Sleepy Teens as Novice Drivers (STAND): Does Better Sleep Improve Adolescent Driving Skills?

Final Grant Report

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INTRODUCTION

Despite safety advances, accidental injuries – primarily from automobile crashes – remain the single greatest cause of death amongst Ohio's adolescents, and further cause a disproportionate degree of disability and societal cost compared to drivers in other age ranges. This study applied experimental methods to understand whether extending the sleep of adolescents who regularly get 5-7 hours of sleep on school nights can improve adolescent driving skills.

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EXECUTIVE SUMMARY

Despite major public health efforts, adolescent drivers in Ohio continue to have higher crash rates and crash-related death rates – and are also more likely to be at fault – than any other age group. Ohio's crash-related teen deaths, which had been improving steadily, have changed little in recent years, raising questions of how to further advance crash prevention. Preliminary evidence suggests that the short sleep that millions of adolescents regularly get on school nights contributes to their high crash rates. Public health efforts to promote adolescent sleep could be the next pivotal step in improving driving safety. However, it has been difficult to justify the costs of such large scale efforts, since prior research had not definitively shown a cause-effect relationship between teens' sleep and their driving skills.

Prior work at Cincinnati Children's has shown that shortened sleep *causes* teens to have problems with attention and mood regulation, suggesting mechanisms by which short sleep could affect teen drivers. This study was a small-scale efficacy trial to test whether alleviating sleep restriction during the school year improves teens' driving skills. This trial focused on licensed 16-18 year-old high-school students who regularly obtained 5-7 hours of sleep on school nights. About 1/3 – 1/2 of high school students get that much sleep on school nights.

Each teen in our study completed a 5-week experimental protocol: a baseline week to determine habitual sleep, followed by 2-week spans in which school-night bedtimes and rise times were (a) matched to the baseline or (b) modified to increase time in bed by $\geq$ 1.5 hours/night. All sleep took place at home, continuously monitored using objective actigraphy (wristwatch-like device similar to, but better validated than, Fitbit® or Fuelband®). At the end of each sleep condition, we assessed teens' skills in a driving simulator on a course that presented realistic driving scenarios that challenged mood regulation and attention. During the same visit,

we gathered parent and teen-reports of driving issues, behavior, mood, and cognitive tempo, as well as computerized measures of cognitive skills.

The study timeline was prolonged by initial delays executing the contract, and as such data collection continued through November, 2016. In the end, 26 participants completed all 5 weeks of the study, with 25 of the 26 averaging at least 30 minutes more sleep on school nights across the 2-week extended sleep condition than the 2-week period of their habitual sleep schedule. To date, we have several sets of findings to report. (1) It is feasible for habitually short-sleep adolescents to get more sleep on school nights for two full weeks with a brief behavioral intervention. (2) That intervention resulted in significantly less sleepiness, as well as better "metacognitive skills" (e.g., planning, organization) and mood compared to the adolescents typical sleep patterns. (3) Adolescents who had the greatest impact of the sleep intervention on their thinking skills were also those who had the greatest reported change in their driving skills.

Lengthening sleep appeared to improve driving skills in at least a subset of short-sleeping adolescents. In the coming months, we will continue to use institutional funds to fully process the extensive eye tracking and driving simulator data to objectively probe these apparent effects and potential mechanisms for them (e.g., is change in driving skills related to change in glances away from the roadway?). If our preliminary findings are correct, this study could provide Ohio with a new approach to improve driving safety in our most vulnerable drivers, reducing morbidity, mortality, damage-related costs, and societal burden.

INVESTIGATORS AND RESEARCH SETTING

Primary Personnel

Principal Investigator: Dean Beebe, Ph.D. is a Professor of Pediatrics at the University of Cincinnati College of Medicine, Director of the Neuropsychology Program in the Division of Behavioral Medicine and Clinical Psychology at Cincinnati Children' Hospital Medical Center (CCHMC), and Co-Director (with Dr. Epstein) of the Driving Simulation Lab at Cincinnati Children's. His research program, which investigates the daytime effects of inadequate sleep, has been continuously funded by the NIH and other granting agencies since 2000, with the past 10 years focused on adolescents. He has an established record of converting time-limited small-grant investments into scaled-up, high-impact work. For example, he quickly followed up on findings from a small foundation-supported pilot study on the functional impact of adolescent obstructive sleep apnea with a larger, definitive NIH-funded project that is now impacting clinical care (K23 HL075369). He also used small foundation funding to develop his lab's at-home adolescent sleep manipulation, which led directly to two larger NIH-funded studies (R01 HL092149; R01 HL120879) that have shown that realistic levels of sleep restriction can have serious daytime consequences for adolescents. Similarly, the long-term plan is to use data from this initial small-scale efficacy trial to justify, craft, and empirically test a full-scale driving safety program that is enhanced by a focus on better sleep. Dr. Beebe oversaw all aspects of the proposed study. He ensured fidelity of the protocol execution, had direct contact with families to promote subject retention, and trained and oversaw the activities of research staff during data collection and management. He has worked and will continue to work with the co-investigators in data analysis, interpretation, and dissemination of knowledge. Finally, he has been responsible for all aspects of subject safety, working closely with the Institutional Review Board (IRB; the hospital's research ethics board).

Co-Investigator: Joseph Rausch, Ph.D. very recently left his position as Associate Professor of Pediatrics at CCHMC and the University of Cincinnati College of Medicine. He specializes in the design and statistical analysis of studies involving repeated measures, particularly those involving nested and randomized cross-over designs, and has published on methodological and statistical issues in high-quality journals such as *the Annual Review of Psychology*, *Psychological Methods, Applied Psychological Measurement*, and the *Journal of Clinical Child and Adolescent Psychology.* He and Dr. Beebe's had a long-standing working relationship, and he set up Dr. Beebe with critical analytic tools prior to leaving Cincinnati. Dr. Rausch oversaw data management as conducted by research staff and the Divisional Data Core, and worked with the other investigators on data analysis and interpretation.

Co-Investigator: Annie Artiga Garner, Ph.D. recently graduated her Post-Doctoral Research Fellowship in the Divisions of Behavioral Medicine and Clinical Psychology and General Pediatrics at CCHMC. She is now an Assistant Professor at St. Louis University, continuing to investigate the relationship between sleep, attention, and driving skills in adolescents. During her training, she gained essential practical experience in the day-to-day operations of driving simulation, including work with adolescent drivers. As a Co-Investigator, Dr. Garner assisted with programming the simulated drives, worked side-by-side with other study staff during data collection, has been preprocessing and extracting driving simulator data, and has assisted with data management, analysis, and interpretation.

Clinical Research Coordinator – II: Catharine Whitacre, B.A. has worked within the Cincinnati Children's system for a number of years, and join Dr. Beebe's lab at the beginning of this study. She took a lead role in subject recruitment, screening, and scheduling, as well as data collection and management. She inventoried and ordered supplies, arranged for reimbursement funds, and facilitated the PIs maintenance of all needed IRB and institutional paperwork.

"Behind the Scenes" Personnel

Co-Investigator: Jeff Epstein, Ph.D. is a Professor of Pediatrics at CCHMC, with a joint appointment in the University of Cincinnati's Department of Psychology. Dr. Epstein is also the Director of the CCHMC Center for ADHD and Co-Director (with Dr. Beebe) of the Driving Simulation Lab. His research, which has been continuously-funded by the NIH for 20 years, focuses on the etiology, phenomenology, and treatment of attention disturbances in children and adolescents. His team recently demonstrated, for the first time, that much-publicized associations between adolescent text messaging and driving accidents actually reflect cause-effect relationships.[1] As co-investigator on the study, he lent his expertise in the measurement and quantification of attention deficits in adolescents and assist with data interpretation and dissemination.

Co-Investigator: Adam Kiefer, Ph.D. is an Assistant Professor of Pediatrics in the Division of Sports Medicine at CCHMC. An experimental psychologist, Dr. Kiefer directs the Research Education and Training Enhancement and Analysis of Movement (TEAM) in the Virtual Reality (VR) Laboratory. As a Co-Investigator, he was responsible for programming and data collection for the eye tracker and has been assisting with data analysis, interpretation and dissemination.

Environment

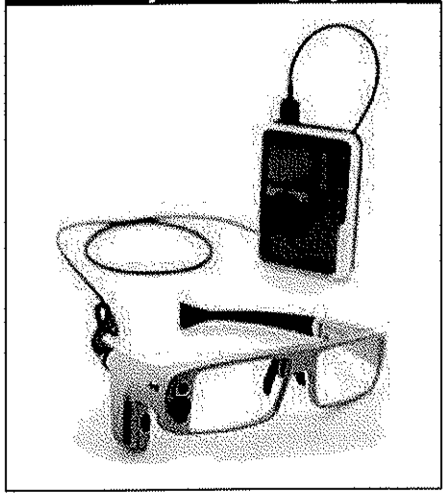
Cincinnati Children's Hospital Medical Center (CCHMC) was founded in 1883 and has grown to a 500+ bed, non-profit organization serving as the only children's hospital in the Cincinnati metropolitan area (population 2.3 million). Consistently ranked within the top 5 Children's Hospitals by *U.S. News & World Report, Parents Magazine,* and *Child Magazine,* CCHMC exceeds 1 million patient encounters per year. There are few pediatric research facilities in the country that are as well-prepared as CCHMC to support research to benefit the health of children and adolescents. CCHMC ranks 2nd in the US among pediatric medical centers in NIH-funded research, with yearly extramural awards over $173 million. It has the computer, office, telecommunication, and other resources one would expect with such success in funding. Total space dedicated to research exceeds 1 million square feet, leading the nation's pediatric facilities. For this study, we worked with the CCHMC Clinical Trials Office marketing and recruiting staff for the design, printing, and targeted distribution of recruitment materials.

The seat of study activities was the Division of Behavioral Medicine and Clinical Psychology (BMCP). BMCP occupies >15,000 square feet for use in clinical care (>30,000 outpatient encounters/year) and clinical research operations. BMCP has a vibrant, supportive academic environment, with >70 faculty and staff psychologists, 11 post-doctoral fellows and >50 pre-doctoral students. Yearly direct grant support exceeds $7 million. High-quality research is systemically promoted via division-specific grants administration support, a Division Data Core, psychologist representation in research administration and on important institutional committees (e.g., IRB), and the collective experience of faculty members who have served on NIH and other grant review committees.

Dr. Beebe in the Simulator

BMCP is also home to the Driving Simulation Lab, co-directed by Drs. Beebe and Esptein. The simulator is run on a software platform designed by Systems Technology Incorporated (STI; www.stisimdrive.com) that allows both pre-made and flexibly-programmable driving scenarios. STI has over 40 years' experience with driving simulation, and their systems are in widespread academic, industry, and military use. Our system has 3 driving displays, a 135-degree driver field-of-view with integrated rear-view and side mirrors, a full-size steering wheel with dynamics-based feedback, full-sized foot pedals, and a fixed-base, adjustable full-size car seat. The simulator is equipped with a high-definition digital camera to record the behaviors of the driver, with excellent resolution for facial expressions and gestures.

Tobii® Eye-Tracking System



The driving simulator is outfitted with a Tobii® mobile eye tracking system, a portable apparatus that consists of a video-based eye tracker fully integrated into a lightweight glasses frame. The glasses are outfitted with infrared reflective lenses that allow the position of the pupil to be tracked via retinal reflection. A forward-facing scene camera is also fixed to the frame and enables the participant's field of view to be recorded. The position of the pupil is then registered with respect to the scene camera, and a small device that fits in the user's pocket processes the video and saves the data. The Tobii system also includes infrared markers that are placed in the environment (i.e., the driving simulator space) and these enable the tracking system to map the eye data to the experimental environment. Each marker is tracked via an infrared camera that is fixed to the glasses frame below the scene camera. Thus, the glasses detect and identify the markers in real time and record the position of each marker with respect to the scene camera. Custom software is then used to integrate the real-time data with the visual display and allows for the tracked eye data to be mapped to the scene during post-processing.

REVIEW OF LITERATURE AND PRIOR WORK IN THIS AREA

The High Cost of Adolescent Driving Crashes

The accident rate in teen drivers is higher than at any other age,[2] which has led to major public health efforts including intensive education, improved vehicle and roadway design, graduated licensing, restrictions on late-night driving, and bans on high-risk behaviors such as driving with peers, while texting, and after consuming alcohol. Despite these efforts, auto crashes are still the leading cause of death among 16-18 year-olds [2,3] and a major cause of non-fatal injuries.[4] Across the US, a single year of teen crashes costs $11 billion when compounded across the expected lifespan of those who were injured.[4]

In the State of Ohio, adolescent drivers not only have the highest accident and crash-related death rate, but also are more likely to be at fault than any other age group.[5] After years of progress, Ohio's crash-related adolescent death rate has moved little over the past five years,[6] raising questions about the next steps in prevention. Laws around risky driving can help, but reach a point of diminishing returns; adolescent non-adherence to adult directives is common,[7] prohibitions can add to the mystique of risky behaviors,[8] and some of the behaviors targeted by legislation are rare among adolescents. For example, alcohol is a factor in only 16% of fatal teen crashes[7] and even fewer non-fatal crashes,[9] with these rates in adolescents being *lower* than for adult drivers.[7] Given the high costs of teen crashes, there is a clear need for novel approaches that address new risk factors.

Short Sleep on School Nights: An Unaddressed, Modifiable Risk Factor?

Teen crash rates correlate inversely with sleep duration; teens who sleep less have more crashes.[10] Large-group studies have also shown that metropolitan areas with teens who sleep longer have lower crash rates than very similar areas with teens whose sleep is restricted by early school start times.[11] Similarly, one study from Kentucky showed that local teen crash rates went down after a county-wide school district delayed high school start times by an hour, even as teen crashes increased in surrounding areas.[12] Moreover, as detailed below, our research team has shown that experimental sleep restriction impairs multiple aspects of adolescents' attention, as well as their ability keep a clear head in emotional situations,[13-15] which may be particularly important for teen drivers.[7,16]

The average adolescent is chronically sleep-deprived, sleeping 1-3 hours less on school nights than is recommended.[15,17] Teens now sleep less than at any other time in modern history,[18] after having undergone a secular decline that is not matched by younger children[18] nor by adults.[19] If adolescent sleep restriction impairs teen drivers, it could represent a tremendous prevention opportunity. Teen sleep duration is modifiable, both on an individual level (e.g., changing bedtime[13]) and on a population level (e.g., starting school later[12,20]). Yet sleep targets are completely absent in teen crash prevention programs from the Centers for Disease Control and Prevention,[21] National Highway Traffic Safety Administration,[22] Insurance Institute for Highway Safety,[23] and Allstate Foundation.[24]

What Stands in the Way?

This prevention gap reflects a research gap. It remains unclear whether short sleep and adolescent crashes have a cause-effect relationship. Correlational findings with teens have been limited by an overreliance on self-report and the potential for hidden confounds. For example, it may be that emotional disturbances cause some teens both to sleep less and to have more driving crashes, or that holding an evening job not only deprives adolescents of sleep, but also increases miles driven after dark. In both scenarios, prevention efforts directed at sleep would miss the mark, because the crashes would be caused by something other than sleep deprivation. Similarly, studies comparing crash rates in areas with differing school start times have not been able to definitively show cause-effect relationships because they have not used experimental methods to rule out potential confounding factors (e.g., differences in substance use, miles driven).[11,12]

It is important to establish a cause-effect relationship because sleep promotion efforts are not free. Efforts to increase adolescent sleep could divert resources from other prevention work (e.g., time spent teaching about sleep could reduce time teaching about distracted driving), further stretch already strained school budgets (to change transportation and high school start times), and disrupt family and community schedules.[25-27] These costs have led critics to question whether adolescents are getting too little sleep, noting a lack of work that balances experimental rigor with real-world outcomes.[25,28,29]

Given this, experimental work is essential to demonstrate a true cause-effect relationship between adolescent sleep and driving safety. However, outside of our research team, experimental studies with teens have been few,[15] have limited sleep far more severely than occurs in the general community,[30-32] and have lacked outcome measures that resemble driving. Although there have been many more experimental sleep deprivation studies with adults, these too have typically used extreme sleep deprivation (e.g., 1-2 nights of total sleep deprivation) that markedly differ from the ongoing partial sleep restriction experienced by most teens on school nights.[28] Further, adolescent sleep differs from that of adults in important ways, including overall need (greater in teens), sleep architecture (rapid shifts in recuperative slow wave sleep), and the optimal timing of sleep (teens falling asleep and rising later) due to developmental changes in circadian rhythm and how sleep pressure accumulates across the day.[33-40] Perhaps most importantly, the task of driving is simply different for teens. Novice drivers need to allocate more mental resources to attention and decision-making [16] and teen crashes rarely occur during long boring drives (e.g., long commutes, trucking routes), which is when sleepy adults are most vulnerable.[41,42]

Thus, while chronic sleep restriction may be an important risk factor for the deaths and injuries associated with teen crashes, costly prevention efforts await convincing research evidence.

Preliminary Evidence from Cincinnati Children's

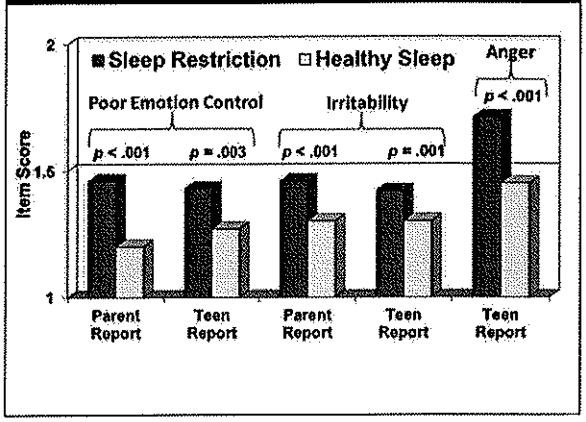
For the past decade, we (Dr. Beebe's lab) have led a research program focused on the neurobehavioral effects of sleep disorders and chronic sleep restriction in adolescents. In 2006, our group was the first to report that it is feasible to conduct a summertime home-based adolescent sleep restriction protocol that mimics the experience of 20-25% of teens on school nights.[13] In that protocol, each teen experienced 5-night stretches of sleep restriction (6.5 hours in bed) vs. healthy sleep opportunity (10 hours in bed), with the order of these two conditions randomly mixed across participants. Of the 168 teens who were randomized into that protocol, 87% went on to complete both conditions with good adherence to the sleep regimen. By changing their bedtimes alone, they averaged 2.5 hours more sleep per night in the healthy sleep condition than when in the sleep restriction condition.

More importantly, that success allowed us to examine the impact of chronic sleep restriction on several skills that are critical for young drivers. Adolescent drivers face a unique task. They must apply rules of the road and execute maneuvers that are far from automatic and therefore require more attention that is true for experienced drivers.[7] At the same time, they must actively problem-solve during emotionally-loaded situations, even though many have not yet reached emotional maturity.[16] Finally, they must attend to potential hazards in the face of substantial distractions, which appear to pose a greater risk to novice drivers than experienced drivers. [43] This is noteworthy because today's adolescents face unprecedented sources of distraction, including new technology (e.g., smartphones) and older technologies that offer more distracting options (e.g., satellite radio) or are designed to attract more attention (e.g., digital billboards).[43] Our preliminary data suggest that sleep restriction alters both mood regulation and attention in ways that could be dangerous for adolescent drivers.

Sleep Restriction and Mood Regulation

As shown in Figure 1, both parents and adolescents report that teens have poorer control of their emotions after sleep restriction, and that they are especially prone to irritability and anger.[13,44] We have also found that teens with disordered sleep have impaired emotional decision-making skills.[45] Together, these findings suggest that, when they are low on sleep, young drivers may respond more negatively to irritating driving situations (e.g., being "cut-off" by another driver), and may consequently make risky driving decisions.

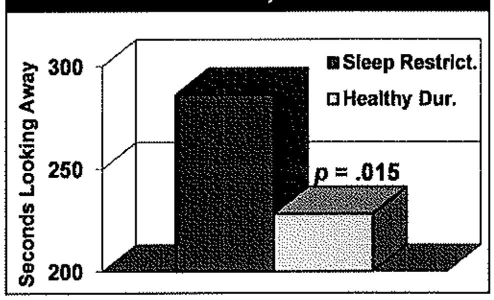
Figure 1. Sleep Restriction Worsens Teens' Mood Regulation and Increases their Irritability and Anger



Sleep Restriction and Attention

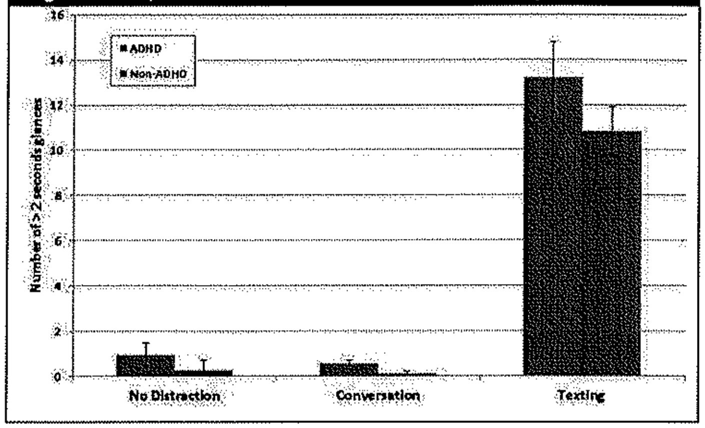
Even in less emotional situations, driving requires continuous regulation of attention. Visual attention must be directed primarily at the roadway, coupled with brief checks on non-roadway information (e.g., dashboard), picking out the most salient information from the many stimuli around them at any given time.[46-49] Looking away from the roadway precedes as many as ¾ of motor vehicle crashes,[50] and young, inexperienced drivers are at particular risk for extended glances from the roadway.[43,51,52] This risk may be worsened when adolescents lack sleep. We have shown that otherwise healthy teens look away from an instructional video significantly more after sleep restriction than when well-rested, even when they know they will be tested on the content (Figure 2).[14]

Figure 2. Sleep Restriction Causes Adolescents to Look Away From a Task



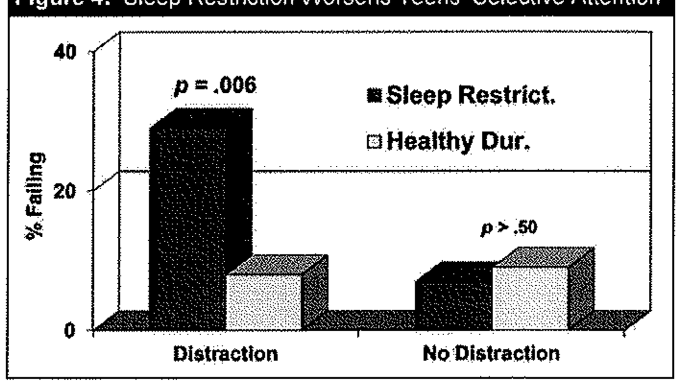
This behavior is similar to what our co-investigator (Dr. Epstein) has observed in adolescents with attention deficits (ADHD), whose poor performance in a driving simulator [1] is statistically mediated by their heightened time spent looking away from the roadway, both without distractions and during text-message interactions (Figure 3, next page).

Figure 3. Impact of Teen Inattention on Looks Away From Road



Other preliminary data suggest that adolescents who have not gotten enough sleep have trouble allocating attention to the most important information in a distraction-filled environment. In the context of our experimental sleep protocol, we gave teens a simple attention task that required them to watch for repetitions in a series of letters. In the *no-distraction* version of the task, only one series was presented in the center of a computer screen. In the *distraction* version, two sets of stimuli were shown, one on each side of the screen; teens were asked to selectively attend to only one side at a time, ignoring the other side. Success was defined as responding to at least 75% of target stimuli with mean reaction times <750 ms. As shown in Figure 4, fewer than 10% of adolescents failed the no-distraction version, and teens who were well-rested were similarly successful even when faced with distraction. However, after sleep restriction, 3.5 times as many teens failed the distraction task, including ¼ of the teens who passed the task when well-rested. The distractions were not compelling – certainly less than a ringing cell phone or a digital billboard – yet sleepy teens had much more difficulty blocking them out to focus on the most important visual information.

Figure 4. Sleep Restriction Worsens Teens' Selective Attention



These preliminary findings provided intriguing evidence that correlations between short sleep and adolescent automobile crashes might reflect a true cause-effect relationship. Of note, experimentally induced short sleep affects adolescents' emotion regulation and attention even while they are clearly awake. This is important because teen crashes rarely resemble the long-drive "fall-asleep" crashes that have been most clearly linked to sleep deprivation in adults. Indeed, we posit that deficits in attention and emotion regulation are critical mechanisms by which short sleep hampers the skills of our most vulnerable young drivers. However, our preliminary findings had 4 key limitations:

1. We gathered data only during summer months. While ethically sound – experimentally restricting teens' sleep could harm their school performance – the summer-only protocol raises questions about whether the same effects would be found during the school year. The school year is accompanied by a unique set of driving patterns (teen crashes cluster near schools and time periods near the start and end of the school day)[9] and sleep patterns (e.g., school-night sleep restriction).[17]
2. We used the same sleep schedules for all participants, regardless of their habitual sleep patterns. While this guaranteed a gap between the well-rested and sleep-restricted conditions, it is not clear how much our effects have been due to lengthening sleep vs. restricting sleep relative to a given adolescent's usual sleep schedule. If the goal is to prevent crashes during the school year, it will be important to determine the effect of lengthening sleep for those most exposed to sleep restriction.
3. Our sleep protocol was limited to five-night periods. While it was a clear step ahead of the single-night full-deprivation protocols that had dominated (and are still most common in) sleep research,[13] our protocol could not capture the potential for week-to-week accumulation of sleep debt. The limited available research on longer-term sleep restriction in adults suggests that objective performance can continue to decline from week to week, even after subjective ratings of impairment level off.[53]

4. The outcome measures for our sleep restriction protocol have not resembled driving. It remains to be seen whether, for example, sleep restriction will affect visual attention to a roadway in the same way it does for an instructional video.

Because of these limitations, we considered our findings prior to the current study to be promising, but as-yet insufficient to justify large-scale, potentially costly motor vehicle crash prevention efforts that target adolescent sleep.

MOVING THE FIELD FORWARD: THE CURRENT STUDY

Overview

Before large-scale efforts to address adolescent sleep are undertaken, a small-scale efficacy trial was needed to test whether alleviating exposure to sleep restriction during the school year improves driving skills. To allow for a true test of cause-effect relationships, the trial had to be experimental. Further, the trial had to be done with adolescent (not adult) drivers because of differences in sleep patterns and the unique challenges faced by novice drivers. It also had to address the limitations of our preliminary work, particularly with respect to the nature and timing of the sleep protocol and the applicability of outcome measures to driving situations. Finally, it had to do so in an ethical manner that does not increase the risk for injury, school failure, or other adverse outcomes.

The Ohio EMS grant funded a small-scale trial that met all of these criteria. For this trial, we focused on healthy, licensed 16-18 year-old high-school students who regularly obtained 5-7 hours of sleep on school nights. Just under half of high-school students do so,[17,29] heavily exposing them to chronic sleep restriction (the clinical recommendation for teens is 9 hours).[33,54] We capitalized on periods of relative stability in sleep patterns during the school year to run 26 participants through a 5-week protocol: a baseline week to determine habitual sleep, followed in counterbalanced order by 2-week spans in which school-night bedtimes and rise times are (a) matched to the baseline or (b) modified to increase time in bed by $\geq$ 1.5 hours/night. This protocol provided a real-world test of the benefits of lengthening the school-night sleep of habitually sleep-deprived teens. Further, the protocol mitigated ethics concerns, since it never restricted sleep below each teen's habitual level.

As in our past work, sleep was objectively monitored to verify adherence. At the end of each sleep manipulation condition, we assessed participants' skills in a driving simulator on a course designed to mimic daily suburban and light urban driving. State-of-the art eye tracking and performance monitoring within the simulator was paired with table-top and questionnaire measures of attention and mood.

Study Design Details

Data collection occurred during the 2014-2015 school year and the first half of the 2015-2016 school year. We had anticipated being done with data collection by the end of that first school year, but the study start was delayed at first while contract details were worked out.

Recruitment, Screening, and Informed Consent/Assent Procedures

With the assistance of the Clinical Trials Office at CCHMC, flyers were placed in the community and on electronic media (e.g., CCHMC's Facebook presence). Once a prospective participant contacted us, study staff followed up with the parent and adolescent via telephone to provide more information and conduct an initial eligibility screening (verified in-person at the baseline office visit).

Inclusion Criteria:

- Adolescents were considered for inclusion if they were 16-18 year old licensed drivers attending high school at the time of participation.

Exclusion Criteria:

For ethics reasons, we excluded for:

- Parent report of a professionally-diagnosed psychiatric disorder, suspicion of recurrent illegal substance use, or a history of neurologic illness or injury; such adolescents are considered to be particularly vulnerable subgroups and therefore less suited for this preliminary clinical trial;
- Routine sleep <5 hours/night on school nights; this was judged too far from recommendations to ethically prescribe during the TYP condition (instead, we will offer sleep clinic referral information).

To ensure relevance and rule out conditions that could interfere with the sleep manipulation or measurement of our outcomes, we further excluded for:

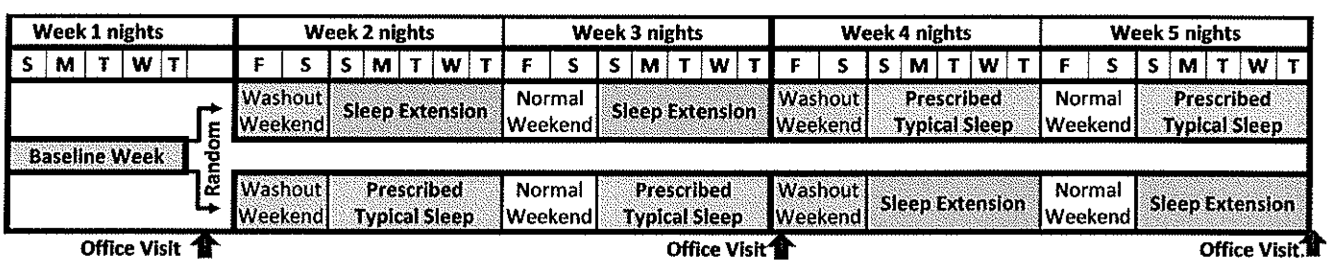
- Habitual sleep >7 hours on school nights (for this initial study, the focus was on teens clearly exposed to habitually restricted sleep);
- Use of a medication that affects sleep or daytime alertness, which could affect the success of our sleep manipulation or could mask manipulation-induced changes in daytime functioning;
- Symptoms of obstructive sleep apnea or periodic limb movement disorder (via validated screeners),[55,56] which could undermine any benefit of longer sleep;
- Inflexible obligations that would require bedtime later than 10 pm on school nights for a 2 week period (e.g., a job that cannot be temporarily shifted to allow for the sleep extension condition);
- Daily consumption of >1 coffee or "energy drink" or >3 caffeinated sodas, which could mask the effects of changes in sleep or introduce caffeine withdrawal effects;
- Obesity sufficient to risk discomfort in our driving simulator (BMI > 30; height and weight screened via self-report on the phone, then confirmed objectively at the baseline visit).

After passing the phone pre-screening, families were scheduled such that no participation occurs during the first week of a semester, final exam week, or vacation. The family was mailed a copy of the consent and assent materials and encouraged to review them in advance. To minimize the chances of losing track of subjects due to changes in phone number or address, staff obtained multiple contact options at the time of the initial screening, including alternate phone numbers and e-mail addresses (if available). Around 2-3 weeks prior to their scheduled participation in the study, each family was contacted to solicit and answer questions regarding the study, confirm contact information, confirm dates of participation, set up a plan for delivery of the sleep monitoring equipment (generally via Fed-Ex with tracking), and review the consent/assent forms and information. When the family arrived for the first office visit at Children's, we reviewed and had families sign consent and assent forms.

Sleep Protocol

Similar to our prior work,[13,14,44,57,58] we used a within-subjects, randomized cross-over design, with all sleep obtained at home, monitored via sleep diaries and objective actigraphy. A within-subjects design (each participant completes all conditions) was selected over a between-subjects design (random assignment to different conditions) for three reasons: (1) within-subject designs maximize statistical power by minimizing the impact of subject-to-subject differences in driving skills, (2) a within-subject design helped ensure complete recruitment, as between-subjects designs usually need at least twice the subjects to get adequate power, and (3) a within-subject design maximized interpretability of results by eliminating the confounding variables that can occur in modest-sample between-samples work (e.g., inadvertent differences across groups in sex, socioeconomic status, driving experience). A randomized cross-over design – meaning that every participant got both experimental conditions, but the *order* they got them was randomly assigned – ensured that the sleep intervention conditions did not systematically occur in the same order, which otherwise would confound the effect of the condition with the effect of completing our measures multiple times. Finally, we chose to have teens sleep at home instead of in a tightly-controlled inpatient setting for three reasons: (1) a long inpatient stay would be unfeasible for most families, (2) inpatient stays can cause atypical sleep quality because sleep is sensitive to environmental cues, and (3) the findings and lessons learned from a sleep-at-home study will more readily translate to future larger-scale effectiveness/ dissemination work.

As illustrated below, each participant who completed the study was involved for 5 weeks,



beginning with a *Baseline Condition* comprised of five school nights during which he or she kept a normal sleep schedule. Excluding nights reported to be highly atypical, this became the reference point for subsequent weeks. Sleep monitoring was done continuously at home throughout the study. On the Friday afternoons at the end of the baseline and both experimental conditions, teen/parent dyads came to Cincinnati Children's for 2-hour office visits between 2 - 6 pm, the time-frame with the greatest concentration of fatal [59] and non-fatal [9] teen crashes. The baseline visit focused on gathering background data, introducing teens to the driving simulator and other measures, reviewing sleep diary and actigraphy data with the parent and teen together (allows for detection of artifacts and reinforces teens' awareness of sleep monitoring), and discussing the next condition's sleep schedule. After successful completion of the baseline visit, participants were randomly assigned to either (a) go through a prescribed typical sleep condition followed by sleep extension or (b) go through a sleep extension period followed by a return to prescribed typical sleep. These two conditions are described below.

Prescribed Typical Sleep (TYP). Bedtimes and rise times on school nights matched the baseline. Office visits on the Friday afternoon at the end of this and the sleep extension condition included the outcome measures, joint review of sleep monitoring data, and sleep instructions for the next condition.

Sleep Extension (EXT). In this condition, we problem-solved with teens and their parents ways to extend the teen's sleep by ≥1.5 hours on school nights. This typically involved detailing the events of each day and planning activities in a way that either freed up more time in the evening or in the morning (though results below reflect that adolescents were rarely able to carve out time to sleep in the morning; they already awaken about as late as they can on school days).

Weekends. To maximize real-world generalizability, and to promote adherence by giving teens planned "breaks," we allowed them to self-select their bedtimes and rise times for the weekends, provided they did not shift their sleep phase (bedtimes and rise times) by >2 hours.

Of note, two nights of adequate sleep has been shown to normalize thinking skills in sleepy teens and adults.[32,60-63]

Caffeine Use and Napping

Excessive caffeine use (>300 mg/day) can impact sleep and daytime functioning. Half of teens have some caffeine daily,[17,64,65] but 93% have $\leq$150 mg (one 8-12 oz coffee or energy drink, or 2-3 sodas).[64] To retain a representative sample but avoid artifacts of heavy caffeine use or withdrawal,[66] we allowed mild use but excluded teens who regularly drank >1 coffee/energy drink or >3 caffeinated sodas per day. At the time of consent and each office visit, teens were asked not to have more than 2 such sodas or 1 coffee/energy drink per day during the study, nor any caffeine after 1 pm. Caffeine effects are dose-dependent, so such limited use has negligible effect on sleep.[67,68] Weekday napping is rare in teens,[17] and we asked them not to nap during the study.

Measures

Sleep/Adherence Monitoring

Throughout each teen's 5-week participation, he or she wore a Micro-Motionlogger SleepWatch® (Ambulatory Monitoring, Inc.; AMI) and reported his or her sleep-wake patterns on a daily sleep diary. The SleepWatch actigraph functions outwardly as a wristwatch, while covertly collecting movement data that are entered into an algorithm to infer sleep and wake states. Similar technology is now used in commercial products such as Fitbit® and FuelBand®, though the AMI units have better-established validation data. Sleep-wake estimates derived from AMI materials and algorithms have >90% agreement with EEG-defined sleep in healthy teens.[69,70] Data were uploaded at each office visit assessment and, with the support of the sleep diaries and follow-up queries to teens and parents, research staff identified artifact-free periods for processing to obtain objective indexes of sleep onset, offset, and duration.

Driving Simulator and Driver Tracking System

Our driving simulator at Cincinnati Children's is overseen by Drs. Beebe and Epstein, and was developed in coordination with Systems Technology Incorporated (STI; www.stisimdrive.com). Our system provides a 135-degree driver field-of-view with integrated rear-view and side mirrors, a full-size steering wheel with dynamics-based feedback, full-sized foot pedals, and a fixed-base, adjustable full-size car seat. The simulator is equipped with a high-definition digital camera to record the behaviors of the driver, with excellent resolution for facial expressions and gestures. In addition, the simulator is outfitted with a Tobii mobile eye tracking system (www.tobii.com)—a portable, wireless apparatus that consists of a video-based eye tracker fully integrated into a lightweight glasses frame.

This system allows us to present diverse driving challenges in a relatively immersive environment while recording the driver's performance, outward appearance, and eye gaze. While driving simulators are not real-world, they allow for careful control of driving conditions, precise measurement of driver behaviors, and the presentation of driving challenges that would be impossible to ethically reproduce with adolescent drivers in a real-world setting (e.g., it would be unethical to purposefully put young drivers in situations that could cause a crash). It is also reassuring that STI systems have been found to validly predict real-world driving errors in healthy adults [71] and in other high-risk groups such as older [72] and brain-injured adults.[73] Finally, STI systems are sensitive to driving impairments related to adult obstructive sleep apnea,[74,75] adult sleep deprivation,[76-78] clinical attention deficits in adolescents,[1] and teen text messaging.[1,79]

Participants completed an initial 7.5 minute training drive at the baseline visit to familiarize them with the controls and "feel" of the simulator. That training drive also introduced and desensitized them to a brief mood rating procedure, in which a recording periodically asked the teen to rate 3 emotions on a 1-10 scale (10 = most intense): tired, nervous, angry. These questions were asked just prior to the starting the training drive, then approximately every 2.5

minutes during the drive, to minimize the novelty of the process. This procedure allowed us to gauge the participants' subjective mood state in a brief conversational manner that has minimal impact on driving (as illustrated in Figure 3, above, and further documented in our published work, simple verbal interactions do not hamper simulator performance).[1]

At each experimental week office visit, adolescents completed a 5-minute practice drive to re-acquaint themselves with the simulator, followed by a 20-minute assessment drive. Two parallel drives were used, in counterbalanced order. Both were adapted from our prior work,[1] reflecting the suburban and light urban driving conditions that confer the highest risk for teen crashes (multiple turns, low speed, moderate traffic, frequent stops).[9] Both drives incorporated similar challenges, but the drives were modified somewhat (e.g., building appearance, look and timing of challenges) to minimize the effect of recall from one condition to the next. Teens were asked to follow all rules of the road, speed limits, and signs.

The 20 minute assessment drive was divided into 10 minutes of free-driving (no added distractions) vs. 10 minutes of a text-message conversation (in randomly counterbalanced order). In our prior work, the text-message interaction was found to reliably challenge visual attention (see Figure 3, above).[1] As in that prior work, the texting period involved a continuous interaction with an out-of-view member of the research staff who was using lists of queries from *The Book of Questions*,[80] ranging from straightforward questions (e.g., favorite food) to more complex situational questions (e.g., what would the teen do if they found a wallet with a lot of money in it). On 4 occasions (2 in non-distracting setting, 2 in distracting setting), the simulator was programmed to present driving challenges that could evoke an emotional response (e.g., cut-off by another driver). Finally, the 1-10 mood ratings occurred at 8 roughly equal intervals.

Data were continuously recorded, with driving and eye tracking data recorded multiple times each second. These data are currently being processed, but will allow for a wide range of potential outcomes, including indexes of steering accuracy and control (standard deviation of lateral position relative to lane), crash rates, missed signals, and eyes spent looking at or away from the road. The driving simulator outcomes are well-established in the automobile safety literature and, although newer, eye tracking data have proven to be reliable and valid in simulated and real driving scenarios, contributing substantially to our understanding of errors by novice drivers.[81-84] Although single-item subjective mood rating scales are subject to moment-to-moment variability, driving impairments have been effectively predicted by such brief self-ratings of sleepiness[77,78,85,86] and single-item mood items are sensitive to overall changes in mood due to sleep deprivation[30] as well as responses to an induced stressor during sleep deprivation.[30]

Other Experimental Week Outcome Measures

We also administered a number of outcome measures outside of the simulator that were intended to tap into real-word driving behaviors and potential mechanisms by which lengthening sleep might affect teen driving:

1. Self-reported driving safety, including , including crashes, moving violations, and near-collisions (adapted from Reason and colleagues' Driving Behavior Questionnaire; DBQ).[87]
2. Teen-completed tests that have been linked to driving impairments or sleep deprivation, including the Psychomotor Vigilance Test[88,89] (sustained attention), Balloon Analogue Risk Task[90,91] (risk-taking), and the divided attention task described above (selective attention).
3. Short-form questionnaires completed by parents and teens that assess the teen's attention, mood regulation, and impulse control.[13,44]
4. A safety check used in our prior work that queries teens about injuries during each condition, as well as the degree to which the teen considers any injuries to be related to sleepiness

Background Information (Baseline Only)

Although not central to our hypotheses, several variables were collected at the baseline visit to characterize the sample and to allow for post-hoc exploration of whether subgroups of teens are particularly helped by sleep extension. These included:

1. Typical driving behaviors and months of driving experience, as indexed by Barkley's Driving Questionnaire[92] and Reason and colleagues' DBQ.[87]
2. Parent- and teen-report questionnaires to assess demographic factors (e.g., sex, race/ethnicity; parent income, education) and the teen's health history and sleep habits,[93,94] tendency towards sensation-seeking,[95-97] and typical/habitual emotion regulation and attention.[98-101]
3. Baseline sleep quality as measured by actigraph indexes of sleep efficiency.
4. Teen Height and weight as assessed using calibrated hospital scales and converted to age- and sex-corrected BMI z-scores using CDC norms.

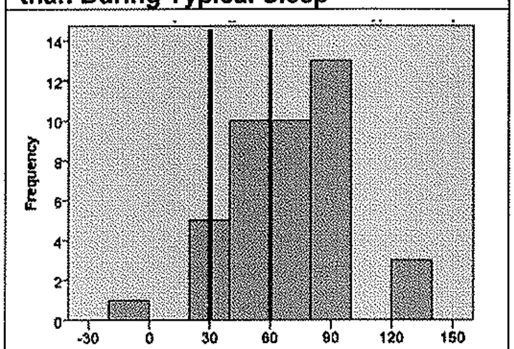
STUDY FINDINGS TO DATE

The simulator and eye tracking data files are fairly massive and require considerable preprocessing before they can be confidently interpreted. Given that the final data collection occurred in November 2015, it is premature to provide findings derived from those measures. We will be harnessing internal funds to continue to process those data and anticipate disseminating the findings within the next year. That said, there are three sets of findings worthy of reporting to date:

1. It is feasible to lengthen sleep in habitually short-sleeping adolescents

The first set of findings was initially presented at the SLEEP 2015 meeting, which is the annual version of the largest sleep research conference in the world.[102] That presentation pooled the data collected to that point in the current study with data from a similar sleep protocol that examined different outcome measures in a different sample of adolescents. At that time, 42 of 68 (62%) enrolled adolescents were able to complete the 5-week protocol. Of those who completed and had full actigraphy data, 93% averaged at least 30 minutes more sleep on school nights during the two sleep extension weeks as compared to the two weeks of prescribed typical sleep. During both weeks of the extended sleep condition, teens averaged 1.1 – 1.2 hr longer sleep on school nights (7.4 hours both weeks) than during either week of the prescribed typical sleep condition (6.1 – 6.2 hours), $p<.001$. Sleep duration during both weeks of the prescribed typical condition was similar to the baseline week (6.4 hours). This overall pattern of results was also evident in the final sample for the current study. We scheduled 42 teens, of whom 37 showed and were randomized to an order of sleep conditions, and 26 (62%) completed all 5 weeks. Of the 26, all but one (96%) averaged at least 30 minutes

Minutes More Sleep During Extension than During Typical Sleep



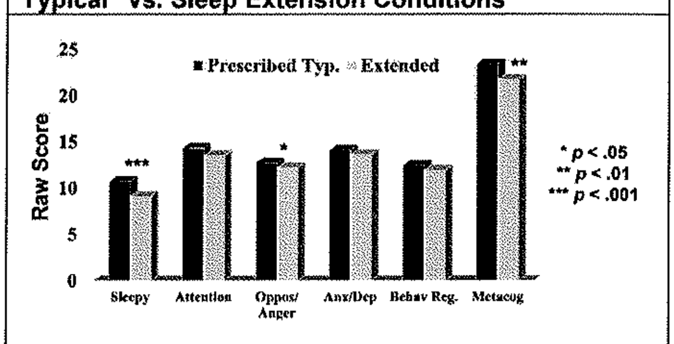
more sleep on school nights during the sleep extension condition than the prescribed typical sleep condition. Of note, essentially all of that additional sleep time during sleep extension was due to going to bed earlier; the adolescents in this study reported that they generally could not rise any later in the morning or they would risk being late for school.

These initial feasibility findings are important for several reasons. First, they show that a relatively brief problem-solving intervention can result in substantive changes in sleep, even amongst adolescents who habitually get well below the recommended nightly amount of sleep. Second, they suggest that the effects can be sustained across multiple weeks, which allows for the study of the impact of sleep changes on phenomena that may take some time to develop or occur infrequently (e.g., driving safety/accidents). Third, the feasibility of our experimental design will allow us to show true-cause effect relationships. Fourth, because no adolescent was asked to sleep less than they normally do, the protocol was done ethically during the school year. Finally, the study conditions were realistic; they did not involve extreme sleep deprivation, but rather allowed us to look at what might happen if the roughly 1/3-1/2 of adolescents who regularly sleep 5-7 hours on school nights were to, on average, increase that by an hour.

2. Effect of Longer Sleep on Behaviors and Mood

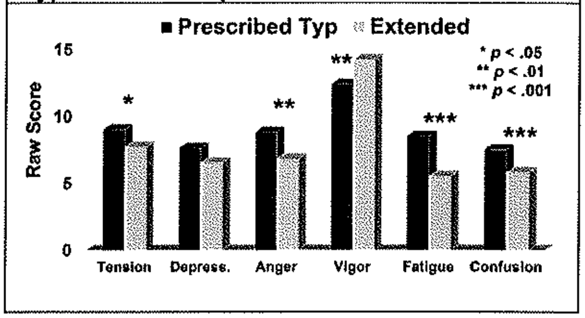
The second set of findings has been submitted for presentation at the SLEEP 2016 meeting and is currently under review. This set was again based upon pooled data, and focused on parent- and teen-report questionnaires asking about the adolescent's behaviors and mood. Compared to when getting their typical amount of sleep, when they were in the sleep extension condition the adolescents both self-reported and were reported by their parents to be less sleepy (p<.01) and to have better

Teen Report of Behaviors in the "Prescribed Typical" vs. Sleep Extension Conditions



metacognitive skills (e.g., planning, organization, p<.01). Teens also self-reported less tension (p<.05), anger, confusion, and fatigue (p<.01) during the sleep extension condition.

Teen Report of Mood in the "Prescribed Typical" vs. Sleep Extension Conditions



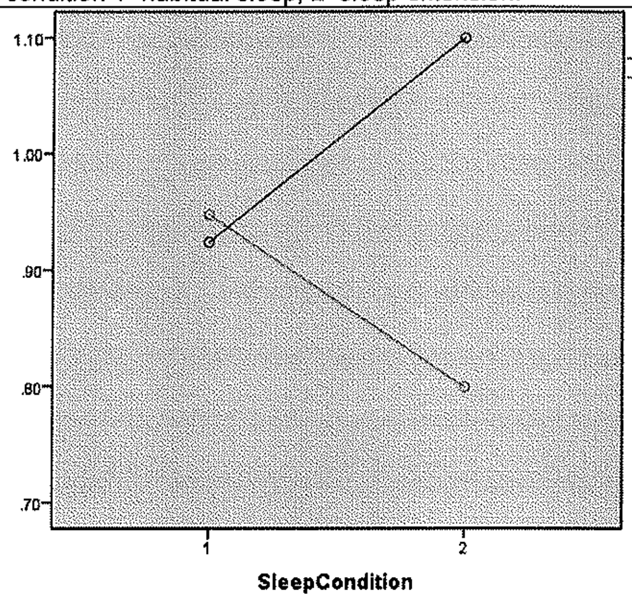
Whereas previous research has shown that experimentally shortening adolescents' sleep causes deterioration in mood and metacognitive skills, this set of findings was the first to show that lengthening the sleep of "naturally" short-sleeping adolescents can alleviate these symptoms during the school year. Insofar as sleepiness, poor planning, disorganization, and anger/irritability, influence adolescents' driving, these data also suggest that lengthening these teens' sleep might reduce driving risk.

3. Effect of Extending Sleep on Sluggish Cognitive Tempo and Report of Driving

One of our secondary measures examined a construct called "Sluggish Cognitive Tempo" or SCT. Initially conceptualized as a deficit intrinsic to attention-deficit/hyperactivity disorder, SCT has since been shown to overlap with ADHD but to be distinct from it. Characterized by fluctuations in arousal and inconsistent ability to arouse attention or react quickly, SCT may be even more closely related to drowsy driving than more "pure" measures of attention. In a second submission to SLEEP 2016 that is currently under review, we report on the impact of our sleep manipulation on measures of SCT and the teen-reported driving behaviors from our adapted DBQ (e.g., "Had to slam on the brakes to avoid a collision"). Adolescents reported fewer SCT symptoms during the sleep extension condition than typical sleep condition (p<.001). Further, the degree of change in those SCT symptoms interacted with the sleep condition to affect reported driving. Specifically, teens who showed the most improvement in SCT symptoms during sleep extension were also those who had the most improvement in reported driving skills.

We have previously published that teens whose attention worsens during induced sleep restriction are the same teens who have concurrent worsening of their skills in a driving simulator.[103] The new findings represent the first evidence that this may be reversible. Improving adolescents' sleep may improve driving safety. If even a subset of short-sleeping adolescents show improved driving after a modest increase in sleep duration, we would have struck upon a largely untapped injury prevention target.

Teens Whose Cognitive Tempo Improved after Sleep Extension also Improved their Driving. Blue line (top) reflects teens who showed an alleviation of sluggish cognitive tempo symptoms during sleep extension; green (bottom) are those who showed no gains. Sleep condition 1=habitual sleep, 2=sleep extension.



PUBLIC POLICY IMPLICATIONS & RECOMMENDATIONS

We continue to analyze data from this study. In the coming months, we will use institutional funds to fully process the extensive eye tracking and driving simulator data to objectively probe these effects and potential mechanisms for them (e.g., is change in driving skills related to change in glances away from the roadway?). If our preliminary findings are correct, this study could provide Ohio with a new approach to improve driving safety in our most vulnerable drivers, reducing morbidity, mortality, damage-related costs, and societal burden.

First, such findings would indirectly support continuation of graduated licensing provisions that limit adolescents' night driving. Not only are the skills needed to drive at night someone unique (e.g., driving with reduced visibility, driving at a disadvantageous point in the internal day-night clock) but staying out late can contribute to chronic sleep restriction. We previously showed that chronic sleep restriction reduces lateral vehicle control in at least some adolescent drivers.[103] Current data suggest that improving the sleep in the roughly 1/3-1/2 of adolescents who regularly get 5-7 hours of sleep on school nights can alleviate this effect. **Recommendation:** Continue restrictions on night driving for newly-licensed adolescents.

Second, findings suggest that public safety may be improved by measures to lengthen adolescent sleep. Because neither we nor the families with whom we worked had any control over school schedules, in practice our "extended sleep" condition involved adolescents going to bed earlier (rather than waking up later, which would have made them late for school). This is the first study to examine the impact of experimental sleep extension on driving-related skills in adolescents, so it still represents an important step. However, there are no sure-fire public policy ways of getting adolescents to bed earlier. Options include public education, restrictions on evening work hours, and limitations on other evening activities (e.g., placing caps on evening athletics). The secondary effects of such activity restrictions are not known (e.g., limiting socially-mandated evening options might lead some teens to turn to less social-mandated options). Public education campaigns have had some success in other aspects of adolescent health, though they need to be done carefully to be effective. **Recommendation:** Incorporate sleep recommendations into state guidelines for educating adolescent drivers. Consider a public health education campaign emphasizing the importance of prioritizing sleep for adolescents' health and safety.

An alternative that is likely to have a fairly immediate impact would be to shift early high school start times closer to accepted "business hours" of adults. Middle schools and high schools in the State of Ohio start typically start before 8 am, earlier than 80% of other states, and earlier than the bordering states of Indiana, Michigan, Kentucky, and West Virginia.[104] Although we are unaware of state-by-state data on adolescent sleep, it has been repeatedly shown that earlier high school start times are linked to shorter student sleep.[105] Further, large-group studies have shown that metropolitan areas with teens who sleep longer have lower crash rates than very similar areas with teens whose sleep is restricted by early school start times.[11] One study from Kentucky showed that local teen crash rates went down after a county-wide school district delayed high school start times by an hour, even as teen crashes increased in surrounding areas.[12] Of note, Kentucky's middle and high schools now start later than most other states.[104] Although thorough coverage of the potential benefits of delaying school start times extends beyond this report, the reader is referred to several references [105-107] and videos (http://www.cehd.umn.edu/carei/sleepresources.html) for guidance. **Recommendation:** Promote guidelines for high school start times in the state of Ohio that conform to standards set by the American Academy of Pediatrics.[107]

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