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Design of an experimental protocol to examine medication non-adherence among young drivers diagnosed with ADHD: A driving simulator study

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ABSTRACT

The diagnosis of ADHD among teens and young adults has been associated with a higher likelihood of motor vehicle crashes. Some studies suggest a beneficial effect of ADHD medication but the exact efficacy is still being debated. Further, medication adherence, which is low in this age group, can further reduce effectiveness. Our long-term objective is to reduce unsafe driving among drivers with ADHD by detecting medication non-adherence through driver behavior modeling and monitoring. As a first step, we developed the described lab study protocol to obtain reliable driver behavior data that will then be used to design and train behavior models built through machine learning. This experimental study protocol was developed to systematically compare driving behaviors under two medication conditions (before and after intake of medication) among young adults with ADHD and a control group of non-ADHD. A driving simulator was used to examine driving behaviors and interactions with traffic. The primary outcome was speed management for two comparisons (ADHD vs. non-ADHD and before vs. after medication), and secondary objectives involved understanding differences among the participants utilizing self-reported surveys about ADHD symptoms, drivers' knowledge, and perception about safety. The study protocol was designed to maximize participant safety and efficiency of data collection, as multiple measures were collected over two 2-h study visits. The sampled ADHD drivers were demographically and psychosocially similar but clinically different from the non-ADHD group. Overall, this protocol was effective in participant recruitment and retention, allowed staggered data collection, and can be incorporated in a subsequent clinical trial that examines the efficacy of a machine-learning based driver monitoring intervention.

1. Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a prevalent neurobehavioral disorder in children and adolescents [16,38]. Approximately two-thirds of patients with a childhood diagnosis of ADHD continue to experience clinical symptoms into adulthood [6], intersecting with a period when many young adults start to drive independently. Drivers who are diagnosed with ADHD have shown significant driving impairments [1,2,19], including higher likelihood of motor vehicle crashes, speeding violations and poorer vehicle control, with a relative risk of 1.23 when controlling for exposure [39]. However, not all individuals with ADHD are affected uniformly [17] and it remains unclear the extent to which measures can be developed to distinguish between low and high risk drivers with ADHD on a group level and between low and high risk characteristics on an individual level [15].

Medication intervention, especially stimulant medication, appears to improve the driving deficits exhibited by ADHD drivers [17], although the exact efficacy is still being debated [3,5,8,11,12,24,37]. While the discrepancies may come from methodological limitations and sample size concerns, one general consensus is that the benefits and effects of medication on individuals with ADHD are not uniform [20], confirming the challenges for developing effective measures to distinguish between low and high risk drivers as well as strategic and sustainable treatment plans. In addition, medication adherence is a major problem in adolescence and young adulthood [18,32], as they

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transition from parent-managed medication to self-managed medication. Therefore, medication non-adherence can further degrade effectiveness of stimulant medication in reducing crash risk.

Despite these safety concerns, very little work has been done to evaluate interventions that can improve ADHD symptom management and driving safety during adolescence and young adulthood, when the crash risk is the highest [33]. To address this gap in knowledge, our long-term objective is to create a machine-learning based monitoring intervention to help manage ADHD symptoms while driving. Such a system is expected to effectively monitor driving behavior in situations where ADHD symptoms are under relative control and when they are not, as determined by levels of medication adherence. As the first step toward fulfilling this long-term goal, we have designed an experimental protocol that involved the use of a driving simulator and other assessment measures and allowed for the comparison of driving behaviors between medication conditions (before and after the consumption of daily stimulant ADHD medication) and groups of participants (with and without ADHD). The current paper reports the design of an experimental protocol for collecting reliable driver behavior data; the recruitment and assessment strategies for the study sample – young adults with and without ADHD; and the comparisons of clinical, psychosocial, and demographic characteristics between the two groups.

2. Research design and methods

2.1. Study design

The primary objective is to quantify the differences in vehicle control behaviors between two groups of participants – individuals with and without ADHD – as well as between two medication conditions (before and after medication administration) among individuals with ADHD. Traditional statistical methods and data mining techniques will be used to compare and contrast patterns of driving behaviors. The secondary objectives include conducting exploratory analysis to examine potential mechanisms and covariates that may explain the behavioral differences between the two groups and the two medication conditions.

2.2. Recruitment strategies

Participants (individuals with self-reported ADHD and zip code matched individuals without ADHD who served as controls) were recruited through a variety of clinical and community settings. These included posting flyers at universities, university counseling centers, bus stops, coffee shops, grocery stores, psychology department subject pool, emailing listservs of undergraduate students and university disability services office, and word-of-mouth referrals from students and colleagues. The study received Institutional Review Board approval from the first author's university.

2.3. Eligibility criteria

ADHD participants: Eligible participants were adults 18–24 years of age who had a confirmed diagnosis of ADHD, had a current prescription for stimulant medication for ADHD, held a restricted or an unrestricted driver's license, had normal or corrected-to-normal vision, and had normal hearing abilities. The exclusion criteria were self-reported pregnancy (females), self-reported neurodevelopmental disorders, intellectual disabilities, psychotic disorders, bipolar disorder, or seizure disorders, as well as participants with a confirmed diagnosis of ADHD but who took non-stimulant medication.

Non-ADHD participants: Eligible participants were adults 18–24 years of age who held a restricted or an unrestricted driver's license, had normal or corrected-to-normal vision, and had normal hearing abilities. The exclusion criteria were the same as those of ADHD participants with the addition of self-reported diagnosis of ADHD.

In addition, the Motion Sickness History Screening Form (MSHSF) [22,23] was used to assess the likelihood of experiencing simulator sickness (a form of motion sickness). The MSHSF includes questions about the frequency of getting carsick, seasick, and airsick. Based on the reported frequencies (a composite score of 7 or higher), we discouraged further participation. For participants who were discouraged but still wished to continue participation, the potential risks and safeguard measures were explained, and they were ensured they would be checked and monitored closely during the study.

2.4. Outcome measures

The primary outcome was participant's average speed while driving in a simulator. This and other associated variables were collected from a high-fidelity, motion-based driving simulator, sampled at 60-Hz. It has an open-cab configuration equipped with a motion-base system capable of a single degree of pitch motion and a 90 ± degree high-quality yaw motion, a 3-channel visual system covering 180-deg forward field-of-view, and a force-feedback steering wheel. The variables derived from the simulator included vehicle control variables (e.g., velocity, throttle, brake, pitch) and vehicle diagnostics variables (e.g., gear, engine RPM). Three cameras capturing the foot movement, over the shoulder view (steering wheel movement), and upper body and face view were also recorded. The traffic scenarios used in the current study as well as the process for computing driving behaviors were previously developed and validated [26,31,34].

To examine secondary objectives, the study included several self-reported surveys:

a) Demographic information was collected using questions about socio-demographics, driving experience, driving history (accidents), licensure type, learning-to-drive experience (who taught them to drive?), as well as four validated rating scales: Safe Speed Knowledge Test (SSKT) [27], Driving Anger Scale (DAS) [13], Brief Sensation Seeking Scale (BSSS) [30,41], and Driving Behavior Survey (DBS) [9].
b) ADHD history questionnaire was completed by each participant with ADHD and a friend or family member. These questions collected information about each participant's ADHD medication, symptom onset (age, symptom-related problems), and severity of problems or concerns currently caused by ADHD symptoms (when not taking the medication) in School, Work, Family Relationships, Social Relationships, and Self-Esteem categories.
c) Conners' Adult ADHD Diagnostic Interview (CAADID) [14] was administered individually. It produced comprehensive demographic and developmental history to support a categorical diagnosis based upon the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV™) criteria for ADHD, during both adulthood and childhood. For screening purposes, both the quantitative and qualitative responses helped delineate the ADHD medical and symptom history by assessing each participant's demographic history, developmental course, ADHD risk factors, and comorbidity screening questions.
d) Conners' Adult ADHD Rating Scale (CAARS) self-report and observer-report, screening versions [10] were administered individually. The screening versions consisted of 30 items about behaviors or problems sometimes experienced by adults. These rating scales were administered on-line via Multi-Health Systems' management program, and the calculated profile reports included normative T scores on inattentive symptoms, hyperactive-impulsive symptoms, total ADHD symptoms, and ADHD index.
e) Post-drive survey was used after each driving simulator session. Participants were asked to rate the realism of the simulation and if there were concerns about the traffic scenarios. They were also asked to rate the percentage of time they were speeding, driving inside a lane, and following traffic rules.