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Effects of Recent Concussion on Simulated Driving Performance in Young Drivers

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Abstract

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The symptoms of a concussion include difficulties with balance, concentration, ocular-motor function and sensory integration. Concussions are common among young people given their exposure to sports and risky behavior. Driving safely can pose challenges for healthy teens and young drivers who are learning new skills. Young drivers are at greater risk of crash compared with experienced drivers. Drivers under 19 years of age are three times as likely to be in a fatal motor vehicle crash compared with drivers who were 20 years or older. The impact of recent concussion on driving ability has not been well studied.

This prospective cohort study examined the impact of concussion on young drivers between 16 and 25 years of age. Case and control participants were evaluated by cognitive testing, survey response, and simulated driving. Case participants performed study tasks within two weeks of injury, and again after four to six weeks of recovery. Control participants were young drivers in the same age group who had no recent history of concussion, and performed the same tasks as case participants. At baseline, drivers with recent concussion had more difficulty engaging in a secondary task while driving at the baseline visit, but did not have the same difficulty in comparison to control participants at the follow-up drive. Significant differences were observed in performance using a tactile detection response task (TDRT) during simulated driving. The concussion group showed slightly riskier driving behavior, reaching higher speeds, rates of acceleration, and allowing less time-to-collision. The data from this study suggest the need for additional studies to examine the association between concussion and real-world driving risk.

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Chapter 1. INTRODUCTION

Concussion is a traumatic brain injury induced by biomechanical forces. Most individuals who sustain a concussion will have symptoms lasting between 1 to 4 weeks, from which they completely recover (McCrory et al., 2017). The effects of a concussion vary widely, depending on the severity of the injury, age, health, individual factors and recovery time. Concussion symptoms may include physical symptoms like headaches, impaired balance and nausea to cognitive symptoms such as difficulty with concentration or memory. The 2016 Berlin Concussion Conference updated recommendations on returning to school, work or physical activity, but there is insufficient evidence to guide recommendations regarding driving after concussion (McCrory et al., 2017).

Driving is a component of independent functioning for many individuals, particularly where there is little access to public transportation. Particularly for young and inexperienced drivers, operating a vehicle is a demanding cognitive task. Younger drivers are an inexperienced and relatively vulnerable population with high crash rates (CDC, 2016). Brain maturity is not complete in young adults until the early twenties (Johnson et al., 2009).

Teens and young adults who remain symptomatic following a recent concussion may face additional driving risk. Concussion symptoms such as memory loss, slowed reaction time, or impaired concentration may also increase the likelihood of driver error or crash risk. Previous work, however, has suggested that concussed individuals may continue drive for expediency (Preece et al., 2010). This goal of this cohort study was to explore whether concussion was associated with performance differences during a simulated driving task for in young drivers aged 16 to 25 years. Case participants were young drivers who sustained a concussion within two weeks of enrollment. Control participants were drivers in the same age group, but had not recently sustained a concussion. Participants agreed to complete surveys as well as cognitive testing and simulated driving tasks, once at a baseline visit and once at a repeat visit 4-6 weeks later. The repeat visit allowed the study to (attempt to) measure driving abilities over the concussion recovery period.

This thesis is separated into five sections. Chapter 2 is a review of scientific literature and provides the background for the research study. Chapter 3 describes participant recruitment and data collection. Chapter 4 describes the analytical approach for each research question. An analysis of variance (ANOVA) analysis examined the associations between simulated driving performance measures and concussion. Chapter 5 examines the limitations of this study and considers implications for future research. Chapter 6 reviews study conclusions and summarizes the study findings.

Chapter 2. LITERATURE REVIEW

2.1 YOUNG DRIVERS, CRASH RISK, AND CONCUSSION

Driving is perhaps the most dangerous activity for young adults (16-25 years), Motor vehicle crashes are the leading cause of death for U.S. teenagers (Centers for Disease Control and Prevention, 2016). According to the Centers for Disease Control and Prevention (CDC), drivers aged 16-19 years are nearly three times as likely to be in a fatal motor vehicle crash compared to drivers aged 20 years and above (CDC, 2016). Young drivers may lack the experience or skills to identify a rapidly emerging driving risk and may fail to react quickly and decisively. They are generally riskier drivers, are susceptible to distractions, and in recent years, young drivers are increasingly attached to technology like smartphones (O'Connor et al., 2017). Additionally, crash risk for teen drivers increases for males, those driving with teen passengers, and drivers in the first few months of licensure (CDC, 2016).

Driver inexperience is significantly associated with teen and young driver crashes. According to a report by the National Academy of Sciences, using a compilation of various national sources, drivers within the first six months of licensure are eight times more likely to be involved in fatal crashes than the most experienced group of drivers, and still two to three more times as likely after six months (National Research Council, 2007). Crash risk is highest in the first 500 miles driven after licensure (McCartt et al., 2003). Inexperience has also been shown to be a greater risk factor than age/immaturity, according to a study analyzing 16-19 year old driving behavior (McKnight & McKnight, 2003).

Within the young driver population, differences exist between male and female drivers

and their crash rates (Amarasingha & Dissanayake, 2014). In this 2014 study using crash data from Kansas (KDOT), young, male drivers had higher crash rates and were at higher risk of being involved in vehicle crash. For young male drivers, driving with young passengers significantly increased crash severity. Contributing factors were relatively similar between male and female drivers: driver inattention, speeding, failure to yield, and disregard for traffic control were contributors to crash risk (Amarasingha & Dissanayake, 2014).

The variability in risky driving behavior of young people is difficult to quantify. A 2013 naturalistic driving study followed 42 teenagers within the first 18 months of driving, using instrumented vehicles to measure crash and near-crash rate. Three "risk" groups were defined as high, moderate, and low crash risk. Crash risk declined over time only for the moderate-risk group, meaning that the high-risk group appeared to be insensitive to experience (Guo et al., 2013).

Researchers at the University of Michigan Transportation Research Institute (UMTRI) studied the risk behaviors of young drivers. Distraction, inattention, and risky behaviors led to crashes, and increased risk taking. In a 2015 driving simulator study, young male drivers, when placed with a "risk-accepting" passenger, were more likely to continue through yellow lights, overtake vehicles, and run occluded stop signs, than when driving alone or with a "risk-averse" passenger (Bingham et al., 2016).

Further research into peer pressure and normative behavior in teens and young adults demonstrated that peer influence may not always be detrimental. Some teens reported that they would intervene if a friend engaged in risky behavior (Buckley & Chapman, 2016). While a large portion of research on young drivers focuses on driver behavior and influences, some feel that a comprehensive systems approach may be most effective. A 2015 study considered the

possibility that education, training, and public policy (safe driving campaigns) may not be sufficient in reducing teen driving mortality rates, and that considering the safety of the external road system may be a key component. Comparing systems and drivers across multiple countries, the study found that countries with lower system-induced exposure to risk had lower fatality rates among teen drivers relative to countries with high system exposure to risk (Twisk et al., 2015).

2.2 BACKGROUND ON CONCUSSION

A concussion is defined as a blow, bump, or jolt to the head, causing a force transmitted to the head, that interrupts normal brain activity, and can range from mild to severe (CDC, 2017; McCrory et al., 2017). Following a concussion, individuals may have difficulties with cognitive tasks, processing speed, concentration, reaction time, dizziness and disorientation. Guidelines recommend that individuals who have sustained a concussion seek evaluation from a health professional (Buckley & Chapman, 2016). Concussion symptoms vary depending on the individual and the severity of injury. Concussion may impair normal functionality in four main categories: thinking, sensation, language, and emotion (CDC, 2017). This includes symptoms from headache, dizziness, and nausea, to trouble sleeping, understanding, or feeling sad or depressed. General recommendations for recovery are vague at best, and the CDC advises avoiding strenuous physical activity and mentally taxing tasks. For young people, it is advised that returning to sports and school activities be approved by a physician (McCrory et al., 2017).

Concussions may cause short- and long-term effects. A 2004 World Health Organization study compiled and analyzed existing concussion literature on prognosis after concussion. In adults, short-term cognitive effects (such as headache, dizziness, fatigue, forgetfulness, and

trouble sleeping) typically resolve within the first month after concussion (Carrol et al., 2004). Symptoms like headache are also prevalent in the general population, which can complicate the point at which concussion symptoms are judged to have resolved. The most recent literature suggested that concussion symptoms generally resolve over the course of a month (McCrory et al., 2017), but may persist among some individuals.

Few studies have addressed post-concussive depression and psychological distress, although a 2016 experiment on collaborative care showed that this type of post-concussion care resulted in better symptom recovery than traditional care methods in young a young population suffering persistent symptoms (Carroll et al., 2004; McCarty et al., 2016).

The same 2004 study by Carrol *et al.* examined literature concerning adults with persistent symptoms after sustaining a concussion. Persistent symptoms were associated with patient gender, specifically females, prior physical limitations, life stressors, history of prior head injury, and the inability to return to work. Few studies have examined the longer-term impact of concussion, although a 2014 study examined the long-term effects of concussions among military recruits, and examined possible links between concussion and to diseases like Alzheimer's dementia, Parkinson's disease and chronic traumatic encephalopathy (CTE). This study suggested that just one concussion can lead to neurodegeneration (McKee & Robinson, 2014).

Awareness of concussion has been growing, most notably in relation to sports concussions and CTE, with suicide, neurological changes, and behavioral changes seen in popular athletes of relatively young ages (Greer, 2014). Mainstream media outlets now recognize this increased awareness in football-related concussions. A 2013 Sports Illustrated special report examined the effect concussion has on football at all levels, how it impacts players and coaches,

how tackling technique is changing, and how some may be mishandling concussion incidents (King, 2013). A star-studded 2015 film, "Concussion", attempted to address the issue of CTE in American NFL Football players. The film is fictional in nature, but its release highlights the mainstream concern over repeated head injuries and concussions sustained in sports and their possible consequences.

2.3 CONCUSSION AMONG YOUNG PEOPLE

Between 2002 and 2012, twice as many emergency department visits for sports related head injuries were among the under-19 population (Coronado et al., 2015). Sports concussions are widely studied, and Washington State led the way in implementing "return to play" rules for young athletes with implementation of the Zackery Lystedt law in 2009 (DOH, 2009). Young people may also sustain concussions in many other non-sports related manners (Sojka, 2011). Victims of violence, drivers or occupants in motor vehicle crashes, falls and contact with hard surfaces are other common mechanisms for concussion among young people (CDC, 2017).

Adolescents who report a concussion may be somewhat more likely to report subsequent violent or risky behavior, according to a 2016 study of Australian teens (Buckley & Chapman, 2016). Much of the research in concussion in young people comes from sport related injuries. Several studies have suggested that individuals who sustain a concussion may be susceptible to short-term and long-term risks such as motor system changes and memory and response changes (De Beaumont et al., 2007; Catena et al., 2009).

A 2002 study evaluated the short-term effects of concussion among male high school/college football players, roughly half of whom took a baseline cognitive test at the start of the football season. A follow-up cognitive test was administered at the conclusion of the season

(McCrea et al., 2002). Players who had sustained a concussion took the same concentration test at the time of injury and 15 minutes, 48 hours, and 90 days after injury. Among this sample, 3.8% of the male participants sustained a concussion during the season. Four out of five did not display retrograde amnesia or lose consciousness. Among concussed athletes, cognitive scores were significantly lower at the time of injury and 15 minutes later; however, there were few significant differences noted after 48 hours, however symptoms do persist after this time. Short term symptoms and cognitive performance observed in players with loss of consciousness and retrograde amnesia were significantly worse.

Recent efforts to better educate athletes, parents and coaches about the identification and management of concussion has resulted in the adoption of standardized guidelines for "return to play" and "return to school" (Zirkel, 2016). Even with these protocols in place, a 2000 concussion study of high school and collegiate football players found that 30.8% of injured players returned to the field on the same day as injury (Guskiewicz et al., 2000). Further research and recommendations require that players may not return to the field on the same day of injury (McCrory et al., 2017).

2.3.1 SCAT-3 and Trail Making A and B and Cognitive Testing

The Standardized Concussion Assessment Tool-3 (SCAT-3) and Trail Making (A and B) are two commonly used neuropsychological tests that measure memory, concentration, balance, and can determine impaired performance against a norm (Committee on Sports-Related Concussions in Youth, 2014; Zimmer et al., 2014, Tombaugh, 2004). The SCAT-3 is commonly used for sports-related concussions, and can be conducted on sidelines and physician offices, in order to diagnose and evaluate concussion (British Journal of Sports Medicine, 2013). The

SCAT-3 was the most updated protocol as of this experiment, however an updated version, the SCAT-5, was recently agreed upon at the 2016 Berlin Concussion Conference (Echemendia et al., 2017). The Trail Making tests are hypothesized to measure concentration and speed of processing, and at least one study has shown that the Trail Making test significantly "reflects cognitive abilities of speed and fluid intelligence", meaning that research supports its use in testing for cognitive impairments (Salthouse, 2011).

2.4 CONCUSSION AND DRIVING RISK

There is limited research on the safety of continuing to drive after sustaining a mild traumatic brain injury such as a concussion, and so recommendations have largely been based upon expert opinion. Physicians may recommend that an individual refrain from driving while symptoms are present, howeverthere is no commonly accepted protocol for driving recommendations after a concussion (Preece et al., 2010). Neyens and Boyle examined crash patterns in drivers who had sustained a traumatic brain injury (TBI). Crash rates did not differ between cases and controls, and their study showed no increase in severity of crashes for post-TBI drivers versus controls (Neyens & Boyle, 2012). However, drivers who had sustained a TBI were significantly more likely than controls to get in multiple crashes during the same study period. Other research has shown that young drivers do not necessarily intend to reduce or moderate their driving behavior following a concussion (Preece et al., 2012).

Schneider and Gouvier (2005) showed that the Useful Field of View (UFV) test was a significant predictor for elderly drivers and crashes, to examine concussion victims. The UFV is an extensively researched test for predicting driving ability, crash risk, and performance on other

everyday tasks (Wood & Owsley, 2014). This study found no significant difference in test performance between concussion and control participants (Schneider and Gouvier, 2005).

The additional risks of concussion on driving ability among novice drivers has not been well studied. Driving is a relatively new and challenging task for the younger population given the limited years of experience, and additional safety implications following a concussion are not known.

2.4.1 Tactile Detection Response Task and Cognitive Load

One validated method in testing cognitive load while driving is the tactile detection response task (TDRT); it is a standard method of measuring cognitive workload (ISO/DIS 17488, 2015). The task involves a tactile vibration stimulus, after which the participant is asked to press a button in response. Response time following the tactile task, and miss rates can be measured. One study found that TDRT testing may be most sensitive to the attentional effects cognitive loads (Young et al., 2013). A 2015 study supported this finding, and reported that for simulated and on road driving, the TDRT was a sensitive and reliable method of testing the effects of a secondary task on driver attention and cognitive load (Hsieh et al., 2015).

With a shift toward in-vehicle information systems that rely more on cognitive demand (such as voice controlled systems) rather than the visual and manual systems of the past, there are new risks for drivers. A study by Bengler, Kohlmann, and Lange tested a visual and tactile detection system with different levels of difficulty for listening and counting distraction tasks. They found that visual and tactile detection paradigms could discriminate the difference in task levels, and were sensitive for testing cognitive load (Bengler et al., 2012). For this study, participants were asked to simulate a voice control navigation task with an in-vehicle display

screen, as is detailed in the study methods section.

2.5 SUMMARY

Young drivers and recently concussed individuals may be at increased risk of crash. Driving requires concentration and the ability to react quickly, which can be impacted by concussion. Recent concussion and its impact on the ability of novice drivers is relatively unknown, and research in this area is needed. Chapter 3 describes study methods, including participants and recruitment, study instruments, simulator specifications, study procedures, and analysis.

Chapter 3. STUDY METHODS

Study participants were drivers aged 16 to 25 years of age. We recruited case participants who had sustained a concussion within two weeks of enrollment (n=19); case participants were recruited through campus advertising and social marketing (n=30). Each participant agreed to attend a baseline study visit, during which concussion testing and a baseline driving simulation was performed. Study participants returned for a follow-up visit and simulated driving performance 4-6 weeks following the baseline visit. Participants received \$50 compensation at each simulator visit, baseline and follow-up, as well as a \$30 Amazon gift card at both the baseline visit and upon study completion. The price of parking in the closest parking garage was also covered for each participant.

This study recruited case participants who had a concussion within two weeks of the baseline visit date. Two weeks was chosen as the time frame in an attempt to maximize observed symptoms (and how they affect driving ability) but also to accommodate the schedules of teens and young adults.

3.1 BASELINE VISIT CONSENTING AND SURVEYS

At the baseline visit, the participant reviewed and signed consent to participate in the study. For participants under 18 years of age, a parent also signed consent to participate in the study signed an Informed Consent (IRB Number 51776). The research assistant guided the participant through the requirements, expectations, potential risks and benefits of the study to ensure that the participant had a full understanding. Each participant signed a written consent

form. Participants were also asked to sign a hHealth Insurance Portability and Accountability Act (HIPAA) form, allowing access to medical records concerning possible concussions. These documents are included in Appendix B.

At the baseline visit, participants completed computer-based surveys. Surveys included questions about demographic variables, socio-economic factors, driving behaviors, risky behaviors, cell phone use, recent crash history, concussion details (when applicable), and a 9item depression screening tool: the Patient Health Questionnaire (PHQ-9). Participant surveys are included in Appendix B. Participants were were permitted to skip questions they did not wish to answer.

3.2 CONCUSSION TESTING

After completing the surveys, each participant performed tests of cognition, concentration, balance, and memory (Committee on Sports-Related Concussions in Youth, 2014). The first was the SCAT-3 instrument, which included short-term and long-term memory testing, as well as a commonly used balance test known as the Balance Error Scoring System (BESS) (Bell et al., 2011).

The Standardized Concussion Assessment Tool-3 (SCAT-3) consists of five different activities. For the first activity, the participant is read a list of five words and asked to repeat back as many as they can remember, in any order. This test is repeated two additional times, regardless of whether or not the participant repeats all five words correctly. The second activity involves reading a list of numbers (consisting of three, four, five, and six numbers). Participants are asked to repeat the numbers in reverse order. If the participant is unable to correctly repeat a list in reverse after two attempts, the activity concludes and is scored according to how many

lists out of four were correct. The third activity is a concentration test, in which the participant is asked to list the months of the year backwards, starting with December and ending with January. The fourth activity is a balance test. The participant is asked to stand on her non-dominant foot, other leg lifted, with hands on hips and eyes closed as the researcher counts aloud to twenty. Stumbles are counted and scored according to how many times the participant had to put the other foot down. The fifth activity is a delayed recall test, in which the participant is asked to repeat as many of the 5 words they remember from the initial word list.

Participants also completed the Trail Making test (A and B), a timed concentration test in which participants connect numbers and letters (in circles, scattered on a blank page) in ascending order. A copy of each test is included in Appendix C. Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 – 25, and the participant is directed to draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 - 13) and letters (A - L); as in Part A, the participant is to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The participant is instructed to connect the circles as quickly as possible, without lifting p en or pencil from the paper. The participant is timed as she connects the "trail." If the participant makes an error, the researcher may point it out and allow the participant to correct it. Errors affect the participant's score only in that the correction of errors is included in the completion time for the task.

3.3 DRIVING SIMULATOR

A NADS miniSim 2.2 system from the University of Iowa was used for this study (see Figure 3.1). The miniSim is a PC-based driving simulator used for research purposes.



Figure 3.1 miniSim Fixed-Base Driving Simulator

The simulator provides a sense of realism to the driving environment for an automatic transmission vehicle. The miniSim is a fixed-base simulator and the driver of the simulator does not experience simulated movement. The simulator has a steering wheel, brake and acceleration pedals, a blinker, and a shifter. There are three front display television screens, each 3' by 1.7', which show the driving environment, as well as an instrument panel display screen showing the "dashboard" information like speed and gear. There is also a small touch-screen to the right of the steering wheel which projects information used for navigation and radio tasks, mimicking an in-vehicle information system. The miniSim has a 2.1 audio system, a tactile transducer, a display for the operator/researcher, and collects data at 60 Hz. The miniSim will automatically record driving measurements during a driving session; the measurements of interest are listed below in the dependent variables section.

Video data was collected using GoPro at 720 resolution, with only the miniSim display screens in view. The drive was recorded through a playback system on the miniSim, in which the projection to the display screen is recorded and can later be replayed on the simulator screens.

3.4 SIMULATOR PROCEDURE

Following the signing of the informed consent, surveys, and concussion testing, each participant performed two drives. One was a rural drive involving distraction tasks, and one was a city drive requiring reactions and interactions in a programmed scenario, using the NADS miniSim 2.2 system from the University of Iowa. The simulator experiment was designed as a within-subjects design, with each participant conducting two drives at each visit: a rural drive followed by a city drive.

The order of drives was not randomized in this study. The city drive contained more visual stimulation (turns, braking events, and potential near-collisions) and had a greater potential for causing simulator sickness, so ending with this drive allowed concussion participants to complete the majority of driving activity and for maximum data collection to occur. The experiment was repeated at the follow-up visit. Participants repeated driving simulation tasks one month after the baseline driving simulations study. For case participants, this time interval was selected for resolution of concussion symptoms.

Cohort	Baseline Drive	Follow-Up Drive
Concussion (n=19)	Concussion Baseline (n=19)	Concussion Follow-Up (n=18*)
Control (n=30)	Control Baseline (n=30)	Control Follow-Up (n=29*)

Table 3.1 Cohort Study Design

*two participants did not complete follow up drives (1 concussion, 1 control)

At each visit, participants completed a 2-3 minute practice drive to become comfortable

with the tasks and to accustom themselves to the the simulator steering, braking, and acceleration.

3.4.1 Rural Drive

In the rural drive, participants were asked to maintain a speed of 50 mph while following a lead vehicle. During the rural drive, participants were asked to perform the tactile detection response task (TDRT) and voice control navigation tasks. For the first three minutes of the drive, the participant was asked to focus on driving while also performing the TDRT. Following this, the participant was asked to perform a sequence of voice control tasks in addition to the continuous TDRT. Each participant was asked to perform nine voice controlled tasks. After the nine voice control tasks were completed, the participant was asked to focus on the TDRT for one minute. Four more voice control tasks (in addition to the TDRT) were conducted, followed by another one minute TDRT-only segment to end the drive. The administration of TDRT tasks is shown in Figure 3.2. The lead vehicle drove at 50 mph and braked four times throughout the drive. The drive lasted approximately 10 minutes for most participants.



Figure 3.2 Rural Drive Sequence



Figure 3.3 In-Vehicle Display and Rural Drive Environment

3.4.2 City Drive

In the city drive, specific events were programmed to measure braking behavior, reaction time, and ability to maintain the speed limit and lane position. Braking behavior was measured at three 4-way stops, two vehicle "pull-out" events, and two lead vehicle braking events. Reaction time was measured at both lead vehicle braking events. Speed limit, standard deviation of speed limit, and standard deviation of lane position were measured along straightaways in the scenario. Within the scenario, other vehicles and bicycles were present in order to simulate a real city, provide the opportunity for surprise events, and avoid boredom. Events were designed so that they would not put the driver at risk of a collision. The simulate drive environment was designed to minimize simulator sickness, which was particularly important for patients with concussion symptoms. The city drive was designed to be a somewhat challenging but generally positive driving experience, which lasted about 15 minutes.

At the follow up visit, the city drive done was programmed with the same events in a different order so that the participant could not use their memory of the first drive to predict the exact location of braking events or stops.



Figure 3.4 City Drive Environment

3.4.3 City Driving Scenarios

Within the city drive, several event scenarios were developed in order to obtain measurements for braking, acceleration and speed.

Stops and Signals. Several of the stoplights in the city drive were timed on random 30-second signal timings. Two were programmed to be flashing red, four-way stops in which the participant was expected to stop and then continue straight. These types of stops were included to guarantee that all participants stopped at several of the same locations, and that each had two measurements for braking and acceleration behaviors to and from a complete stop.

Lead Vehicle Braking. Two events were programmed in which lead vehicles brake in front of

the participant. These were programmed to be straightforward so that there was no risk a crash. The events allowed measurement of braking behavior profile.

Pull-Out Events. Two pull-out events were included in the driving scenario. Both involved a vehicle unexpectedly turning right into the lane in front of the participant's vehicle as he or she proceeded straight through a green light. The pull-out events were programmed to measure time-to-collision (TTC) and harsh braking behavior.

Passing and Turning Events. Several bicycles were programmed into the scenario in order to measure how close (time-to-collision) the participant was willing to get before passing, and also to add interest and minimize the possibility of the participant getting bored.

Straight Segment Driving. There were three long segments within the city scenario in which no passing, lane changing, or braking was required. In these segments, participant speed (maximum, average, standard deviation) and standard deviation of lane position (SDLP) was measured.

3.5 VARIABLES

There were two independent variables of interest: the driver group (2 levels) and the visit (2 levels).

Case and Control Driver Group. Case participants were those who had sustained a recent concussion; control group had not sustained a recent concussion. These participants were classified as either "Case" or "Control" participants. Each participant in each group performed the exact same tasks within the study.

Baseline and Follow-Up Visit. Each participant was tested twice, once for the baseline visit and once for a follow-up visit 4-6 weeks after the baseline visit. The concussion group participants had their baseline visit within 1-2 weeks of sustaining a concussion. The participant

measurements were classified as either "Baseline" or "Follow Up".

Explanatory Variables/Covariates. All participants completed self-reported symptom evaluation checklists as well as the concussion assessment instruments (SCAT-3 and Trail Making Tests) at each visit. These checklists and assessments were scored to determine how symptomatic participants were at the time of visit.

3.5.1 Dependent Variables

Variable Name	Variable Description		
Rural			
TDRT Reaction Time	Average reaction time measured for each participant during entire drive, during VCS activities, during drive only time, and the difference between the two.		
TDRT Accuracy (Miss Count)	A measure of how many times the participant fails to press the button in reaction to tactile stimulation.		
Speed	Maximum speed, average speed, and standard deviation of speed.		
Lane Position and Departures	A measure of ability to maintain lane position; standard deviation of lane position and lane departures		
City			
Speed	Maximum speed, average speed, and standard deviation of speed.		
Time-to-Collision (TTC)	A measure of how close to a collision a driver comes, measured in seconds and based on the speed of driver vehicle relative to the lead vehicle.		
Acceleration	Maximum acceleration as a measure of driving aggressiveness.		
Deceleration	Maximum deceleration at braking events as a measure of harsh braking.		
Standard Deviation of Lane PositionA measure of ability to maintain lane po along a straight segment with no lane ch necessary.			

Table 3.2 Dependent Variable Descriptions

Table 3.2 shows the dependent/outcome variables measured within the rural and city drives. These variables were recorded as we hypothesized that concussion may be associated with these driving performance measures.

Speed The ability to follow and maintain a certain speed limit can require careful attention. Studies have shown that drivers exhibit compensatory behavior when distracted, which leads to lowering speeds while distracted (Young and Regan, 2007). Younger drivers were more susceptible to the effects of distracted driving than were more experienced drivers. The standard deviation of speed is a measure of how difficult it is for a driver to maintain the speed limit.

Time-to-collision Time to collision (TTC, seconds) is a measurement calculated as the difference between the lead vehicle velocity and the velocity of the driver's vehicle. A larger TTC is consistent with a greater degree of safety. Standards for use of this measure also show that a TTC greater than 15 seconds can be ignored. "Safe" TTC thresholds can depend on the speed of vehicles and roadway traffic, so its criteria are relative to driving behavior and environment (Engineers and Committee, 2015).

Acceleration and braking "Hard" braking or accelerating can be tracked using a driving simulator, in braking event situations and stopping at four-way stops. According to Verizon's Telematics Technical Information Bulletin used in fleet management, "hard" or aggressive braking occurs at a threshold of 8.77 mph/s (3.92 m/s²). The threshold for hard acceleration is 7.90 mph/s (3.53 m/s²) (Verizon). A measurement of acceleration and deceleration behavior has the potential to provide insight on reaction and braking behavior and differences in aggressive driving between concussion and non-concussion sustaining young drivers.

Standard Deviation of Lane Position (SDLP) Kircher, Uddman, and Sandin (2002) report 0.2 meters as being a typical value for standard deviation of lane position (SDLP)

for an alert driver. According to this 2002 study, SDLP is defined as "a measure of how much the driver 'keeps her track', and is seen as a general performance measure." In their study, the authors found that SDLP increases with fatigue and drowsiness. According to a literature review of 36 studies, SDLPs ranged from 0.13 m to 0.85 m, with a mean of 0.26 m (Green et al. 2004).

3.6 DATA REDUCTION

The miniSim provides data for over 200 variables including all the ones being analyzed for this study. For this analysis, key measurements were needed only at certain events or places within each drive.

For the rural drive, the measurements were taken for the TDRT speed and accuracy continuously, as the TDRT was performed throughout the entire drive. Measurements for lane position and departure were also taken continuously through the drive. Speed (maximum, mean, and standard deviation) was taken along segments in which the lead vehicle maintained a constant speed. Maximum speed was a one-time measurement of the maximum speed attained during the entire drive. The drive was segmented into data log streams of approximately 500 feet of distance so that measurements could be related back to places within the drive.

For the city drive, certain measurements were collected at events or along certain segments of the drive. Reaction measurements, such as braking, acceleration, and time to collision (TTC) were examined at braking or pull-out events. Speed, speed standard deviation, and standard deviation of lane position (SDLP) were measured on segments where the driver was expected to maintain speed and lane position. As in the rural drive, the city drive was segmented into data log streams every 500 feet of distance so that events could be pinpointed for data extraction.

3.7 ANALYTICAL METHODS: INFERENTIAL ANALYSIS

3.7.1 ANOVA Between Driver Groups (Concussion vs. No Concussion)

We compare driving performance between participants with a recent concussion to control participants without a recent concussion. An analysis of variance (ANOVA) compared three different measurements: the baseline visit, the follow-up visit, and the difference between performance at the two visits. The null hypothesis (h₀) was that there were no significant differences between measures of each group and that the means are equal. The F-statistic determines whether the null hypothesis should be accepted or rejected.

Formula:

*H*₀: $\mu_1 = \mu_2$

H_A: the two means are significantly different

Independent ANOVA:

$$F = \frac{MS_b}{MS_W} = \frac{MS_b}{MS_{error}}$$
 Equation 3.1

Where MS_b is the mean sum of squares between-groups and MS_w is the mean sum of squares within groups.

All ANOVAs were done using the group, concussion case versus control, as the independent variable.

3.7.2 MANOVA between Driver Groups

A multivariate analysis of variance (MANOVA) was performed on measures of the dependent variables that displayed significant correlation. A MANOVA is a multivariate generalization of ANOVA in which the dependent variables in the analysis are related to each other. The Pillai Test was used due to the relatively small sample size.

3.8 ANALYTICAL METHODS: PREDICTIVE MODELING

3.8.1 Regression Models for Count Data

Poisson regression assumes that the mean (expected value) and variance are equal, and uses one parameter, $\lambda = \mu =$ expected value = variance. The Poisson model regression equation is

$$log(\mu) = \beta_0 + \beta_1 X_1$$
 Equation 3.2

where β are coefficients and μ is the expected value of the count variable. This model is relatively inflexible, and unable to properly deal with over dispersion, where the variance is greater than the mean of the data.

The negative binomial regression model is similar to Poisson, but includes an error term to account for over dispersion. The model equation is

$$log(\lambda) = \beta_0 + \beta_1 X_1 + \varepsilon$$
 Equation 3.3

where β are coefficients, ε is the error term, and λ is the expected value of the count variable. Negative binomial regression is generally used instead of Poisson when over dispersion is detected.

3.9 SUMMARY

The methods detailed in Chapter 3 were used to conduct the study and record data on 49 participants from October 2016 to May 2017. Each participant was either a concussion case or a control, and each participant had a baseline visit and a follow-up visit. Chapter 4 below describes the study results, analyzed using the methods presented in Chapter 3. Chapter 4 presents the results in three ways: using summary statistics, analysis of variance, and regression modeling.

Chapter 4. ANALYSIS AND RESULTS

Recruitment of participants aimed to match case and control participants on age and gender. Table 4.1 shows the breakdown in recruitment by case/control, gender, and age.

 Table 4.1 Recruitment by Age and Gender Matching

Age/Gender	Case	Control
16 M	1	1
16 F	3	1
17 M	4	1
17 F	1	0
18 M	1	0
18 F	1	1
19 M	2	1
19 F	0	1
20 M	0	0
20 F	0	1
21 M	1	2
21 F	0	1
22 M	0	3
22 F	1	7
23 M	2	2
23 F	0	2
24 M	1	4
24 F	0	0
25 M	0	1
25 F	1	1
Total Males	12	15
Total Females	7	15
Total	19	30

The data collected from the simulator study was analyzed using descriptive and inferential techniques: studying summary statistics, identifying differences between groups (ANOVA/MANOVA), and regression modeling.

4.1 SUMMARY STATISTICS

Demographic information such as participant age and standard deviation of age, race, gender, and other data collected through the surveys is displayed in the following table.

	Concussion	1
Characteristic	No (n=30)	Yes (n=19)
Age	21.6 [2.5]	19 [3.0]
Gender		
Female	15 (50.0)	7 (36.8)
Male	15 (50.0)	12 (63.2)
Grade		
In high school	3 (10.0)	11 (57.9)
In college	15 (50.0)	4 (21.1)
In graduate school	2 (6.7)	0 (0.0)
Not a student	10 (33.3)	4 (21.1)
Hispanic		
No	28 (93.3)	17 (89.5)
Yes	2 (6.7)	2 (10.5)
Race*		
White	19 (63.3)	16 (84.2)
Black or African American	1 (3.3)	2 (10.5)
Asian or Pacific Islander	10 (33.3)	3 (15.8)
American Indian or Native American	0 (0)	1 (5.3)
Other	1 (3.3)	0 (0)
Born in US		
No	6 (20.0)	2 (10.5)
Yes	24 (80.0)	17 (89.5)

Table 4.2 Participant Demographics and Breakdown

Note: Mean [sd]

Count (percent)

* Participant could choose more than one race
Symptom information and cognitive testing (SCAT-3 and Trail Making) scores were summarized and are shown in tables 4.3 and 4.4.

	Conc	cussion	
	No (n=30)	Yes (n=19)	P-Value
SCAT-3, mean			
Symptom severity score (max=126)	3.4	23.1	0.001
Immediate memory score (out of 15)	14.5	14.7	0.204
Concentration score (out of 5)	4.6	4.1	0.059
Single leg balance error count (out of 10)	1.2	2.1	0.224
Delayed recall score (out of 5)	4.5	4	0.120
Trail Maker Test (in seconds), mean			
Part A	22.3	29.2	0.002
Part B	51.3	65.1	0.014
Part A and B	73.6	94.3	0.005

Table 4.3 Baseline Symptom and Cognitive Testing Score Means

Table 4.4 Follow-Up Symptom and Cognitive Testing Score Means

	Conc	cussion	
	No (n=28)	Yes (n=16)	P-Value
SCAT-3, mean			
Symptom severity score (max=126)	3.29	26.5	0.001
Immediate memory score (out of 15)	14.4	14.7	0.164
Concentration score (out of 5)	4.6	4.4	0.294
Single leg balance error count (out of 10)	1.3	1.8	0.525
Delayed recall score (out of 5)	4.5	3.9	0.087
Trail Maker Test (in seconds), mean			
Part A	21.4	27.9	0.003
Part B	48.7	59.4	0.008
Part A and B	70.1	87.3	0.002

4.2 INFERENTIAL ANALYSIS RESULTS

4.2.1 Baseline and Follow-Up Visit Scatterplot Matrix and Correlation Analysis

Because many of the outcome variables were similar, it was hypothesized that some may

be highly correlated. A correlation analysis was done on groups of similar variables from each drive, including a scatterplot matrices and correlation values. These are shown in Figures 4.1-4.4; Figure 4.1 also includes a scatterplot for the difference in outcomes for TDRT measurements, as significance was observed during analysis. The deceleration, acceleration, and time to collision measurements had two outcomes per drive, so those variables were analyzed separately (Figure 4.4). Highly correlated variables were considered to have a correlation of greater than 0.50, and multivariate analysis of variance was used for those instead of univariate analysis of variance. As seen in the figures, outcomes from using the TDRT were highly correlated, as well as some of the maximum and average speeds. None of the TTC, braking, or acceleration outcome measures were considered highly correlated.

Outcome measures were all checked for normality, as that is an assumption of ANOVA and MANOVA. All of the outcome measures were checked graphically and acceptable for this analysis. The figures are included in Appendix A.





















4.2.4 Baseline Visit MANOVA and ANOVA Results

In analyzing the tactile detection response task (TDRT) reaction times, no statistically significant (p < 0.05) differences were observed in MANOVA or ANOVA between concussion case and control groups. It is worth noting that averages between concussion case and control groups approached statistical significance and that this pattern in reaction times may be important to explore in future work. All times are reported in milliseconds (ms).

TDRT reaction time averaged over the entire rural drive: F(1, 46)=1.78, p=0.189, Case (mean=767ms), Control (mean=627ms).

TDRT reaction time during VCS tasks: F(1, 46)=2.55, p=0.117, Case (mean=963ms), Control (mean=767ms).

TDRT reaction time during no VCS task: F(1, 46)=1.58, p=0.215, Case (mean=621ms), Control (mean=500ms).

TDRT reaction time difference between VCS task and no VCS task: F(1, 46)=1.409, p=0.241, Case (mean=342ms), Control (mean= 268ms).

There were differences in the miss rate (count) for the rural drive TDRT. Drivers in the concussion group had greater TDRT miss rates (average miss rate=8.17) during the rural scenarios when compared to drivers with no known concussion (average miss rate=4.33), p = 0.021, F(1, 46)=5.713.

There were differences in the maximum speed (mph) for the rural drive when analyzed using MANOVA with maximum speed for the city (mph), F(1, 46)=3.991, p=0.025. There were no other significant differences in the average speed (mph) or standard deviation of speed for the rural drive, but these measures approached significance when using MANOVA. The maximum rural speed, as a univariate outcome, approached significance, F(1, 46)=2.823, p=0.0997,

between case (mean = 54.2 mph) and control (mean = 52.8 mph).

There were no significant differences in total lane deviations or SDLP between concussion and control groups in either drive.

Drivers in the concussion group drove slightly slower during urban driving scenarios (mean = 34.7 mph) compared with control group (mean = 35.5 mph), though the difference did not reach statistical significance (p=0.064). There was no significant difference between case and control groups found in maximum city speed, SDLP, or speed standard deviation.

Differences approaching significance were found in the acceleration behavior of case versus control participants, F(1,47)=2.993 and p=0.0902 with the case participants (4.98 m/s²) accelerating more aggressively after stoplights than controls (4.68 m/s²). These acceleration measures are all high in comparison to the "aggressive" threshold used by Verizon's in-vehicle driving device (3.53 m/s²).

Braking behavior approached significance, with the concussion group decelerating more quickly (3.19 m/s^2) than controls (2.84 m/s^2) .

The full results are summarized in tables 4.5-4.7.

Multivariate Outcomes		Df	Pillai	approx F	num Df	den Df	P-Value
Mean TDRT, TDRT	Concussion	1	0.122	1.489	4	43	0.222
with VCS, Difference in							
TDRT Time, Miss Rate	Residuals	46					
Max Speed, Mean Speed, Speed Standard	Concussion	1	0.107	1.748	3	44	0.171
Deviation (Rural)	Residuals	46					
Max Speed (Rural),	Concussion	1	0.151	3.991	2	45	0.025 *
Max Speed (City)	Residuals	46					
Mean Speed, Max	Concussion	1	0.074	1.972	2	45	0.178
Speed (City)	Residuals	46					

Table 4.5 Baseline MANOVA Coefficients and P-Values**

** Table Abbreviations (all ANOVA/MANOVA tables):

Df = Degrees of freedom Num = numerator Den = denominator SS = Sum of Squares MSS = Mean Sum of Squares

Outcome Variable		Df		SS	MSS	F Value	P-Value
TDRT Average	Concussion		1	218614	218614	1.778	0.189
	Residuals		46	5656178	122960		
TDRT VCS	Concussion		1	430412	430412	2.553	0.117
	Residuals		46	7755680	168602		
TDRT Only	Concussion		1	164807	164807	1.583	0.215
	Residuals		46	4798626	104122		
Difference in TDRT	Concussion		1	62547	62547	1.409	0.241
	Residuals		46	2041353	44377		
TDRT Miss Rate	Concussion		1	165.312	165.312	5.713	0.021 *
	Residuals		46	1331.17	28.938		
Max Speed (Rural)	Concussion		1	19.997	19.997	2.823	0.0997 .
	Residuals		46	325.8	7.083		
Avg Speed (Rural)	Concussion		1	5.166	5.166	2.564	0.116
	Residuals		46	92.689	2.015		
Speed SD (Rural)	Concussion		1	0.432	0.432	0.433	0.514
	Residuals		46	45.875	0.997		
SDLP Rural	Concussion		1	0.058	0.058	1.768	0.19
	Residuals		46	1.503	0.033		
Average Speed (City)	Concussion		1	8.398	8.398	3.594	0.064 .
	Residuals		46	107.48	2.337		
Max Speed (City)	Concussion		1	6.304	6.304	0.6392	0.428
	Residuals		46	453.62	9.861		

Table 4.6 Baseline ANOVA Coefficients and P-Values

		D	-		1 100	F I I I	D. I. I.
Outcome Variable		Df	2	SS	MSS	F Value	P-Value
Time-To-Collision							
Error: ID	Concussion		1	0.77	0.77	0.155	0.696
	Residuals		47	232.88	4.955		
Error: Within							
	Residuals		45	153.6	3.413		
Stop Event Braking							
Error: ID	Concussion		1	2.697	2.697	1.859	0.179
	Residuals		47	68.18	1.451		
Error: Within							
	Residuals		45	17.01	0.378		
Stop Event Acceleration							
Error: ID	Concussion		1	2.828	2.828	2.993	0.0902 .
	Residuals		47	44.41	0.9449		
Error: Within							
	Residuals		45	15.13	0.336		

Table 4.7 Baseline ANOVA Coefficients and P-Values

4.2.5 Follow-Up Visit MANOVA and ANOVA Results

In the follow-up drives, some outcomes became insignificant and others newly showed significant differences between groups. Some of the TDRT measures again approached significance, but the TDRT miss rate, highly significant in the baseline drive, was not: F(1, 42)=.7227, p=0.4001.

More difference between groups emerged in the analysis of maximum and average speeds during the rural drive. In the MANOVA of maximum speed, average speed, and speed standard deviation, significant differences were observed between groups, F(1, 42)=1.4516 and p=0.0867. In the univariate analysis, maximum speed was determined to be trending toward being higher for concussion group participants (mean = 52.9 mph) than for controls (mean = 51.6 mph), F(1,42)=3.078 and p=0.0867. Similarly, this was also seen in the average rural speed, F(1,42)=3.978 and p=0.05262, with the concussed group (mean = 47.7 mph) driving slightly faster than the controls (mean = 46.8 mph).

Although not significantly different, trends were also seen between case and control participants in TTC outcomes at the follow-up, F(1, 34)=2.999 and p=0.0924, with controls (TTC = 3.19s) having slightly larger TTC measures than concussion cases (TTC = 2.46s). Similar differences in acceleration behavior were also found, with concussion cases (4.98 m/s2) accelerating quicker than controls (4.39 m/s2), F(1,34)=2.892 and p=0.0982.

The results are shown in tables 4.8-4.10.

Multivariate Outcomes		Df	D:11.	opprov E	num Df	dan Df	D Valua
Multivariate Outcomes		DI	Fillal	approx r	IIuIII DI	dell DI	r-value
Average TDRT, TDRT							
with VCS, Difference in	Concussion	1	0.0860	0.9170	4	39	0.4638
TDRT Time, Miss Rate	Residuals	42					
Max Speed, Average							
Speed, Speed Standard	Concussion	1	0.09818	1.4516	3	40	0.08667 .
Deviation (Rural)	Residuals	42					
Max Speed (Rural), Max	Concussion	1	0.06883	1.5153	2	41	0.2318
Speed (City)	Residuals	42					
Average Speed, Max	Concussion	1	0.0711	1.5691	2	41	0.2205
Speed (City)	Residuals	42					

Table 4.8 Follow-Up MANOVA Coefficients and P-Values

Outcome Variable		Df		SS	MSS	F Value	P-Value
TDRT Average	Concussion		1	265477	265477	2.218	0.1439
	Residuals		42	5027038	119691		
TDRT VCS	Concussion		1	293447	293447	1.708	0.1983
	Residuals		42	7215253	171792		
TDRT Only	Concussion		1	233555	233555	2.319	0.135
	Residuals		42	4230342	100722		
Difference in TDRT	Concussion		1	3414	3414	0.1077	0.7445
	Residuals		42	1331920	31712		
TDRT Miss Rate	Concussion		1	13.09	13.09	0.7227	0.4001
	Residuals		42	760.79	18.114		
Max Speed (Rural)	Concussion		1	19.378	19.378	3.0776	0.08667 .
	Residuals		42	264.445	6.296		
Avg Speed (Rural)	Concussion		1	7.754	7.754	3.9777	0.05262 .
	Residuals		42	81.875	1.949		
Speed SD (Rural)	Concussion		1	1.26	1.26	1.6186	0.2103
	Residuals		42	32.695	0.7785		
SDLP (Rural)	Concussion		1	0.0224	0.0224	0.467	0.498
	Residuals		42	2.0105	0.0479		
Average Speed (City)	Concussion		1	0.9667	0.9667	0.5725	0.4535
	Residuals		42	70.912	1.6884		
Max Speed (City)	Concussion		1	5.15	5.15	0.5297	0.4708
	Residuals		42	408.29	9.7212		

Table 4.9 Follow-Up ANOVA Coefficients and P-Values

Outcome Variable		Df		SS	MSS	F Value	P-Value
Time-To-Collision							
Error: ID	Concussion		1	8.449	8.449	2.999	0.0924 .
	Residuals		34	95.77	2.817		
Error: Within							
	Residuals		36	115.2	3.2		
Stop Event Braking							
Error: ID	Concussion		1	0.2296	0.2296	0.275	0.604
	Residuals		34	28.41	0.8355		
Error: Within							
	Residuals		36	8.968	0.2491		
Stop Event Acceleration							
Error: ID	Concussion		1	4.054	4.054	2.892	0.0982 .
	Residuals		34	47.66	1.402		
Error: Within							
	Residuals		36	9.516	0.2643		

Table 4.10 Follow-Up ANOVA Coefficients and P-Values

4.2.6 Differences between Baseline and Follow-Up: MANOVA and ANOVA

We hypothesized that patients with concussion would have a relative improvement in performance between baseline and follow-up simulated driving sessions as their symptoms resolved, compared to control participants. For this analysis we compared the performance of each individual at follow-up to the participant's baseline performance measures. The analyses of the differential data show some important significance to note: The performance on the TDRT task, both in reaction time and miss count, shows that the concussion and control groups differ in how much they improve upon their baseline performance in the follow-up visit.

The MANOVA showed that the two groups differed in how they improved in performance of the TDRT outcomes as a whole. More specifically, the concussion cases improved more than controls in their performance on TDRT misses and reaction time during the VCS tasks. Concussion participants improved by an average of almost 4 misses, while the case participants missed just over 1 fewer times, F(1,42)=5.7256, p=0.02127. For the reaction time during VCS tasks, the concussion group improved more (mean = 177 ms) than the controls (mean = 96.7 ms), F(1,42)=3.0106, p=0.09005. Figures 4.5 and 4.6 display these differences using interaction plots.

No other significant (or approaching significant) variables were found in the differential between visits. The MANOVA and ANOVA data is shown in tables 4.11-4.12.



Figure 4.5 TDRT Miss Count Interaction Plot



Figure 4.6 TDRT Reaction Time Interaction Plot

Multivariate Outcomes Df Pillai approx F num Df den Df P-Value Average TDRT, TDRT with VCS, Difference in Concussion 1 0.17977 2.1369 39 0.09452. 4 **TDRT Time, Miss Rate** Residuals 42

Table 4.11 MANOVA of Differences: Coefficients and P-Values

Table 4.12 ANOVA of Differences:	: Coefficients and P-Values
----------------------------------	-----------------------------

Outcome Variable		Df	SS		MSS	F Value	P-Value
TDRT Average	Concussion		1	4742	4742	0.2744	0.6031
	Residuals		42	725828	17282		
TDRT VCS	Concussion		1	65214	65214	3.0106	0.09005 .
	Residuals		42	909771	21661		
TDRT Only	Concussion		1	1481	1481	0.06	0.808
	Residuals		42	1036275	24673		
Difference in TDRT	Concussion		1	47037	47037	1.2862	0.2632
	Residuals		42	1535937	36570		
TDRT Miss Rate	Concussion		1	71.117	71.117	5.7256	0.02127 *
	Residuals		42	521.68	12.421		

4.3 PREDICTIVE MODELING

Once ANOVA was used to determine differences in groups, predictive modeling was done for the TDRT miss rate, one of the variables in which group (case vs. concussion) was most highly significant at the baseline visit. Since this measurement was a count variable, two methods of analysis were considered: Poisson and negative binomial regression models.

4.3.1 Explanatory Variables and Data Preparation

Correlation analysis was used to determine which explanatory variables appeared to influence TDRT miss rate as well as which were highly correlated to each other. Explanatory variables included concentration, symptom, balance, and memory scores from the SCAT-3 and Trail Making A and B tests, as well as independent variables like concussion case versus control group and age. Figure 4.7 shows the correlation matrix and values for predictors considered for regression modeling.

One miss count outlier was removed: a count of 26 misses, which was over two standard deviations from the mean. An offset was used in the model, since each drive time varied slightly depending on the participant. This was done to account for any error in miss count due to a slightly longer drive time, and was added as the log of drive time, in minutes.



Figure 4.7 Explanatory Variable Correlation Analysis

Miss rate had the highest correlation with concussion group status, age, Symptom Score 2 (cumulative symptom score severity), and the balance portion of the SCAT-3. These variables were used in the models, along with the Trail Maker B in order to determine its effect since it is a commonly used concussion testing metric. None of the explanatory variables were considered to be too highly correlated to one another. Figure 4.8 shows the probability distribution of the miss count to be modeled.





In order to further visualize the data, a plot of miss count by age and gender breakdown was completed, and is shown in Figure 4.9. No clear trend appears.



Figure 4.9 TDRT Miss Count by Age and Gender

4.3.2 Poisson Regression Modeling

In the Poisson model including relevant predictors, concussion group and SCAT-3 balance score were the only significant predictors. Interestingly, metrics for concentration, symptoms, and age were not significant.

The Poisson model was over-dispersed, with the value equal to 4.49. Simply put, the variance of the miss rate was over four times the value of the mean, and the Poisson model was not truly appropriate to use, since this ratio should be 1.

PoisMod<-glm(Miss~Concussion+Balance+Tmb+Symp2+Age+							
offset(ltime), family=poisson(), data=baseline.model)							
Coefficients:							
	Estimate	Std. Error	z value	Pr(> z)			
(Intercept)	-0.1676	0.5598	-0.299	0.7647			
Concussion	0.3107	0.1650	1.883	0.0597 .			
Balance	0.0490	0.0222	2.204	0.0275 *			
Trail Maker B	-0.0016	0.0035	-0.446	0.6554			
Symptom Score	0.0028	0.0028	1.000	0.3173			
Age	-0.0283	0.0253	-1.200	0.2628			
Null Deviance	215.72 on 4	6 degrees of	freedom				
Residual Deviance	193.61 on 41 degrees of freedom						
AIC				339.35			
Null AIC				358.08			

Table 4.11 Poisson Regression Model

4.3.3 Negative Binomial Regression Modeling

With the Poisson model for TDRT miss count showing over-dispersion, a negative binomial model using similar predictors was created to better represent the data, without violating the Poisson assumption of mean = variance.

The predictors of Trail Maker B, age, and concussion group did not improve the fit of the model over a null model. Therefore, the only variables included in the model, which approached significance but were not significant, were interaction terms of concussion status and balance score, and concussion status and symptom score. The model is shown in table 4.12.

Table 4.12 Negative Binomial Regression Model

NbMod<-glm.nb(Miss~Concussion:Balance+Concussion:Symp2+offset(ltime),							
link=log(), data=baseli	ne.model)						
Coefficients:							
	Estimate	Std. Error	z value	Pr(> z)			
(Intercept)	-0.7597	0.1634	-4.649	3.34E-06	***		
Concussion: Balance	0.0985	0.1650	1.495	0.135			
Concussion:Symptom							
Score	0.0028	0.0066	0.978	0.328			
Null Deviance	59.321 on 4	6 degrees of fi	reedom				
Residual Deviance	55.237 on 44 degrees of freedom						
AIC					262.66		
Null AIC					263.64		

4.4 SUMMARY

The results and analytical methods detailed in Chapter 4 uncovered some interesting findings, as well as some surprisingly insignificant outcomes. There appeared to be some improvements in the concussion group performance at the follow-up visit, as measured by the TDRT task. Other driving measures did not show any clear trends or differences between groups. These findings may help in designing future studies and analyses of recently concussed drivers. Chapter 5 discusses the results, their implications, and how they relate to existing literature.

Chapter 5. DISCUSSION

The study compared simulated driving performance between two groups of drivers: case drivers who had sustained a recent concussion, and control drivers. Participants returned for a simulated drive one month after the baseline visit, allowing an opportunity for case participants to recover from their concussion symptoms.

The study results indicated several notable differences in the driving capabilities of concussion and case participants. The most notable differences were seen in the measures of reaction time and accuracy while performing the rural drive, with a voice control task and TDRT. At baseline, response times approached significance between groups, and the miss rates between groups were significantly higher among participants who had a recent concussion. One month following concussion, the TDRT miss counts between the case and control groups was no longer statistically significant. We hypothesize that the differential improvement (concussion group improved by 4 misses, controls by 1 miss) in simulated driving performance between the baseline and follow-up time periods among drivers who had a concussion may have resulted from recovery over the course of four weeks.

Participants in both groups had slower reaction times during the voice control task, supporting previous research concerning the cognitive load of completing voice controlled invehicle tasks (Mehler et al., 2016). Among drivers who had a recent concussion, TDRT reaction time during the voice control tasks showed significant improvement over time compared with drivers in the control group. We hypothesized that this differential improvement paralleled the resolution of concussion symptoms. Both TDRT miss count and reaction time during VCS tasks showed insignificance after four to six weeks, supporting research stating that most concussed

patients' symptoms almost entirely resolve within a month (McCrory et al., 2017).

Few other outcomes differed significantly between case and control drivers. There was no statistically significant difference in braking deceleration, vehicle acceleration, mean speed, lane position or lane deviation. We noted considerable variability in driving behavior of young people irrespective of the history of concussion, who tend to fall into high, moderate, or low risktaking groups regardless of experience level or personality traits (Guo, 2013). Very few drivers in this study were in the first 6 months of licensure, which is a critical predictor of hard braking activity (Simons-Morton et al., 2009).

Where differences between concussion case and control participants were seen, concussion case participants were the group driving slightly faster, braking/accelerating harder, and allowing less time to collision. The ANOVAs and MANOVAs showed that on average, concussed participants reached or maintained significantly higher speeds in both drives. The shorter time to collision among drivers who had a concussion may signify riskier driving behavior; this difference persisted among concussion group participants at the follow-up drive. While statistically significant, these absolute differences were relatively small in the simulated environment.

The results in the driving measures may indicate riskier driving habits for concussed participants. It is unknown if this is due to concussion symptoms or because they are predisposed to riskier behavior. As discussed, research has shown that there is a link between concussion and risky behavior (Buckley & Chapman, 2016), but how that relates to driving habits is a topic for additional investigation.

We were not able model the count data using negative binomial regression, showing that the predictors used (SCAT-3, Trail Maker, symptoms) may not be appropriate for estimating differences in driving behavior. From the differences in the means of the reaction times and miss count, it is clear that post-concussion participants had more difficulty performing multiple tasks at once. Research has shown that post-concussion scores on the SCAT-3 and Trail Making A and B tests return to baseline performance can be as early as 48 hours after concussion (McCrea et al., 2002), however for many individuals recovery is much slower (McCrory et al., 2017). It is possible that these two tests of cognitive ability may recover more quickly than driving performance itself. It is also possible that the SCAT-3 is not challenging enough to see these differences. A revised SCAT-5 has recently been released with slightly more difficult tasks; for example, there are 10 words to repeat for immediate memory instead of 5 words (Echemendia et al., 2017). The self-reported nature of the symptom data could also be causing some error, as people often over or under-report symptoms (Butler et al., 1987).

Since the Poisson regression model was over-dispersed and inappropriate for use, the significance of the explanatory variables should be interpreted with caution. The balance testing which forms a component of the SCAT-3 concussion evaluation appeared to be the best symptom-related predictor for the number of missed TDRT responses. Recent history of concussion group was also significant, which means that a concussion and trouble balancing may help predict trouble completing a visual-cognitive task (VCS) while driving, leading to more missed TDRT responses.

5.1 STUDY LIMITATIONS

The study was exploratory in nature, meaning that a wide variety of variables were considered in the experiment and analysis in order to determine where differences may (or may not) be observed. Cognitive measures while driving, such as eye glance behavior, n-back testing in which participants recall a letter "n" trials previous (Miller et al., 2009), and continued use of the TDRT may be particularly useful, since the difference in TDRT miss rate and reaction time were interesting findings in this study (Mehler et al., 2009; Liang et al., 2015). Cognitive tests may be more useful than braking, speed, or other specific driving behaviors since the individual variability of those measures is relatively high among young drivers, and understanding this variability may require additional predictors.

Although we aimed to achieve a balance in age and gender among case and control participants during recruitment, challenges in finding eligible participants for the concussion group within 2 weeks of injury was challenging in this relatively short study period, and therefore in practice the control group was older than the case group on average. Rapid recruitment of drivers with concussion remained a challenge, as these individuals typically did not seek medical care. Recruitment included Seattle area hospitals, sports medicine clinics, and as many other sources of reported concussions as possible. A longer study period would have made it easier to recruit more study participants with concussion.

Another limitation of the simulator experiment was the missing data points due to participants' unpredictable driving behavior or failure to follow rules, such as "stay in the right lane except to pass" or failure to follow traffic signals. In the future, the programming and measurements in the driving simulation could be improved upon to control better for unpredictable behavior and increase the amount of observations of repeated measures.

The data collected in this study should be used for further analyses, including for generalized linear models, stratified – by age and gender – conditional models, regression analysis, and using methods that can increase the power of the results and control for as much as possible, such as blocking by participant ID, controlling for subject variability. The ANOVA

presented here did not benefit from the nearly 2:1 ratio of control to case participants recruited in this study, but other modeling methods may benefit from this and use repeated measures to increase power.

Another potentially useful tool, used in hospital and health services research, could be the use and creation of propensity scores for participants and their behaviors (MacKenzie et al., 2006; Herzig et al., 2009). Instead of stratifying by age and gender, which may not be the best predictors, more appropriate "risk" propensity scores could help to model participant behavior and concussion recovery. These scores are derived using generalized estimating equations (GEE), and grouping using this method may lead to better comparability between groups.

Finally, future work will examine the association between simulated and real world driving performance among participants who had a concussion, compared with those without a recent concussion history. The final aspect of this study is to monitor driving behavior of participants for three months using an in-vehicle device, which has the capability to collect many more data points and driving measures, which were so limited in the simulator driving. This will be able to measure risky driving behavior as well as differences in driving habits and ability through the recovery period after a concussion. Literature has shown that post-TBI patients got in more crashes than non-TBI controls in the same time period (Neyens & Boyle, 2012), so there is potential to see some significance in crash rate for concussed participants.

Chapter 6. CONCLUSION

6.1 Key Findings

In this prospective cohort study, simulated driving performance was compared between a case cohort with history of a recent concussion, and the control participants with no recent concussion. There were significant differences found in the behavior of concussion case and control participants. The difference in reaction ability, as well as the improvement in miss rate and reaction time, shown by the TDRT suggest that the cognitive capabilities of recently concussed drivers may be lower within two weeks, but that significant recovery occurs in four-to six-weeks' time.

There is variability found in this driver age range as well as in symptoms and severity of concussion, which make clear conclusions difficult to draw, so the reasons behind the differences are still relatively unknown. Differences between groups could be due to concussion symptoms making driving and related or secondary tasks more challenging, while other differences could be due to the risky behavior of certain individuals or concussion participants as a group.

6.2 NEXT STEPS

The study will continue to monitor real-world driving behavior for three months after beginning participation. This will allow researchers to determine any significant differences in risk for concussed versus control participants enrolled in this study.

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APPENDIX A: R-CODES AND NORMALITY PLOTS



Figure: Baseline Normality Plots



Figure: Follow-Up Normality Plots
Sample R-Code:

#Checking Normality

```
qqnorm(baseline$AvgSpeed.Rural, main="Normal Q-Q Plot: Mean Rural Speed")
qqline(baseline$AvgSpeed.Rural)
qqnorm(baseline$SDLP.City, main="Normal Q-Q Plot: SDLP City")
qqline(baseline$SDLP.City)
```

#ANOVA

```
speedrural.aov <-aov(AvgSpeed.Rural ~ Arm, data=return)
summary(speedrural.aov)
print(model.tables(speedrural.aov,"means"),digits=3)</pre>
```

#MANOVA

```
Y <- cbind(differences$Overall.Average,differences$TDTwVCS,differences$TDT.Diff,
differences$Miss)
fit <- manova(Y ~ Arm, data = differences)
summary(fit)
summary.aov(fit)
```

#Poisson Model

```
library(MASS)
library(Intest)
TDTMissModel <- glm(Miss~Arm*Scat3+Tmb+SympScore2+ Age+
offset(ltime), data=baseline.model,family=poisson())
summary(TDTMissModel)
PoisMod_null<-glm(Miss~1, family=poisson, data=baseline.model)
summary(PoisMod_null)</pre>
```

#NB Model

```
NBModel<-glm.nb(Miss~Arm:Scat3+Arm:SympScore2+offset(ltime), data=baseline.model)
summary(NBModel)
NBModel_Null<-glm.nb(Miss~1, data=baseline.model, link=log)
summary(NBModel_Null)
```

#Correlation graphs

concanalysdf2<-data.frame (baseline\$MaxSpeed.Rural, baseline\$AvgSpeed.Rural, baseline\$SpeedSD.Rural, baseline\$MaxSpeed.City, baseline\$SpeedSD.City)

names(concanalysdf2)<-c("MaxSpeed.R", "AvgSpeed.R", "SpeedSD.R", "MaxSpeed.C", "AvgSpeed.C", "SpeedSD.C") chart.Correlation(concanalysdf2, histogram=TRUE, pch=19, main="Pairwise Scatterplot of Longitudinal Outcome Measures (Baseline)")

APPENDIX B: CONSENT AND BASELINE SURVEYS



HIPAA Authorization

For the Use of Patient Health Information for Research

Research Title: Lead researcher: Institution of lead researcher: Concussion and Driving Skills in the Young Driver Beth E. Ebel, MD, MSc, MPH University of Washington

A. Purpose of this form

The purpose of this form is to give your permission to the research team to obtain and use your patient information. Your patient information will be used to do the research named above.

This document is also used for <u>parents</u> to provide permission to the research team to obtain the patient information of their minor children, and for <u>legally-authorized representatives</u> of subjects (such as an appropriate family member) to provide permission to the research team to obtain patient information of individuals who are not capable themselves of providing permission. In such cases, the terms "you" and "your patient information" refer to the subject rather than the person providing permission.

A minor's signature is required to release the following information about the minor: 1. Age 14 and older – information relating to reproductive care, including but not limited, to birth control and pregnancy-related services and sexually-transmitted diseases, including HIV/AIDS and 2. Age 13 and older – substance abuse diagnosis or treatment, and mental health information.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

B. The patient information that will be obtained and used

"Patient information" means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, and medical record number.

1. Location of patient information

By signing this form you are giving permission to the following organization(s) to disclose your patient information for this research.

- UW Medicine (includes University of Washington Medical Center & Clinics; Harborview Medical Center & Clinics; UW Medicine Neighborhood Clinics; University of Washington Sports Medicine Clinic; UW Medicine Eastside Specialty Center; Hall Health Primary Care Center; University of Washington Physicians)
- Seattle Children's Hospital
- · Harborview Injury Prevention and Research Center

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2. Patient information that will be released for research use

This permission is for the health care provided to you during the following time period: from August 15, 2016 until the end of this research study.

The specific information that will be released and used for this research is described below:

- Hospital discharge summary
- Radiology records
- Medical history / treatment
- Consultation
- Radiology films (like X-rays or CT scans)
- Laboratory / diagnostic tests
- Psychological testing
- Pathology reports
- Diagnostic imaging report

C. How your patient information will be used

- 1. Who may receive your patient information
 - University of Washington
 - Seattle Children's Hospital
 - Harborview Injury Prevention and Research Center
- 2. Why your patient information will be used and/or given to others
 - To do the research
 - · To study the results, and
 - · To see if the research was done right

If the results of this study are made public, information that identifies you will not be used. The researcher will use your patient information only in the ways that are described in the research consent form that you sign and as described in this HIPAA Authorization.

You can ask questions about what the research team will do with your information and how they will protect it.

The privacy laws do not always require the receiver of your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission.

The study procedures do not include a plan to share your research results, though you may be able to request them through the Washington State Public Records request system after the study is done.

D. Expiration

This permission for the researchers to obtain your patient information ends when the research ends and any required monitoring of the study is finished.

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E. Canceling your permission

You may change your mind at any time. To take back your permission, you must send your written request to:

Dr. Beth Ebel Harborview Injury Prevention and Research Center 325 Ninth Avenue Box 359960 Seattle WA 98104

If you take back your permission, the research team may still keep and use any patient information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you will need to leave the research study. This means that you would not have any more research treatments or tests. Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

F. Giving permission

I have read this HIPAA Authorization form describing how my patient information will be used. I have had a chance to ask questions about the use of my patient information and I have received answers to my questions. I agree to the use of my patient information for this research.

Printed Name of Research Subject	Birthdate
Signature of Research Subject	Date of signature
Printed Name of Person Authorized to Give Permission	- * • • • • • • •
Signature of Person Authorized to Give Permission	Date of signature
Relationship to Subject and Description of Authority	

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UNIVERSITY OF WASHINGTON CONSENT FORM

Concussion and Driving Skills in the Young Driver

Researchers:

Beth Ebel, MD, MSc, MPH	Principal Investigator	(206) 744-9430
Suzanne Peck, BA	Research Assistant	(206) 884-1356

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Learning to drive is an important skill for teens and young adults and parents who are juggling after-school activities, employment, and recreation. Learning to be a good driver is also a complicated task for teens and young adults. The goals of this study are: (1) to safely test the impact of recent concussion on teen and young adult driving ability; (2) test how driving ability recovers as concussion symptoms improve in the month following injury; and 3) collect data on driving performance and crash history in the three months following enrollment.

After a concussion, young drivers may find that the concussion and its symptoms make it more challenging to drive safely. This study will compare driving performance between young drivers who have had a concussion, compared to young drivers who have not had a concussion in the past year. Young drivers will be invited to test driving skills in a driving simulator machine. Driving experience and several driving performance measures will be followed for the next three months, using a commercially available cell phone app (CellControl). We will also measure reported crashes in the year following enrollment.

STUDY PROCEDURES

About 60 people between the ages of 16-25 will participate in this study.

Timepoint	Procedures	Location	Time Commitment
Baseline Visit	Demographic and Health Risk Data: Study participants will be asked nationally standardized questions about their health, activities (sports participation, academic achievement) and risk behaviors (including alcohol and drug use, school performance). Driving Behavior: This survey reviews safety and	University of Washington	5-10 minutes 5 minutes
	risk behaviors for drivers. We will also ask about past driving history and crash history. Text messaging and Cell Phone questionnaire:		
	These brief surveys measure texting and cell phone		5 minutes

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Timepoint	Procedures	Location	Time Commitment
	use patterns by study participants. Concussion Assessment: All study participants will complete two short tests which are used to measure symptoms and signs of concussion. These tests are called the SCAT3 and Trail-Maker B (TM-B) tests. Prior concussion testing results will be requested where applicable. Participants with recent concussion will complete several additional questions to indicate past history of concussion, timing of injury, and injury mechanism. The concussion instruments will be collected again at the second driving simulation and at the conclusion of the study.		20 minutes
Baseline Visit	Driving Simulator: The study will be conducted in driving simulator at the University of Washington. Each participant will have a short "familiarization" drive to ensure that they are comfortable with the use of the driving simulator controls. The research team will design and test the driving scenarios in which drivers respond to typical and unexpected driving conditions.	University of Washington	30 minutes
Baseline Visit	Release of medical information (HIPPAA form). Participants who have had a concussion will be asked to release medical records pertaining to the concussion and concussion screening	University of Washington	2 minutes
Follow-Up Visit 4-6 weeks post baseline visit	Concussion Assessment: Participants in both groups will complete two standard concussion forms (SCAT3 and Trailmaker B). Participants will be asked about their recent driving experience.	University of Washington	20 minutes
Follow-Up Visit 4-6 weeks post baseline visit	Driving Simulator: The study will be conducted in driving simulator at the University of Washington. Each participant will have a short "familiarization" drive to ensure that they are comfortable with the use of the driving simulator controls. The research team will design and test the driving scenarios in which drivers respond to typical and unexpected driving conditions.	University of Washington	30 minutes
3 month period	Cell Control: This commercially available smart- phone based application works by communicating with a small device inserted into the vehicle OBD port. The app collects data on driving time, miles travelled, sudden stops, speed and cell phone/texting use.	Automobile	When driving
Monthly for 3 months	Driving history check-in. Once every month you will receive a short text message asking you to complete a two-minute survey on your driving experience. We will ask if you have had any crashes or fender-benders. Participants who have not completed the on-line survey will be contacted by telephone.	Telephone or on-line survey	2 minutes

Concussion and Driving Skills in the Young Driver 08.23.16

Timepoint	Procedures	Location	Time Commitment
1 year	The researchers will gather publically available crash records by linking driver licenses to Washington State police-reported crash and citation records.	UW/Seattle Children's Research Institute	O hours

RISKS, STRESS, OR DISCOMFORT

The main risk is the loss of subject privacy. Some participants may experience a feeling of motion sickness in the driving simulator. Individuals who do not feel well may stop the simulator test at any point; many people are helped with a drink of water or a snack. You might feel uncomfortable answering some questions on the questionnaires. The questionnaires ask about risky and/or illegal behavior. You could skip any questions you did not want to answer. There are no additional risks incurred by study participants. The Cell-Control system will passively report information on driving time, driving distance and driving performance. We will not examine these data until the end of the study.

Survey data collected from participants will be coded, and linked de-identified data will be used for all analyses. All survey data will be entered into password protected computer systems and maintained at the HIPRC facilities. All personal health identifiers will be destroyed after study completion. No individual information will be shared in manuscript preparation and dissemination without express separate parent and child written permission.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to be in this study, you can continue being seen by a doctor for your symptoms. Please talk to your doctor or the research team about these options.

BENEFITS OF THE STUDY

You will not directly benefit from participating in this study. Information learned from this study is may benefit young drivers and society by better understanding the impact of concussion on driving safety. The information gained from the study will be important guides for public policy on driving safety following concussion.

SOURCE OF FUNDING

Seattle Children's Hospital, Seattle Pediatric Concussion Research Collaborative

CONFIDENTIALITY OF RESEARCH INFORMATION

We will not put your child's name or anything else that could identify him/her directly on the data we collect. Instead we will label them with a code which will be linked to his/her name in a separate location. The PI will keep a master list linking the code to participant names on a password protected computer secured behind a locked office door on a restricted access floor of the clinic. We will keep this code linked to your child's identifying information until the completion of the study. Results of the research may be presented at meetings or in publications, but your child's name will not be used. Government or university staff may review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your child's records may be examined. The reviewers will protect your child's privacy. The study records will not be used to put you or your child at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to: a member of the federal government who needs it in order to audit or evaluate the research; individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly; the federal Food and Drug Administration (FDA), if required by the FDA; and authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

All teen participants will also receive \$30 (cash or gift card) for completing the baseline and follow-up questionnaire, and \$50 (cash or gift card) for each simulator session.

RESEARCH-RELATED INJURY

In the highly unlikely event that you have a medical problem or illness related to this research study, please contact Dr. Beth Ebel, MD. The 24-hour telephone number at 206-744-3000. Ask to page Dr. Beth Ebel. If there is an emergency for any reason, please contact 911 directly, and then page Dr. Ebel with the number above.

Printed name of study staff obtaining consent

Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. I give permission to the researchers to use my medical records as described in this consent form. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject

Signature of subject

Date

When subject is a minor:

Printed name of parent

Signature of parent

Date

Copies to: Researcher Subject

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BACKGROUND INFORMATION

1a. Have you recently had a concussion (within the past 2 months)?	Y	N
1b. If yes, please tell us when and how the injuries happened:		
1c. Was there any loss of consciousness? Y N		_
1d. Were any seizures observed after the injury? Y N		
1e. Are there things before or after the injury that you do not remember? Y	Ν	
1f. Have you had previous head injuries or concussions (more than 2 months a	igo)? Y	N
1g. If so, please tell us when and how the injuries happened:		
1e. How old are you?		

Te. How old are you?		-	
2. What sex are you?	М	F	
3. What grade are you in?			<u>Not a student</u>
4. Are you of Hispanic or Spanish origin?	Y	Ν	

- 6. What is your race? (If you are of more than one race, you may choose more than one) White Black or African American Asian or Pacific Islander American Indian or Native American Other
- 7. Were you born in the United States? Y N
- 8. Are you in school? (If not, skip to question 10) Y N
- 9. At the most recent grading period, what was your grade in each of the following subjects? If your school does not give letter grades, select "No letter grade".

English/ Language Arts

Mathematics History/ Social Studies Science

10. Do you live with your biological mother, stepmother, foster mother, adoptive mother, other, N/A? (Circle one)

11. How far in school did she go?

Less than high school diploma High school graduate or GED College graduate Graduate school training <u>I don't know</u> <u>N/A</u>

13. Do you live with your biological father, stepfather, foster father, adoptive father, other, N/A? (Circle one)

14. How far in school did he go?

Less than high school diploma High school graduate or GED College graduate Graduate school training I don't know N/A

16. In the time between when you got your license and when you enrolled in the Study, did you ever get a warning ticket from law enforcement?

__Yes __No

17. In the time between when you got your license and when you enrolled in the Study, did you ever get an actual ticket from law enforcement?

__Yes __No

18. In the time between when you got your license and when you enrolled in the Study, have you ever been the driver in a collision or had a "fender bender"?

__Yes __No

If yes, describe the collision and whether you were found to be at fault or not.

19. What factors were important in your decision to join this study? Please pick the statement that best matches your belief.

MY IDENTITY

The following questions will help us get a sense of who you are. Even though some of these questions may not apply to you, it's normal for everyone to have some of these behaviors and beliefs. These questions are not intended to be a judgment of your personality.

Please circle the response that shows how well each statement describes you:

	Not at all	Somewhat	A lot
	like me	like me	like me
I'd do almost anything on a dare	1	2	3
I enjoy the thrill I get when I take risks	1	2	3
I like to live dangerously	1	2	3
I like to take chances when the odds are against me	1	2	3

Thinking about your life in general, how well do each of the following statements describe you?

	Not at	Somewhat	A lot
	all like	like me	like me
	me		
I don't think there is ever a good reason for hitting anyone	1	2	3
If people annoy me, I let them know exactly what I think	1	2	3
of them			
I like to argue with other people just to annoy them	1	2	3
If I have to use force to defend my rights, I will	1	2	3
When I get angry at someone, I often say really nasty	1	2	3
things			
When I really lose my temper, I've been known to hit or	1	2	3
slap someone			
If people push me around, I hit back	1	2	3

In the past 12 months, how often have you:

	Never	Once	Twice	3-5	6-9	10 +
				times	times	times
Damaged public or private property	1	2	3	4	5	6
Started a fight and hit someone	1	2	3	4	5	6
Started an argument and insulted the	1	2	3	4	5	6
other person though it wasn't called						
for						
Damaged something valuable because	1	2	3	4	5	6
you were angry						

How wrong do you think it is to:

	Very			Not
	wrong			wrong
Give a fake excuse for missing work	1	2	3	4
Not showing up for a meeting, or cutting class	1	2	3	4
Damage public property on purpose	1	2	3	4
Start a fight and hit someone	1	2	3	4
Give false information when filling out a job or load	1	2	3	4
application				
Shoplift something of value from a store	1	2	3	4
Start an argument and insult the other person even	1	2	3	4
though it isn't called for				
Damage something valuable because you are angry with	1	2	3	4
the person it belongs to				
Use your debit card/checkbook even though you know it	1	2	3	4
might bounce				
Lie to people close to you to cover up something you did	1	2	3	4
Take things of value that do not belong to you	1	2	3	4

How sure are you that:

	Very			Not
	sure			sure
Other people will respect how hard you work	1	2	3	4
You will win promotions at work (school) because other	1	2	3	4
people will recognize your abilities				
	1	2	3	4
The people you work with (go to school with) will think				
highly of your work				
You will move up the job ladder faster than others	1	2	3	4
because of your skills				

HEALTH AND BEHAVIOR QUESTIONS

Please think about things you may have done over the past year. Some of these questions ask about sensitive topics. Feel free to skip any question or section you want to.

	No chance		Some chance		About 50:50		Pretty Likely	•	It will happen
Live to age 35	0	1	2	3	4	5	6	7	8
Be married by age 25	0	1	2	3	4	5	6	7	8
Be killed by age 21	0	1	2	3	4	5	6	7	8
Get HIV or AIDS	0	1	2	3	4	5	6	7	8
Graduate from college	0	1	2	3	4	5	6	7	8
Have a middle- class	0	1	2	3	4	5	6	7	8
family income by age									
30?									

On a scale from "No chance" to "It will happen" what do you think are the chances you will:

Since school started this year, how often have you had trouble:

	Never	A few	Once a	Almost	Everyday
		times	week	everyday	
Getting along with your teachers	0	1	2	3	4
Paying attention in school	0	1	2	3	4
Getting your homework done	0	1	2	3	4
Getting along with other students	0	1	2	3	4

Outside of school/work hours, how much times do you spend:

	None	Less than	1 to 2	3-4 hours	More than
		1 hour	hours		4 hours
Watching television or movies on an	1	2	3	4	5
average school day?					
Playing portable video games/ cell	1	2	3	4	5
phone games					
Using the computer	1	2	3	4	5
Talking on a cellular phone	1	2	3	4	5
Text messaging	1	2	3	4	5

In general, how hard do you try to do your school work/job well?

I try very hard	I try hard enough, but	I don't try very hard	I never try
1	2	3	4

Have you had a drink of beer, wine, or liquor – not just a sip or a taste of someone else's drinkmore than two or three times in your life?

YES

NO

In general, how is your health?

Excellent	Very good	Good Fair	Poor
1	2	3	4

During the past twelve months, how often did you:

	Never	Once or	Once a	2 or 3	Once or	3 to 5	Nearly
		Twice	month	days a	twice a	days a	every
			or less	month	week	week	day
Smoke cigarettes?	0	1	2	3	4	5	6
Drink beer, wine, or	0	1	2	3	4	5	6
liquor?							
Race on a bike, on a	0	1	2	3	4	5	6
skateboard or roller							
blades, or in a boat or car?							
Do something dangerous	0	1	2	3	4	5	6
because you were dared to							
Lie to your parents or	0	1	2	3	4	5	6
guardians?							
Skip school without an	0	1	2	3	4	5	6
excuse?							
Get into a physical fight?	0	1	2	3	4	5	6

During the past year:

		0	1	2	3	4	5	6	7
8.	How often did you wear a helmet while riding a bicycle?	Never	Rarely	Some- times	Most of the time	All of the time	N/A	Don't know	Refused
9.	How often did you ride a								

	motorcycle?				
10.	When you rode a				
	motorcycle, how often				
	did you wear a helmet?				
11.	How often did you drive				
	a car?				
12.	How often do you wear a				
	seatbelt while driving or				
	riding in a car?				
13.	How often did you talk				
	on the phone while				
	driving a car?				
14.	How often do you send				
	text message while				
	driving a car?				

During the past year:

		Yes	No	Don't	Refused
				Know	
15.	Did you ever ride in a car with a driver who had been	1	0	8	9
	drinking or was high on drugs?				
16.	Have you ever driven while drunk?	1	0	8	9
17.	Have you ever driven while high on drugs?	1	0	8	9
18.	Did you ever carry a weapon on you? (e.g. knife, club, or	1	0	8	9
	gun)				
19.	Were you arrested?	1	0	8	9
20.	Were you involved in lawsuit or legal proceeding?	1	0	8	9

<u>Source:</u> National Institute of Child Health and Development. National Longitudinal Study of Adolescent Health (Add Health).

DRIVING HABITS

1. Please rate how often you do the following activities while driving your car.

 Most

 Never
 Rarely
 Weekly
 Daily
 Trips

Talk on a cellular phone	1	2	3	4	5	
Read a text message		1	2	3	4	5
Compose a text message		1	2	3	4	5
Eat		1	2	3	4	5
View video/youtube Look at or post to social networking (Facebook/Instagram/Snapchat)	site 1	2	3	4	5	
Use a non-phone non-music device (e.g., a laptop)		1	2	3	4	5
Tune the radio	1	2	3	4	5	
Change the heat or air conditioning		1	2	3	4	5
Apply make- up	1	2	3	4	5	
Shave		1	2	3	4	5
Change clothes	1	2	3	4	5	
Read (book, magazine, etc.)		1	2	3	4	5
Use a built-in GPS system	1	2	3	4	5	
Use your phone for navigation	1	2	3	4	5	
Look for an item in wallet/purse/bac	kpack	1	2	3	4	5
Daydream		1	2	3	4	5
Think about something difficult (cor problem, relationship, argument, etc.	nplex .) 1	2	3	4	5	

2. How often have you seen your parent/guardian drive and:

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Most

		Never	<u>Rarely</u>	<u>Weekly</u>	<u>Daily</u>	<u>Trips</u>
Talk on a cellular phone	1	2	3	4	5	
1	2	3	4	5		
Enter navigation information into cell	phone					
Read a text message		1	2	3	4	5
Compose a text message		1	2	3	4	5

3. How often has the following occurred because of activities you do while driving?

		Never	Rarely	Weekly	<u>Daily</u>	Most <u>Trips</u>
Forgotten to fasten seat belt	1	2	3	4	5	
Drifted out of your lane	1	2	3	4	5	
Missed an exit on the highway	1	2	3	4	5	
Nearly hit the car in front of you		1	2	3	4	5
Forgotten where you were going		1	2	3	4	5
Forgotten how you got to your destina	tion	1	2	3	4	5

5. In a normal week, which days do you drive (check all that apply)?

- ____Sunday
- ____Monday
- ____Tuesday
- ____Wednesday
- ____Thursday
- ____Friday
- ____Saturday

6. How many miles did you drive in the past week? _____ miles

7. How many miles do you drive from home to school/work (one way)? (check one)

- ___1 mile or less
- ____1.1 to 3 miles
- ____3.1 to 5 miles
- ____5.1 to 10 miles
- ____10 or more miles

8. Who are your usual passengers? (check all that apply)

- ____Sibling(s) (age 6 and younger)
- ____Sibling(s) (age 7+)
- ____Adult(s) (over age 21)
- ___Friend(s)
- ___None

CELL PHONE USE SCALE

The next section asks questions concerning the use of your cell phone. Each of them should be rated according to the amount that you feel, think, or experience what is

expressed. Please, select the response that best expresses your feelings. Please feel free to skip any questions that you do not wish to answer.

	Never	Almost never	Sometimes	Often	Almost always	Always
1. Do you often think about possible calls or messages you may receive on your cell phone?						
2. Do you think about your cell phone when it is turned off?						
3. How often do you make new friends through your cell phone?						
4. How often do you choose to spend time on your cell phone rather than doing other activities of interest?						
5. Have your family or friends ever said you spend too much time on your cell phone?						
6. Have you ever risked an important relationship or job due to overuse of your cell phone?						
7. Do you think that your school grades have been negatively impacted by the use of your cell phone?						
8. Do you lie to your family or friends about how much time or how often you spend on your cell phone?						
9. Do you use your cell phone to escape from your problems?						
10. How often do you replace bad thoughts with other thoughts about how good using your cell phone makes you feel?						

TEXT MESSAGING QUESTIONS

Please use the following response choices key when answering the eight questions below.

1 = Rarely 2 = Occasionally 3 = Frequently

4 = Often

5 = Always

_____1. I feel preoccupied with using text messaging.

<u>2</u>. I feel the need to use text messaging with increasing amounts of time to achieve satisfaction.

_____ 3. I have repeatedly made unsuccessful efforts to control, cut back or stop text messaging use.

_____4. I feel restless, moody, depressed or irritable when attempting to cut down or stop text messaging use.

_____ 5. I use text messaging longer than originally intended.

<u>6.</u> I have jeopardized or risked the loss of a significant relationship, job, educational, or career opportunity because of using text messaging.

_____7. I have lied to family members, therapists, or others to conceal the extent of involvement with text messaging.

8. I use text messaging as a way of escaping from problems or of relieving a bad mood.

Text Messaging Questions

Please use the following response choices key when answering the eight questions below.

1 = Rarely 2 = Occasionally 3 = Frequently 4 = Often 5 = Always

_____1. I feel preoccupied with using text messaging.

_____2. I feel the need to use text messaging with increasing amounts of time to achieve satisfaction.

_____ 3. I have repeatedly made unsuccessful efforts to control, cut back or stop text messaging use.

_____ 4. I feel restless, moody, depressed or irritable when attempting to cut down or stop text messaging use.

____ 5. I use text messaging longer than originally intended.

<u>6. I have jeopardized or risked the loss of a significant relationship, job, educational, or career opportunity because of using text messaging.</u>

_____7. I have lied to family members, therapists, or others to conceal the extent of involvement with text messaging.

8. I use text messaging as a way of escaping from problems or of relieving a bad mood.

Cell Phone Use Scale

The next section asks questions concerning the use of your cell phone. Each of them should be rated according to the amount that you feel, think, or experience what is expressed. Please, select the response that best expresses your feelings. Please feel free to skip any questions that you do not wish to answer.

	Never	Almost never	Sometimes	Often	Almost always	Always
1. Do you often think about possible calls or messages you may receive on your cell phone?						
2. Do you think about your cell phone when it is turned off?						
3. How often do you make new friends through your cell phone?						
4. How often do you choose to spend time on your cell phone rather than doing other activities of interest?						
5. Have your family or friends ever said you spend too much time on your cell phone?						
6. Have you ever risked an important relationship or job due to overuse of your cell phone?						
7. Do you think that your school grades have been negatively impacted by the use of your cell phone?						
8. Do you lie to your family or friends about how much time or how often you spend on your cell phone?						
9. Do you use your cell phone to escape from your problems?						
10. How often do you replace bad thoughts with other thoughts about how good using your cell phone makes you feel?						

	Never	Almost never	Sometimes	Often	Almost always	Always
11. How often do you think about when you will next use next your cell phone?						
12. How often do you think that life without your cell phone would become boring, empty, and sad?						
13. How often do you get angry or shout if someone tries to interrupt you when you are using your cell phone?						
14. How often do you have nightmares related to your cell phone?						
15. Do you feel irritated or worried if you are not using your cell phone?						
16. Do you feel the need to spend more and more time using your cell phone to feel satisfied?						
17. How often do you try to cut back on the time spent on your cell phone?						
18. Do you choose to spend time on your cell phone rather than hang out with your friends?						
19. Do you feel grumpy, irritable, or sad if you are not using your cell phone, but notice that those feeling disappear as soon as you use it again?						
20. Are you surprised by the amount of time you spend on your cell phone?						
21. Have you ever cut back on the time spent on your cell phone because you felt you were using it too often?						
22. Do you feel that time flies when using your cell phone?						
23. Have you ever felt guilty for spending too much time on your cell phone?						
24. Have you ever tried not to use your cell phone and failed?						

Recent Concussion Survey Concussion and Driving Study

1. In the past month have you been diagnosed with a concussion?

Yes No

If yes:

- 2. When did the concussion occur? Date _____
- 3. How did the concussion happen?
- 4. Did you seek medical care? Yes No
- 5. Have you been cleared to return to activities? Yes No
- 6. Did you stop driving during the period of your concussion? $Yes \quad No$
- 7. Have you resumed driving? Yes No

The Patient Health Questionnaire (PHQ-9)

Patient Name	Dat			
Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
 Little interest or pleasure in doing things 	0	1	2	3
Feeling down, depressed or hopeless	0	Ť	2	3
Trouble failing asleep, staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy.	Q	1	2	3
5. Poor appetite or overeating	0	1	2	3
Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
 Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual 	0	1	2	3
 Thoughts that you would be better off dead or of hurting yourself in some way. 	0	1	2	3

10. If you checked off any problems, how difficult have those problems made it for you to Do your work, take care of things at home, or get along with other people?

□ Not difficult at all □ Somewhat difficult □ Very difficult □ Extremely difficult

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Driving Study Baseline Visit Checklist

- □ Welcome and Visit Overview
- □ Consent signed
- □ HIPAA signed
- □ Baseline Survey completed online
- Text and Cell Phone Usage survey completed online
- □ PHQ2 questionnaire completed online
- □ Recent concussion? Yes No

□ If yes, complete **Recent Concussion survey** online

- □ PHQ9 questionnaire completed online □ N/A
 - □ If yes, what follow up is needed?

S	tudy ID #:							
Simulator C	perator:							
RA Initials:								
Visit Start Time: _	:	_am or pm						
Visit End Time: _	:	_am or pm						
Visit Date: _	/	_/						

SCAT 3	3 comp	leted
--------	--------	-------

- □ Trail Maker B completed
- □ Driving Simulator completed
- Symptom checklist completed (after simulator)
- □ Cell Control installed
 - Not installed; Reason: ______

\Box	Incentive	payment distributed		N/A
--------	-----------	---------------------	--	-----

- □ \$50 check □ \$30 gift card
- □ Parking Coupon provided □ NA

Simulator Operator Initials:

Any known issues with simulator: \Box NA \Box Yes; please describe:

Additional Comments:

APPENDIX C: SCAT-3 AND TRAIL MAKING A AND B TESTS

Concussion and Driving Study Baseline Visit

Study ID_____

Today's date ____/____

SCAT-3

94

Page 1 of 6

Study ID _____

SCAT -3 Symptom Evaluation

How do you feel now? You should score yourself on the following symptoms, based on how you feel now.

	None	None Mild		Moderate		Severe	
Heatlache	0	1 H	2	3	4	5	6
Pressure in head	0	1	2	3	4	5	6
Neck pain	0	1	2	3	- 4	5	6
Nausea or vomiting	0	-1	2	3	4	5	6
Dizziness	0	1	2	3		5	6
Blurred vision	0	-1-	2	3	4	5	6
Balance problems	0	1	2	3	- 4	5	6
Sensitivity to light	0	-1-	2	- 3 -	4	5	6
Sensitivity to noise	0	1	2	3	4	5	6
Feeling "in a fog"	0	-1	2	3	4	5	6
Don't feel right / Not yourself	0	1	2	3	4	5	. 6
Difficulty concentrating	0	-1	2	3	4	5	6
Difficulty remembering	0	1	2	3	4	5	6
Fatigue / Low energy	0	1	2	3	4	5	6
Easily confused	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
Trouble falling asleep	0	1	2	3	4	5	6
More emotional	0	1	2	3	4	5	6
Irritability / Frustration	0	1	2	3	4	5	6
Sadness	0	1	2	3	- 4	5	6
Nervous / Anxious	0	4	2	3	4	5	6
Irritability / Frustration Sadness Nervous / Annious Total number of symptoms	0	1 1 1 maximu	2 2 3 m = 22	3	4		
ymptom severity score		maximu	m = 132				2

Symptom Score	22 minus number of symptoms

____ of 22

SCAT+3 Cognitive Assessment Study ID

Immediate Memory

Trial 1:

I am going to test your memory. I will read a list of words. When I am done, repeat back as many of the words as you can remember in any order (even if you said the word before).

Trails 2 & 3:

I am going to repeat the <u>same</u> list again. Repeat back as many words as you can remember in any order, even if you said the word before.

Complete all 3 trials. Read words at a rate of 1 per second. Score 1 point for each correct response. Total score is summed over 3 trials. Do not inform patient that delayed recall will be tested.

List	Tri	al 1	Tri	al 2	Tri	al 3	Alternate	word lists
elbow	0	1	0	1	0	1	candle	finger
apple	O	1	Ð	1	0	1	paper	penny
carpet	0	1	0	1	0	1	sugar	blanket
saddle	0	1	0	1	0	1	sandwich	lemon
bubble	G	1	0	1	0	1	wagon	insect

Immediate Memory Score

__of15

SCAT-3 Cognitive Assessment Study ID

Concentration Digits Backward

I am going to read you a string of numbers and when I am done you will repeat them back to me in reverse order. For example, if I say 7 - 1 - 9, you will say 9 - 1 - 7.

If correct, go to next string, If incorrect, read the string again and allow trial 2. Stop if incorrect on both trials. Score 1 point for each correct response.

String	Sci	ore	4	Alternate digit sh	rings
4-9-3	0	1	6-2-9	5-2-6	4-1-5
3-8-4-1	0	1	3-2-7-9	1-7-9-5	4-9-6-8
6-2-9-7-1	0	1	1-5-2-8-6	3-8-5-2-7	6-1-8-4-3
7-1-8-4-6-2	0	1	5-3-9-1-4-8	8-3-1-9-6-4	7-2-4-8-5-6

Total number of points: _____ maximum = 4

Months in Reverse Order (or days of the week)

Now I'd like you to tell me the months of the year in reverse order. Start with the last month and go backward. So you will say "December, November..." Go ahead.

1 point for entire sequence correct

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Dec-Nov-Oct-Sep-Aug-Jul-Jun-May-Apr-Mar-Feb-Jan

Alternatively, if they don't know the months of the year, have them say the days of the week in reverse order. (Only 1 of these tests is needed.)

Days in Reverse Order

Now tell me the days of the week in reverse order. The regular order is Sun, Mon., Tue., Wed., etc. Start with the last day and go backward. So you will say "Saturday, Friday..." Go ahead.

	1 point for entire sequence correct				
Sat-Fri-Thur-Wed-Tue-Mon-Sun	о Ц	1 []			
Concentration Score		of 05			

Page 4 of 6

SCAT-3 Balance Examination Study ID _____

Modified Balance Error Scoring System (BESS) testing

Ask: If you were to kick a ball, which foot would you use? This is the dominant leg.

Error scoring

Each 20 second trial is scored by counting errors or deviations from proper stance. Start counting out loud after the patient assumes the proper position. Add one point for each error made in 20 seconds (maximum 10 points). Count just 1 point for multiple simultaneous errors. If patient cannot maintain position for 5 seconds at start of test, assign 10 points for that test.

Types of Errors					
1	Staps, stumbles, falls				

 Remains out of test position for > 5 seconds



Single leg stance

Stand on your [non-dominant] foot. Lift your [dominant] leg in front of you, bent slightly at the hip (30 degrees) and knee (45 degrees). Again, place your hands on your hips and close your eyes. Try to stay in that position for 20 seconds. I will count the number of times you move out of position. If you stumble out of position, open your eyes, get back into position and continue balancing. I will start timing when you close your eyes.

Total Errors

____ of 10

SCAT-3 Cognitive Assessment Study ID_____

Delayed Recall

Do you remember the list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order.

List	Sco	re	Alternate	word lists	
elbow	0	1	candle	finger	
apple carpet saddle	0	1 1 1	paper súgar sandwich	penny blanket lemon	
bubble	0	1	wagon	insect	
Delayed Recall Score				of 05	

Concussion and Driving Study Trail Making Test (TMT) Parts A & B

Instructions:

Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 - 25, and the patient should draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 - 13) and letters (A - L), as in Part A, the patient draws lines to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The patient should be instructed to connect the circles as quickly as possible, without lifting the pen or pencil from the paper. Time the patient as he or she connects the "trail." If the patient makes an error, point it out immediately and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in the completion time for the task. It is unnecessary to continue the test if the patient has not completed both parts after five minutes have elapsed.

- Step 1: Give the patient a copy of the Trail Making Test Part A worksheet and a pen or pencil.
- Step 2 Demonstrate the test to the patient using the sample sheet (Trail Making Part A SAMPLE).
- Step 3: Time the patient as he or she follows the "trail" made by the numbers on the test.
- Step 4: Record the time.
- Step 5: Repeat the procedure for Trail Making Test Part B.

Scoring:

Results for both TMT A and B are reported as the number of seconds required to complete the task, therefore, higher scores reveal greater impairment.

	Average	Deficient	Rule of Thumb
Trail A	29 seconds	> 78 seconds	Most in 90 seconds
Trail B	75 seconds	> 273 seconds	Most in 3 minutes

Sources:

- Corrigan JD, Hinkeldey MS. Relationships between parts A and B of the Trail Making Test. J Clin Psychol. 1987;43(4):402–409.
- Gaudino EA, Geisler MW, Squires NK. Construct validity in the Trail Making Test what makes Part B harder? J Clin Exp Neuropsychol. 1995;17(4):529-535.
- Lezak MD, Howleson DB, Loring DW. Neuropsychological Assessment. 4th ed. New York: Oxford University Press, 2004.
- Reitan RM. Validity of the Trail Making test as an indicator of organic brain damage. Percept Mot Skills. 1958;8:271-276.

Study	ID
weeks y	

Date

Baseline Visit

Page 1 of 7
Concussion and Driving Study Trail Making Test Scores Parts A & B

Study ID _____ Date _____

Trail	Seconds to Complete	
Part A		
Part B		
TOTAL		

Basefine Visit

Page 2 of 7

Concussion and Driving Study Test Administrator Script

"This is called the Trail Making Test. I would like you to connect the circles as quickly as possible, without lifting your pen from the paper."

"This will be a timed test. If you make a mistake you can correct it. And if I've noticed an error I will point it out and you can correct it."

"I'll show you how to do it." (Demonstrate Sample Test Part A).

Give the participant a pen and place Trail Making Test Part A face down in front of them.

When your stopwatch is ready, tell the participant "Please start."

When they have finished, record their score on the score sheet.

"Thank you. There is one more trail making test. This test includes both numbers and letters. I would like you to connect the numbers in ascending order again, but you will alternate between them with a letter. For example, 1-A, 2-B, 3-C, etc."

"I'll show you how to do it." (Demonstrate Sample Test Part B)

"Once again, I would like you to connect the circles as quickly as possible, without lifting your pen from the paper."

"This is also a timed test. If you make a mistake you can correct it. And if I've noticed an error I will point it out and you can correct it."

Give the participant a pen and place Trail Making Test Part B face down in front of them.

When your stopwatch is ready, tell the participant "Start with number one in the middle of the page. Please start."

When they have finished, record their score on the score sheet.

Baseline Visit

Page 3 of 7

Concus	ssion ar	nd Driving St	udy Trail Mak	ing Test	Part A
St	udy ID	Da	te	14	(1)
(15)			6		e
			20	(1	9
	16	6	2		
		હ	8)	02202	14250 U
		5		4	22
	13		6		
(14)		1	(1)	24
U		~ (?)			
	8	(10)		3	
	(9))		6	,
12			U	3	23
0.271		Basel	ne Visit		Page 4

Concussion and Driving Study Trail Making Test Part A - SAMPLE



Baseline Visit

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Concussion and Driving Study Trail Making Test Part B – SAMPLE



Baseline Visit

Page 7 of 7

APPENDIX D: SIMULATOR PROTOCOL AND INSTRUCTIONS

Kelsey's YDC Concussion study (after surveys and concussion testing):

Tell participant they are doing two drives, a rural and city drive. **TDRT is only used in the rural drive.**

Give instruction slideshow packet to read through, last 3 pages are directions about the city so hold those back until before the city drive.

Answer any questions, mal	ke sure they understand	d TDT and the voice control task.
Practice Drive –	Scenario: <u>Krural2</u>	VCS: open from " <u>Kelsey VCS-Practice</u> " folder
(Drive until they've pro go with that for a minu **Exit out of VCS Wit	<i>acticed 4 VCS tasks, state, then begin VCS task</i> adow, don't need to op	<i>"Practice Run" from drop down menu art them driving for 1 minute, then add TDRT, ks)</i> en/close minisim
Main Drive –	Scenario: <u>Krural2</u>	VCS: open from " <u>Kelsey VCS</u> " folder
		"Practice Run" from drop down menu (GoPro Record)
(Drive until end of VCS	5, about 10 minutes)	

Break, give participant city drive rules (last 2 pages of packet) □ Practice Drive - Scenario: <u>KCityPractice</u> (No other tasks)

(Goes for 2 minutes, until screen displays "Please Stop Driving" ****Exit out and reopen minisim before main drive, re-iterate guidelines

□ Main Drive – Scenario: <u>KCity9</u> (GoPro Record)

(Let them drive for 15-17 minutes – THE DRIVE ENDS AFTER THE RED SUV PULLS OUT AT TARGET)

Move TDT File and minisim outputs into YDC-Kelsey Folder on Desktop Backup files on google drive. Folder: Young Driver Concussions -> Study Files -> Real Study Files

Baseline Visit Script and Protocol Concussion and Driving Study

Welcome, and thanks so much for your willingness to participate in this study. The visit should take about an hour and a half. Let me show you where the restroom is (across the hall). Feel free to take a break or use the restroom at any time. We also have snacks, water, juice, and other beverages if you'd like anything. If you don't mind, I'd like to ask you to put your cell phone on silent during this visit.

The first thing we will do is read over the Consent Form together. Please feel free to ask any questions about the study or today's visit. Research is always voluntary and if at any point you decide you don't want to participate that is fine. [Review consent. If the participant is 16 or 17 years old, have both the child and parent sign the consent.]

Did you bring your driver's license today? I just need to confirm that it is valid.

If a parent or friend is attending the visit with the participant, ask them to wait in the adjoining room or outside the lab until the participant has finished the remainder of the visit:

Thank you for joining [participant's name] today. I'd like to ask you to wait outside while he/she completes the surveys, tests and driving simulator. We will call or text you when we're all done or you just come back in about an hour and a half.

Now it's time for you to complete the Baseline surveys using this laptop computer. This should take about 15 minutes. Let me know when you are done.

We will now complete two activities made up of several tests. The first is the SCAT-3, which will give us an idea of how you are feeling and test some of your brain functioning. Let me know if you have any questions.

→ Complete SCAT-3 Test using the script included with test materials.

We will now begin the Trail Making test. This will test your visual attention.

→ Complete Trail Making Test using the script included with test materials.

It is now time for the simulator driving portion of the visit. Before we begin, let's take a break for a snack, drink, or to use the bathroom, if you'd like.

You will be doing two drives today, and we will practice each so that you can get used to the simulator.

Simulator Part 1: Rural VCS

This instructional packet will explain the first drive which is through a rural environment with two distraction activities. Let me know at any point if you have any questions

• Give participant training material packet.

The TDT is a tactile detection task in which you will feel a vibration from a small device, which will be taped on the left side of your neck, and you will react by pressing a button, placed on your left index finger, when you feel the vibration.

In order to get used to the simulator and tasks, we will begin by practicing a rural drive using a voice control navigation system and the TDT. For the voice control, you will hear a voice, think of it as a passenger in your car, telling you something like "find an American restaurant with two stars". In order to activate the VCS navigation system, you will need to repeat exactly what this voice says. Please allow the voice to finish without interrupting it. If you correctly repeat this request, the navigation system will present you with five "yelp" type options on the small navigation screen (point it out). You are to choose the correct restaurant by reading the screen, finding the "two star American" restaurant, and saying "choose option 2" or "Line 2", anything that identifies which option on the list the restaurant is. If you do not repeat the option correctly, the voice control system will not recognize your request and it will move to the next navigation task.

These voice control tasks are designed to be challenging, just do your best. Please follow the lead vehicle at 50 mph, stay in the right lane and do not pass the lead vehicle. The lead vehicle may slow down; if this occurs, you are expected to brake. The TDT will vibrate on your neck, and when you feel it vibrate, you will click the button which is attached to your left index finger. (Show them) Any questions? As I said, we will do a brief practice drive to get used to the simulator and these activities. You will begin by shifting into drive and getting up to speed, then I will add in the TDT only for a while, then start the Voice Control tasks.

Practice First:

- DRT App
 - 0 Open DRT shortcut on desktop
 - O Drag application to operator display and fit correctly
 - O Click "Begin Experiment"
 - O Enter file name "YDC_PID"

- Click Save
- Experiment
 - o "PIDPrac" = Practice Run
 - o "PID" = Main Run

• VCS Wizard Program

- O Open VCS Wizard ("VCS Practice Kelsey" Folder)
 - o Choose Practice Run
- Shrink window: click and drag (inward) the bottom right corner of the window to make it smaller
- o Enter PID
 - Click "Submit"
 - Window turns blue
- o Click on "Show VCS Interface"
- O Drag VCS into Xenarc display
 - Double click the thin blue bar at the very top of the VCS interface to maximize the window
- O On operator display, click "Toggle VCS Borders" or F11
 - This gets rid of borders
 - Windows + up arrow also maximizes screen
- MiniSim v2.2
 - 0 Open MiniSim v2.2
 - o Wait for program to fully boot up (30 seconds or so)
 - O Check "System" tab
 - Make sure all systems are working (turned green)
 - O Choose Scenario "KRural2" from drop down list
 - o Click on DAQ tab
 - Experiment: KGDrivers
 - Participant: PID
 - Recording and Playback

O For practice drive, do not worry about enabling the "record", but if it is checked, it will simply overwrite for the full drive and that's ok!

Any questions? Are you feeling any simulator sickness? Have a snack/beverage now if that would help.

You will now complete the full drive through the same rural environment, following a lead vehicle and completing a navigation task and the TDT button task, similar to as we have practiced. The speed limit is 50 mph. Please follow the 50 MPH speed limit and drive as carefully and attentively as you would in your own vehicle. Do not pass the lead vehicle. If the lead vehicle slows down, you are also expected to slow down. The voice control navigation tasks are designed to be challenging, so simply do your best. Please let me know immediately if you are not feeling well or need to exit the simulator. The drive will last approximately 10 minutes. Any questions?

Before main drive: exit out of VCS from the VCS Practice – Kelsey folder, reload VCS

Main Drive:

- MiniSim is open to "KRural2"
 - Ensure Playback is Enabled and Record option is checked (Settings Tab)
- Open VCS Wizard in "Kelsey VCS" Folder
 - Choose VCS "Practice Run" from drop down menu
 - Type "PID" in PID and hit submit (turns light blue)
 - Click on "Show VCS Interface"
 - Follow same directions as above to maximize display screen
 - Click "Start" on VCS (when ready)
- In TDT Program, delete "Prac" from end of experiment name (PID only)
 - Click "Run Block" on TDT Program (when ready)
- Modify destination name of MiniSim playback video immediately following drive

When ready to begin the drive, click

- "Begin Drive" on Minisim,
- "Start" on VCS, and
- "Run Block" on TDT window
- **Record on GoPro

When drive is over, end TDT, exit out of VCS, exit out of minisim, and change file name of the playback video.

Are you feeling any simulator sickness? Have a snack/beverage now if that would help. We will take a break before the second half of the simulation portion of this study.

***Make sure you change the file name of the playback video!

***Restart Minisim

Simulator Part 2: Urban/City Drive

Are you ready to begin again? In order to get used to the simulator and the urban environment, I'm going to have you do another short practice drive. I have two more training slides to help describe what to expect. [Give them last two training slides]. In this practice drive, you will simply drive straight through an urban environment. Please treat this driving scenario as if you were driving your own vehicle. In this simulator, driving safely is your top priority. Please follow the 35 MPH speed limit, do not turn right on red, and stay in the right lane whenever possible. Any questions? Please let me know immediately if you are not feeling well. [Make sure the trash can is adjacent to simulator in case the participant is feeling nauseous].

Practice drive first:

- MiniSim v2.2
 - o Check "System" tab
 - Make sure all systems are working (turned green)
 - O Click on DAQ tab and select "KCityPractice" Scenario
 - Experiment: KGDrivers
 - Participant: PID
- Begin City Practice Drive for approximately 2 minutes (end of drive is programmed)
 Click "Begin Drive" on MiniSim
- After drive is complete, ask participant if they feel comfortable in the simulator and if they understand the rules of the drive. If they sped during practice drive, remind them that it is important to go the posted speed, 35 mph.
- ***Restart Minisim

You will now complete a drive through the urban environment similar to the one you just saw, now including other vehicles and events that would occur while driving through a city. The speed limit is 35 mph, and you will be given directions on where to turn on the windshield. Please follow the speed limit closely and drive as carefully and attentively as you would in your own vehicle. Please remain in the right lane whenever possible, unless you would like to pass a slower vehicle. The other vehicles may not follow the rules, but you still should. Please let me know immediately if you are not feeling well and need to leave the simulator. The drive should last approximately 15 minutes. Any questions?

"Main" City Drive

- MiniSim v2.2
 - o Check "System" tab
 - Make sure all systems are working (turned green)
 - O Click on DAQ tab and select "KCity9.scn" Scenario ("KCity9_Return" for returning participants)
 - Experiment: KGDrivers
 - Participant: PID
 - Ensure Playback and Record options are checked

Click "Begin Drive"

**Record on GoPro

Drive ends after the red car pulls out at Target, around 15-17 mins.

• The simulator portion is now complete. Ask how they are feeling, offer snacks, etc.

The simulation portion is now complete. We have one very short post-simulator survey left to take. I will get your compensation (and parking validation) ready. Feel free to grab a drink or snacks.

- → Give them the symptom checklist
- → Pay participant
- → Give participant parking validation, if needed
- → Give them the Cell Control unit and explain what it is

When we read the Consent Form we talked about Cell Control. It is a smart-phone based application that you will download on your phone. The application works by communicating with this small device that sits on your dashboard. The app collects data on things like your driving time, sudden stops, and speed. It will also track your phone use, but it won't limit it. The information that's collected is completely protected for you. Here are the instructions for installing it [Give them the instruction sheet "Meet Your New Copilot"].

When you create your online account, you will need to change your Protection Settings so that the app won't block calls and texts while you are driving. On the Protection Settings page under Block, please uncheck the box next to Block Calls and Block Text.

MiniSim Setup

- System Power
 - O Make sure power strip behind the simulator is on
 - o Turn on the light and fan behind left monitor
- Monitors
 - O Main displays: use Vizio remote, press power button and direct at each screen
 - o All other displays should power on automatically
 - Make sure confidence monitor is turned on
- CPUs
 - o Turn on power button that goes to the simulator (green/white circle on top)
 - o Allow steering wheel to center itself
- Screen Navigation
 - O Sim monitors are reached by dragging the mouse to the LEFT
 - 0 Dash monitors are to the RIGHT from operator display

- GoPro
 - O Turn camera on, ensure that it is facing the screen
 - Connect to the wifi open app on cellular device, connected to the wifi network "UW_HFSM_GoPro" password: lindaboyle

Simulator Instructions (given to participants before driving):

Simulator and In-Vehicle Voice Control System:

Training Materials































APPENDIX E: FOLLOW-UP MATERIALS AND SURVEYS

Additional Comments:

	Study ID #:		
Introduction/Visit Overview Recent Driving Experience survey completed in Red Cap	Simulator Operator: RA Initials:		
SCAT 3 completed	Visit Start Time::am or pm		
Trail Maker B completed	Visit End Time:am or		
Driving Simulator completed			
Symptom Checklist completed			
\Box Incentive-Gift Card Distribution \Box N/A			
□ \$50			
Parking Coupon provided INA			
□ Mileage Reimbursement Requested (optional) □ NA			
Simulator Operator Initials:			
Any known issues with simulator: I NA I Yes; please describe	:		

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Recent Driving Experience Survey Concussion and Driving Study

1. In the time between when you enrolled in our study and now, did you ever get a warning ticket from a police officer?

__Yes __No

2. In the time between when you enrolled in our study and now, did you ever get an actual ticket from a police officer?

__Yes __No

3. In the time between when you enrolled in our study and now, have you ever been the driver in a collision or "fender bender"?

__Yes __No

If yes, describe the collision and whether you were found to be at fault or not.

Monthly Driver Check In

1. If you recently had a concussion, do you feel like you have fully recovered from it?

Yes or No

1a. During the past month, did you have a fender-bender, car accident or collision?

Yes or No

IF YES, please answer 1b – 1g. If NO, skip remaining questions and thank participant.

1b. What is the date that the accident or collision occurred on?

Month _____ Day ____ Year _____

1c. Was a police report filed for the accident/collision?

Yes or No

1d. Was another vehicle involved in the incident?

Yes or No

1e. Who caused the accident or collision:

Study Teen or Another Driver or Other

- 1f. What type of accident or collision occurred?
 - (a.) Your car was hit from behind by another vehicle.
 - (b.) Your car ran into the vehicle in front of you.
 - (c.) Your car and another car collided head-to-head.
 - (d.) There was no other vehicle involved.

1g. Describe the details (For example, how did the accident or collision occur, was there damage to any vehicle, where on your car or other vehicle did the damage occur, was bad weather a factor on the day of the incident, were you distracted before the accident?):

2. Were any persons in your vehicle hurt due to the automobile accident?

Yes or No

3. Were any persons in another vehicle hurt?

Yes or No or Don't Know

- 4. After the accident or collision, how would you describe the condition of any vehicle involved:
 - (a) No damage occurred to any vehicle.
 - (b) Minor or limited damage to any vehicle (e.g., small scrapes, dents, or dings).

(c) Moderate damage to any vehicle (e.g., medium sized dent(s) in car or bumper, broken tail light or mirror).

- (d) Major damage to any vehicle (e.g., large dent(s), broken windows, or door damage).
- (e) Your vehicle or another vehicle was damaged enough to require towing.

Medical Care and Treatment Related to Accidents

5. Did anyone require an <u>emergency room visit</u> due to the accident? circle:

Yes or No or Don't Know

6. Were <u>any persons hospitalized</u> due to the accident? circle one:

Yes or No or Don't Know

7. Did persons involved in the accident experience injuries which required additional care from medical providers or other treatments (e.g., doctor visits or care from other providers)?

Describe Injury: _____

Describe treatments or medications:

Vehicle Damage, Repairs and Payments

8. If there was damage to any vehicle, did you report the damage from the accident to your automobile insurance company? (circle)

Yes or No

9a. Did you file a claim with your insurance company to repair the damage from the accident? (circle)

Yes or No

9b. <u>If No</u>, did you have the damage repaired without filing a claim with the insurance company? (circle)

Yes or No

9c. If you paid to repair the damage to the vehicle on your own, without filing an insurance claim, how much was your "out-of-pocket" cost to repair the damage?

\$_____

10. If you processed a claim with the insurance company to repair the accident damage to your car, how much was the total repair cost (deductible amount and amount covered by insurance)?

Your deductible amount: \$ _____

Amount paid by insurance company: \$ _____

11. Following the accident, was there a change in the monthly insurance premium amount for your automobile insurance policy? (circle)

Yes or No or Don't Know

New monthly premium \$ _____

Conclusion Survey

Now that you're at the end of the Concussion and Driving Study, we would like to know about your experience as a participant.

- How would you rate your experience using the Cell Control app? Very dissatisfied Slightly dissatisfied Neutral Slightly satisfied Very satisfied
- 2. How would you rate your experience as a participant in this study?
 - Very good Good Fair Poor Very poor
- 3. How confident would you be in recommending this study to a friend?
 - Extremely Very Moderately Slightly Not at all
- 4. If you had a concussion when you joined the study, are you still experiencing any symptoms?
 - Yes No
- 5. How old were you when you got your driver's license?
 - a. 16
 - b. 17
 - c. 18
 - d. 19
 - e. 20
 - f. 21
 - g. 22
 - h. 23
 - i. 24
 - i. 24 j. 25

6. After you were licensed, in what month/year did you begin driving?

Month		Year
a.	Don't know	2006
b.	January	2007
c.	February	2008
d.	March	2009
e.	April	2010
f.	May	2011
g.	June	2012
h.	July	2013
i.	August	2014
j.	September	2015
k.	October	2016
1.	November	2017
m.	December	

- Would you like to receive the results of this study? Yes
 - No
- 8. If yes, please provide your email address:
- 9. Please let us know if you have any thoughts or comments about this study:

Thanks so much!

- 1. McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sportthe 5th international conference on concussion in sport held in Berlin, October 2016. *Br J Sports Med.* 2017.
- 2. Preece MH, Horswill MS, Geffen GM. Driving after concussion: the acute effect of mild traumatic brain injury on drivers' hazard perception. *Neuropsychology*. 2010;24(4):493-

503.

3. Curry AE, Hafetz J, Kallan MJ, Winston FK, Durbin DR. Prevalence of teen driver errors leading to serious motor vehicle crashes. *Accid Anal Prev.* 2011;43(4):1285-1290.