on the self-reports of participants, any educational records they were able to provide, and, where possible, corroboration of symptoms by someone who knew the participant well (typically parents). The evaluation also included a review of past school records, where available, and completion of the Adult ADHD Rating Scale (see below) by all participants for their current functioning and for recall of childhood, ages 5 to 12 years. We have collected local norms on these rating scales for the self-report forms (Murphy & Barkley, 1996b) to assist us in determining the age-inappropriateness of the participant's ADHD symptoms. Age-inappropriate symptoms were defined as being at or above the 93rd percentile on the current functioning version of this scale. Final diagnosis of ADHD was therefore based on these multiple sources of information, the DSM criteria, and expert clinical judgment. The following percentage of ADHD subtypes was observed in the sample: 87% Combined Type, 11% Predominantly Inattentive Type, 0% Predominantly Hyperactive-Impulsive Type, and 2% ADHD Not Otherwise Specified.

There were 40 males (74%) and 14 females (26%) in this sample. Marital status was as follows: married=26%, never married=67%, divorced or widowed=7%. The ethnic breakdown of participants was: White=83.3%, African-American=3.7%, Hispanic=5.6%, Native American=5.6%, and Other=1.9%. The mean age of participants was 31.3

years (SD=11.3), the mean education was 14 years (SD=2.2), and the mean IQ was 104.7 (SD=9.7). The participants reported an average of 12.5 current symptoms of ADHD (SD=3.1) and an average number of major life activities impaired of 4.7 (SD=1.1; range=2–6). They also reported an average of 14.3 childhood symptoms of ADHD (SD=2.6). The mean onset of their ADHD symptoms in childhood was 7.1 years (SD=2.6 yrs.; range=2–12). The average number of years of driving experience for this sample was 14.5 (SD=11.1) and the mean miles driven per week was reported as 252 (SD=203).

Thirty-six percent of participants were being treated with stimulant medication at the time of recruitment to this study. These participants ceased taking their medication at least 24 hours prior to the day of testing. Any participants taking antidepressant or other forms of psychiatric medication were excluded from this project because of the prolonged washout time such medications typically require before they could be entered in to this protocol. Participants were queried again on the day of their initial evaluation to be certain that they had complied with this request. Those on stimulant medication at the time of recruitment were instructed to inform their prescribing physicians of this requirement to be off medication for the testing session before undertaking the study procedures.

The study was reviewed and approved by the Institutional Review Board of the university medical school.

### 2.3. Medication

Participants were randomly assigned to the six orders of drug and placebo conditions. The examiner was kept blind to the drug/placebo sequence assigned. The hospital pharmacy prepared the placebo (lactose powder) and MPH by placing them in orange opaque gelatin capsules to disguise differences in taste between placebo and medication as well as the differences in dose amounts to be employed. The three capsules prepared for each participant were placed in a paper packet corresponding to each day's medication and numbered to indicate the testing session at which they were to be used with the participant. The participant was required to report to the lab one hour prior to being tested on each of the three testing dates. The medication was then given to the participant to swallow with water and then the participant remained in the lab for 75 minutes before formal testing began. This was done to insure that testing started during the typical peak effect for MPH (60–120 minutes after ingestion).

### 2.4. Procedures

Each participant was initially approached about the study by the expert clinician (K.M.). These participants had either been previously evaluated in the Adult ADHD Clinic by this clinician or had just completed such an evaluation and had the study explained to them immediately following their

feedback conference. If they agreed to participate, they were given a packet of forms to complete, including the Adult ADHD Rating Scale (see *Measures* below), if they had not already completed these forms as part of their clinical evaluation. All participants were interviewed by Dr. Murphy to determine the participant's eligibility for further participation in the study. At that time, the structured clinical interview of ADHD criteria from the DSM-IV was given by Dr. Murphy if it had not already been used in their original clinical evaluation. The participants then met with Dr. Connor for their brief medical evaluation and physical exam to determine their medical appropriateness for this drug trial and to rule out the exclusionary conditions described below. With his approval, participants received the remainder of their baseline evaluation and were enrolled in the drug treatment protocol (three weekly appointments).

At a second appointment typically scheduled within one to two weeks of the first one, the Research Technician administered the intelligence screening as well as the surveys concerning driving history and history of drug and alcohol use. The participants then completed the baseline assessment on the battery of repeated measures described below. Subjects were then scheduled for their three weekly evaluations corresponding to the three drug conditions (placebo, low dose, and high dose).

For each testing session the participants were instructed not to take any medication 24 hours prior to their testing. At the testing session, the research technician gave the participant the medication for that date and observed the participant swallow the capsule. The participant then waited in a waiting room for a period of 75 minutes before the formal evaluation began. Once the 75 minutes elapsed, participants were then tested on the driving simulator (about 15 minutes) after which they were given the continuous performance test. All of the measures were given to all participants in the same sequence of administration each week by the same examiner. The examiner was an MA level psychologist. At the conclusion of the protocol, all subjects were paid \$150.

#### 2.4.1. Exclusionary conditions

We excluded individuals from participation if they had any of the following conditions: (a) a history of motor or vocal tics or Tourette's Syndrome, given some controversy over whether stimulants may create or exacerbate these conditions; (b) a history of cardiac surgery, high blood pressure (sustained blood pressure levels above the 95th percentile for age and sex) at baseline, or cerebral vascular accident, given the known cardiac presser effects of stimulant medication; (c) pregnancy; (d) a history of previous adverse reactions to stimulant medications; (e) receiving any medications that might adversely affect driving performance or might be contra-indicated with stimulants as determined by Dr. Connor; or (f) medical conditions that might affect driving performance (e.g. diabetes, retinal disease).

#### 2.4.2. Screening and baseline measures

**2.4.2.1. Shipley institute of living scale (Shipley, 1946).** This short intelligence test is comprised of a 40 item vocabulary test and 20 items assessing abstract thinking. The composite score correlates well with other measures of intelligence (Zachary, 1988) and was employed here as a screening criterion for study entry (see Participants above).

**2.4.2.2. Structured clinical interview for ADHD.** A paper-and-pencil interview was created that consisted of the criteria from the DSM-IV for ADHD. This interview is employed as part of the selection criteria identifying the groups as ADHD or not (see Participants above). Symptoms of ADHD are reviewed twice, once for current functioning (past 6 months) and a second time for childhood between 5 and 12 years of age.

**2.4.2.3. ADHD rating scale for adults (Barkley & Murphy, 1998).** This scale was used in our previous projects. It contains the 18 items from the diagnostic criteria for ADHD in the DSM-IV. Each item is rated on a scale from 0–3, representing Not At All or Rarely, Sometimes, Often, and Very Often, respectively. Participants completed two versions of this scale, one being for current symptoms and the other for recall of childhood symptoms between ages 5 to 12 years. Norms for both current and childhood recall versions of the scales are available for this region (Murphy & Barkley, 1996b). Validity of the scale has been demonstrated through past findings of significant group differences between ADHD and control adults (Barkley et al., 1996). An earlier DSM-III version of the current symptoms scale also correlated significantly with the same scale completed by a parent ( $r=.75$ ) and completed by a spouse or intimate partner of the ADHD adult ( $r=.64$ ; Murphy & Barkley, 1996a). Two scores are calculated from each version of the scale (current, childhood). One represents the total score for each scale and the other is the symptom count, which is the number of items answered as Often or Very Often.

**2.4.2.4. Driving history survey.** The participant's history of traffic violations, accidents, license suspensions, and other negative outcomes was obtained using a written survey about their lifetime driving history. This survey included questions about when they obtained their driver's license, how long they had their license, and how much driving they currently did in an average week. It also contained questions about the number of traffic violations for which they had received citations, the types of cited violations, and the number of crashes they had while driving a motor vehicle. Moreover the participant was questioned about whether or not they were at fault in the crash. The answers to the interview questions were used to create dimensional frequency scores (e.g., their total number of traffic violations and crashes).

**2.4.2.5. Driving performance rating scale.** The scale contains 26 items that assess the participant's driving behavior and skills in a number of areas including: braking properly at intersections, driving within the speed limit, keeping the radio at reasonably low volume, using mirrors properly, staying a safe distance from other vehicles, and so forth. Each item is rated on a 1–3 Likert Scale (corresponding to Not At All, Sometimes, and Often, respectively). Higher scores reflect better driving behavior and use of sound driving habits. Several previous studies (Barkley et al., 1993; Barkley et al., 1996; Barkley et al., 2002) using this scale have found significant group differences between ADHD teens or young adults and normal control groups both in self-assessments and in the ratings of these same participants by their parents or others who knew the participant's driving well (spouses, friends). Barkley et al. (1993) also found that parent ratings on this scale were significantly associated with the number of past traffic citations received ( $r = -.48$ ) and the number of motor-vehicle crashes by participants ( $r = -.56$ ). The internal reliability of the scale (coefficient alpha) in a prior general population sample of 137 adults was .81. Using that same sample, self-reports correlated .63 ( $p < .001$ ) with the reports from others who knew the participant's driving well.

**2.4.2.6. Drug use survey.** All participants completed a written survey about their types and frequency of alcohol and drug use.

#### 2.4.3. Repeated measures

The following measures were collected in the following order at the baseline evaluation and again at the end of each of the three drug conditions (end of each week):

**2.4.3.1. FAAC virtual reality driving simulator.** The driving simulations were conducted with a virtual reality driving simulator manufactured as a police training simulator by FAAC, Inc. (Ann Arbor, MI). This simulator presents various driving scenarios and measures a number of variables related to driving performance. The simulator consists of a main computer and five image generators that control five 30-inch TV monitors that surround the driving platform (seat and dashboard) and project a driving world to 220 degrees of the visual field. The seat and dashboard of the simulator are taken from a real automobile (Ford Crown Victoria) and are controlled by the computers to behave and interact with the virtual world as they would in reality. Actual engine noise and other auditory feedback are provided to the participant through speakers, and tactile feedback ("road vibration") is conveyed using a subwoofer speaker placed on the floor of the dashboard and on which participants rest their left foot. Airflow through the platform is also provided using a fan mounted above the monitors. The steering wheel offers variable resistance as a function of the virtual road surface conveying an authentic sensory "feel" to the steering of the vehicle.

Two standardized driving scenarios were created by FAAC software engineers specifically for this project. On the first course, participants must drive through highway, country, and city driving environments while following verbal directions ("Take your next right/left turn") administered by the simulator. The participant must react appropriately to nine critical events in the environment. For example, as the participant approaches a car parked along the shoulder of the road, the car suddenly pulls out into the participant's path. The participant must react by braking in time to avoid a collision. Should a collision occur, the examiner presses a key on the master computer that jumps the subject back to the driving location 30 seconds prior to the collision and freezes the scene there. The participant is told that they had a collision and will now be permitted to drive through that portion of the driving route again. The simulator measures used here were: average speed, the standard deviation of driving speed (speed is recorded every 10 seconds), the number of collisions, the number of times the turn signal was activated, variation in steering (deviation from right side roadway edge in inches) recorded every second averaged across the course, and time taken to drive the course (in seconds). This course takes approximately 12 minutes to complete. Two versions of this daytime driving course were created for this project varying simply in the direction in which they entered the same suburban setting, the sequence in which they encountered the critical events, and in the other vehicles involved in those events. Each of these two courses had an identical nighttime driving course in which the course environment was markedly darkened to approximate night-time lighting conditions and the participant was required to use the virtual headlights on the car throughout the course. The participants were given these four courses in the same order as follows: daytime course #1, night time course #1, daytime course #2, night time course #2.

A fifth driving course was also created, this being an obstacle course. It consisted of a short straight section of road. Cars are located in the centerline at periodic intervals. The participant is instructed to drive as fast as possible through the obstacle course created by these parked cars while swerving back and forth between the parked cars (slalom-like) and without leaving the roadway or striking one of the parked cars. Most of the measures collected by the simulator in the first course were collected here as well (average speed, speed SD, steering variability, and course driving time in seconds). Crashes occurred so infrequently in this short course as to preclude analysis of those results. The obstacle course was always administered following the driving course.

Problematic in the use of simulators with human participants is the risk of simulator sickness. This is a form of motion sickness in which participants experience slight cognitive disorientation or dizziness and often nausea. In some cases, this sickness can occur to a degree that

participants cannot complete the 12 minute driving course. In our pilot participants, such sickness occurred in approximately 20% of participants. We were able to reduce this to approximately 10% or less of participant driving trials by several means, including keeping the room temperature to around 68 degrees F, creating airflow through the simulator platform using a fan mounted above the center monitor, instructing participants to periodically look upwards and outside of the simulator, and having all participants wear motion sickness bands on their wrists (SeaBands) that provided a mild electrical stimulation to nerves on the inside of the wrist while driving.

**2.4.3.2. Examiner rating of simulator driving performance.** At the end of the 12 minute driving course, the examiner completed an 18-item rating scale that evaluated how well the participant drove while in the simulator. Items are rated the same as in the Driving Performance Rating Scale above. In addition, participants were rated as to their degree of simulator sickness experienced following completion of driving the simulator using a 0–4 Likert scale (None, Mild, Moderate, Serious-Could not complete the course). Internal reliability for the driving items of the scale for a previous general population sample of 121 adults was .55 (coefficient alpha). In that sample, scores from this examiner completed scale correlated .52 ( $p < .001$ ) with the ratings of driving behavior in natural settings from the Driving Performance Rating Scale (self-reports).

**2.4.3.3. Self-rating of simulator driving performance.** The participant completed another version of the Examiner Rating of Driving Performance with items now worded in the first person. Again, one question also evaluated the extent to which the participant may have felt cognitively disoriented or motion sick while driving the simulator. The internal reliability of the driving items on this scale for a previous general population sample of 121 adults was .90 (coefficient alpha). The correlation between the examiner and self-report scales in this previous sample was .43 ( $p < .001$ ), while in the present sample it was .47 ( $p < .001$ ). The correlation between this self-report scale and the self-reports on the Driving Performance Rating Scale (natural driving behavior) discussed above was .33

( $p < .001$ ) for the same general population sample. The correlation of the simulator sickness self-rating with the examiner rating in the present sample was .67 ( $p < .001$ ).

**2.4.3.4. Conners continuous performance test (Conners, 1995).** This is a standardized computer-administered continuous performance test in which single letters are shown on a computer screen. The letters are shown at three different rates: one every second; one every two seconds; or one every four seconds. The task lasts 12 minutes. The participant presses a button in response to every signal shown but then must cease or inhibit their responding when the target signal appears. Norms are available for this CPT from the publisher (Multi-Health Systems). The dependent measures employed here were the total number of omissions (missed targets) and reaction time (RT) variability as measures of inattention, and total commissions (false hits) and RT as measures of impulsiveness.

### 3. Results

All measures were initially analyzed using a one-way (4 drug conditions) multivariate analysis of variance with repeated measures (general linear model, SPSS 11.0). The drug conditions were baseline, placebo, low dose MPH, and high dose MPH. Significance was set at  $p < .05$ . Where Mauchly's Test of Sphericity was significant, the results for the Huynh-Feldt test are reported. Otherwise, the results for Wilk's Lambda are reported. If the omnibus  $F$ -test was significant, pair-wise comparisons were conducted using  $t$ -tests for paired samples.

#### 3.1. Continuous performance test results

Four measures from the continuous performance test were examined first. The results for these analyses are shown in Table 1. Only the omnibus  $F$ -test for commission errors was significant. Pair-wise comparisons indicated that all three drug conditions (placebo, low dose, and high dose) were significantly improved (fewer errors) compared to the baseline evaluation, suggesting a possible practice effect on this measure. The high dose of MPH also significantly reduced errors relative to the placebo condition.

Table 1

Means, standard deviations, and statistical test results for the CPT scores for baseline, placebo, low dose (10 mg) and high dose (20 mg) methylphenidate conditions

Drug Condition:	1-Baseline		2-Placebo		3-Low Dose		4-High Dose		$F$	$p$	Pair-wise Contrasts
	Mean	SD	Mean	SD	Mean	SD	Mean	SD			
Commission Errors	13.3	6.9	8.5	6.8	7.5	7.1	7.2	6.5	34.1	<.001	1>2,3,4; 2>4
Omission Errors	4.2	7.1	2.8	6.9	3.2	6.6	2.0	4.3	2.69	NS	–
Reaction Time (1/100 sec.)	377.8	77.2	388.4	84.0	383.1	78.4	379.9	81.0	1.02	NS	–
Reaction Time Variability	10.4	7.1	9.1	6.5	9.5	9.1	9.3	7.3	0.55	NS	–

CPT=continuous performance test; SD=standard deviation;  $F$ =results for the omnibus  $F$ -test;  $p$ =probability value for the  $F$ -test if significant ( $p < .05$ ); Contrasts: Results for pair-wise comparisons among the drug conditions where the omnibus  $F$ -test was significant; sec.=seconds.

### 3.2. Simulator driving behavior ratings

Next we examined the ratings of simulator driving behavior. These results appear in Table 2. On both self-ratings and observer ratings, the omnibus *F*-tests were significant. Pair-wise comparisons revealed the same pattern of findings for both measures: all three drug conditions were significantly improved over baseline but there were no differences between the drug and placebo conditions.

### 3.3. Simulator scores-standard courses

Results for the standard simulator-driving course are also shown in Table 2. Significant omnibus tests were found for the number of crashes, steering variability, course driving time, and the number of turn signals activated. Analyses for average driving speed and variability of driving speed were not significant. Pair-wise comparisons for the crash scores revealed that all three drug conditions resulted in significantly lower crash occurrences than at baseline but there were no differences between the drug and placebo conditions. For steering variability, these comparisons showed that variability was significantly greater during the placebo than the baseline condition. However, such variability was significantly lower during the high dose of MPH than during the placebo condition. No other comparisons were significant. Course driving time was found to be significantly shorter during all three drug conditions relative to baseline but with no differences between the placebo and drug conditions. For the turn signal score, again all three drug

conditions resulted in significantly greater use of the turn signal indicator than in the baseline condition. In this case, however, the low dose of MPH resulted in significantly greater turn signal usage than in the placebo condition. None of the other pair-wise comparisons for this score were significant.

### 3.4. Simulator scores-obstacle course

The data for 44 participants were available for analysis for this course (sample size per drug order was PLH=6, HPL=9, LHP=7, PHL=7, HLP=7, LPH=8). The data for the remaining 10 participants was lost due to simulator malfunctioning or simulator sickness arising by this point in testing such that a few participants could not complete the course. The steering variability score for one subject during the low dose condition was extreme, resulting in a non-normal distribution. It was normalized when the mean score for this drug condition was substituted for this participant's score. The same problem occurred for a different participant in the high dose condition and was dealt with the same way.

The omnibus test for average driving speed during this course was significant. Pair-wise comparisons indicated that speed during the low dose MPH condition was significantly greater than at baseline, and speed during the placebo condition was marginally greater than at baseline ( $p=.074$ ). Also, average speed during the high dose MPH condition was significantly slower than the low dose MPH condition, and marginally significantly slower than the placebo condition ( $p=.069$ ).

Table 2

Means, standard deviations, and statistical test results for the driving measures for baseline, placebo, low dose (10 mg) and high dose (20 mg) methylphenidate conditions

Drug Condition:	1-Baseline		2-Placebo		3-Low Dose		4-High Dose		<i>F</i>	<i>p</i>	Pair-wise Contrasts
	Mean	SD	Mean	SD	Mean	SD	Mean	SD			
<i>Standard Course Results:</i>											
Simulator Self-Rating	55.7	8.8	61.4	7.0	60.6	7.5	61.9	7.1	16.5	<.001	1<2,3,4
Simulator Observer Rating	54.4	5.1	59.2	4.3	60.1	4.4	59.7	4.6	26.90	<.001	1<2,3,4
Average Speed (mph)	28.8	4.1	29.5	4.2	29.8	4.1	29.8	4.0	1.82	NS	–
Speed Variability (SD)	14.4	2.1	14.7	1.7	14.7	2.2	14.7	1.8	0.05	NS	–
Crashes-Number	1.7	1.4	0.9	1.1	0.9	1.2	0.7	0.9	8.58	<.001	1>2,3,4
Steering Variability	50.5	16.0	59.5	24.3	55.7	19.4	51.5	11.6	3.13	.031	1<2; 2>4
Course Driving Time (sec.)	606.6	81.5	577.5	79.1	572.0	73.7	572.5	77.2	6.16	.001	1>2,3,4
Number of Turn Signals	15.7	3.8	17.4	4.0	18.2	3.8	17.6	3.9	6.45	.001	1<2,3,4; 2<3
<i>Obstacle Course Results:</i>											
Average Speed (mph)	38.7	10.1	42.5	10.5	42.6	10.5	39.5	10.6	4.21	.011	1<3; 3>4
Speed Variability (SD)	14.7	5.9	14.8	5.6	15.8	6.1	16.7	6.7	2.20	NS	–
Steering Variability	41.5	7.1	37.7	4.9	39.3	13.0	37.4	7.0	2.46	NS	–
Course Driving Time (sec.)	31.8	8.5	29.0	7.7	28.8	7.6	32.0	12.1	2.60	NS	–
<i>Simulator Sickness:</i>											
Self-Rating	0.9	1.0	0.5	0.7	0.5	0.7	0.5	0.7	14.10	<.001	1>2,3,4
Observer Rating	1.0	0.8	0.5	0.6	0.5	0.5	0.6	0.5	13.06	<.001	1<2,3,4

SD=standard deviation; *F*=results for the omnibus *F*-test; *p*=probability value for the *F*-test if significant ( $p<.05$ ); Contrasts: Results for pair-wise comparisons among the drug conditions where the omnibus *F*-test was significant; mph=miles per hour; sec.=seconds.

### 3.5. Simulator sickness ratings

Both omnibus tests for the self and observer ratings of simulator sickness were significant. Yet pair-wise comparisons showed an opposite pattern of findings. Participants rated themselves as significantly less affected by simulator sickness during all three drug conditions relative to the baseline condition. The drug and placebo conditions did not differ. Observers, however, rated the participants as demonstrating significantly *more* signs of simulator sickness during all three drug conditions relative to baseline. Again, there were no differences among the three drug conditions in this regard.

## 4. Discussion

Past studies of driving in ADHD teens and adults have repeatedly found them to be at higher risk for problems with driving performance and with various adverse driving outcomes, including increased speeding, total citations, and crashes. Such findings argue forcefully for attempting to reduce these risks through treatment, and stimulant medication seems to offer the most promising means of doing so. This study therefore examined the effects of two acute doses of methylphenidate on the driving simulator performance of the largest sample of adults with ADHD studied to date. Performance was evaluated on a lab measure of attention and response inhibition (CPT), a virtual reality-driving simulator, and through participant and observer ratings of driving the simulator.

Only a few straightforward beneficial effects of these acute MPH doses were evident on our measures. The high dose of stimulant medication resulted in significantly fewer errors of impulsiveness on the lab CPT relative to the placebo condition. The high dose of medication also resulted in less variability of steering the simulated vehicle during the standard driving course than in the placebo condition; whereas the low dose of MPH resulted in a greater use of the turn signal activator than in the placebo condition. In the obstacle course, the high dose of MPH also resulted in a significantly slower average speed than in the low dose of medication. These results suggest some improvement in driving performance from the use of methylphenidate, particularly at the higher dose of medication used here (20 mg). Apart from these findings, no effects of medication were evident on the other measures in comparison to the placebo condition.

On 5 of the 12 simulator measures, and the two ratings of simulator sickness, however, we repeatedly observed significant differences between all three active treatment conditions (placebo, low dose, and high dose of MPH) and the baseline condition. Such findings potentially imply a significant practice effect on these measures between the first and subsequent testing sessions. Such a practice effect would interfere with the capacity of these measures to detect

effects of medication relative to placebo using a within-subjects crossover design like that used here. Our findings suggest that future research would do well to test participants on the simulator on several occasions in hopes of reducing subsequent practice effects before enrolling them in a crossover design examining the effects of medication.

As in the three smaller prior studies of stimulant medication by Cox and colleagues discussed earlier, we found some beneficial effect of stimulant medication on driving performance, particularly for our higher dose (20 mg) of MPH. Cox et al. (2000) also found improvement on a summary score from their older Atari model simulator from an acute dose of 10 mg of MPH. Our low dose of medication was comparable to the dose used by Cox et al. but we found only one effect of that dose, and it was on the use of turn signals—a measure not specifically examined by Cox et al. (2000). The apparent practice effects that were so evident in our results were not reported in any of the prior studies by Cox and colleagues. It is not obvious from those reports that they examined for potential drug order (sequence) effects or practice effects specifically in their analyses. Other differences between our study and those earlier reports are worth noting. In their initial report (Cox et al., 2000), participants were tested 90 min. after receiving a 10 mg acute dose of drug or placebo in the evening hours while spending the night in a hospital setting in which food intake (restricted before testing) and drug use were controlled. Our participants were tested in an outpatient lab at all hours of the day with no such diet or drug use control. It is possible that driving problems among ADHD adults are most evident in evening hours, perhaps due to fatigue, in comparison to daytime hours when we tested our participants. If so, then an effect of a low dose of MPH might be more apparent on driving using the evening testing procedures of Cox et al. (2000) than in the daytime testing in our study. In their second study, Cox and colleagues (in press) used a long-acting methylphenidate OROS delivery system (Concerta<sup>®</sup>) delivering a higher dose than used here while observing teens with ADHD driving an actual car through a standard driving course in Virginia. The examiner was the only one blinded to the drug or no-drug condition and no placebo was employed in this study. Nor was a simulator employed, making it difficult to compare our results to those in that more naturalistic driving study. It is possible that the higher dose employed in that study as well as the use of observations of actual driving may make a drug effect on driving more obvious than in our study. It is also conceivable that ADHD teens are more impaired in their driving than were the ADHD adults in our study making it more likely that Cox et al. (2000) would detect an effect for medication. In their final study (Cox et al., in press), Concerta<sup>®</sup> was compared to immediate release methylphenidate given three times daily using a simulator with ADHD teens. No placebo was used making comparisons

to the present study difficult. But no significant practice effect was either reported or examined in that study. Our results, using a much larger sample of adults, found a more complex picture in our efforts to detect stimulant drug effects on driving simulator performance in which practice effects may have interacted with medication effects. Despite such methodological differences, our findings are in agreement with the studies by Cox and colleagues in suggesting that methylphenidate may have a beneficial effect on some aspects of driving (less steering variability, slower driving speed, greater use of turn signals, fewer impulsive responses).

The limitations of our study deserve mention. It is possible that part of the problem we experienced in detecting medication effects was the result of our: (a) using a single acute dose of medication just prior to driving rather than treating participants at each dose for an extended time; (b) using relatively low doses in comparison to those likely being employed in clinical practice with ADHD adults; and (c) using immediate release methylphenidate rather than a longer acting delivery system. It is also possible that the virtual reality simulator we employed was insufficiently sensitive to the medication effects. Arguing against this possibility were our many findings that the simulator was exquisitely sensitive to an apparent practice effect, which may have compromised its ability to detect a further effect of medication beyond the effect of practice. It is also possible that the time taken for testing the participants was too short a duration. However, prior studies have found significant drug effects on cognitive tests of equal or shorter testing durations (Rapport Kelly, 1993). Extending the testing session duration would also have increased the likelihood of simulator sickness arising or increasing among our participants. We received frequent comments from participants concerning simulator sickness—a queasy feeling or nausea coupled with some mild light-headed or slight disorientation that increased in likelihood with driving time. Indeed, approximately 5% of our participants could not complete the simulator course due to such sickness. Over a third of the participants (36–39%) rated themselves as having at least mild or greater sickness across the drug conditions while nearly 50% of them (42–57%) were so rated by the examiner across the drug conditions. The vast majority of participants were able to complete the driving course on the repeated testing occasions, however. And such sickness would have occurred equally as often across all drug orders such that sickness is not, by itself, able to explain the absence of clear cut drug effects here on many of our measures. It also needs to be acknowledged that using two different courses and varying the daytime and nighttime conditions across them while repeatedly testing each participant might well have added to the variability of results sufficient to obscure more clear-cut drug effects on this simulator. Using the same simulator course across all testing sessions, as was done by Cox and colleagues,

might well have led to different results. Future research will be needed to clarify these issues concerning the use of simulators to examine drug effects in ADHD teens and adults.

In conclusion, our positive drug effects on simulator performance, when placed in the context of three previous studies finding such a beneficial effect for both ADHD teens and adults, would endorse the use of stimulant medications in clinical practice in an effort to reduce the numerous driving risks previously documented among teens and adults with this disorder.

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