TEST-RETEST RELIABILITY OF THE BRAINFX 360 PERFORMANCE ASSESSMENT

by

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ABSTRACT

Concussions occur at a frequency between 1.6 and 3.8 million injuries per year. Concussion assessment tests have been designed to compare post injury performance with preseason baseline performance. However to date, there is not a gold standard in concussion assessment testing. Many assessment tests lack acceptable reliability. The purpose of this study was to examine the test-retest reliability of the BrainFx 360 Performance Assessment. Fifteen healthy adults recruited from a large university in the south participated in this study. Participants took the initial assessment and returned seven to fourteen days later for the retest. The overall performance of BrainFx had good reliability. The results of most categories and subsections display moderate to acceptable reliability. Some subtests showed extremely low reliability and should be altered or thrown out in order to increase the overall reliability of performance. Future studies should consider using a randomized test order to assess the test-retest reliability.

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CHAPTER I: INTRODUCTION

A concussion injury is identified as a complex process of functional changes that affect the brain resulting from biomechanical forces (McCrory, et al., 2012). Concussions occur at a frequency of 1.6 to 3.8 million injuries per year (Langlois, Rutland-Brown, & Wald, 2006). Concussions result from one or two forces against the skull that cause injury to the brain (Guskiewicz, et al., 2004; Starkey, Brown, & Ryan, 2010). Headache, dizziness, and confusion are the most common concussion symptoms (Gessel, et al., 2007).

Consequences of concussions occur when the injury is not recognized and managed effectively. Second impact syndrome (SIS), post-concussive syndrome, Parkinson’s, dementia, and chronic traumatic encephalopathy (CTE) are possible consequences of concussions that may also affect an individual immediately following injury to several years later in life (Cantu & Voy, 1995; McKee, et al., 2009; Silverberg & Iverson, 2011). The prevalence of psychosocial and cognitive changes within the last decade has been of great significance because of the problems that some athletes have been enduring later in life (Conidi, 2011).

More recently, neuropsychological tests were designed to compare post injury performance with pre-season baseline performances (Collie, et al., 2003). These concussion assessment tests include both non-computerized and computerized tests. The tests discussed in detail within the review of the literature include some of the most commonly used: Standardized Assessment of Concussion (SAC), the Balance Error Scoring System (BESS), Automated

Neuropsychological Assessment Metrics (ANAM), CogSport, and Immediate Post-concussion Assesment and Cognitive Testing (ImPACT). Over the years, the reliability and validity of these tests have been called into question.

Reliability is the ability of a testing procedure or instrument to consistently measure a characteristic when repeated on an individual or group (Baumgartner, 2006). Measures of reliability include test-retest reliability, inter-rater reliability, parallel forms reliability and internal consistency. Test-retest is one of the most common measures of reliability and the desired value for appropriate clinical decision making is a coefficient greater than .7 for motor components and .8 for psycho social components (Baumgartner, 2006; Resch, et al., 2013b). Acceptable reliability is needed for valid results in a testing procedure or instrument.

BrainFx is a company in Canada that designed the BrainFx 360 performance assessment (T. Milner, personal communication, February 11, 2015). The goal of BrainFx was to design an assessment test that could provide visibility to the effects of mild to moderate brain disorders. The assessment test focuses on intermediate to complex cognitive skills that are assessed using real-life activities (T. Milner, personal communication, February 11, 2015). Currently, no reported reliability of the BrainFx 360 performance assessment has been established.

Concussions have become a hot topic in research over the past decade. Healthcare professionals continue to research and find more efficient and effective ways to properly recognize and manage concussion injuries. More recently, concussion assessment testing has erupted as an assessment tool to aid in detecting, managing and return to play decisions. Various assessment tests exist in order to recognize and manage concussions but many of these tests lack reliability. It is inevitable that researchers continue to better the identification of severity and the management of concussions.

Concussions cause a wide variety of symptoms that can last for a few minutes to years later in life. By the time these athletes reach college, 36% already report a history of multiple concussions in their athletic career (Field, Collins, Lovell, & Maroon, 2003). The solution to this problem is finding a way to better identify the severity and manage concussion injuries through concussion assessment testing.

Significance

In order to effectively identify the severity of and properly manage concussion injuries, there must be a concussion assessment testing program which displays good test-retest reliability. This research attempts to determine if the BrainFx 360 performance assessment is reliable and can be used as an assessment testing program for concussions.

Purpose

The purpose of this study is to determine the test-retest reliability of the BrainFx 360 performance assessment.

Specific Aim

The following specific aims are proposed for this study:

1. To establish the test-retest reliability of the BrainFx 360 performance assessment tasks.

Hypothesis

The following hypotheses are proposed for this study:

1. The test-retest reliability of the individual BrainFx 360 performance assessment tasks which include a motor component will be greater than .7.
2. The test-retest reliability of the individual BrainFx 360 performance assessment tasks which include a psycho social component will be greater than .8.
3. All components will have acceptable reliability.

Limitations

The following are the limitations that will be accounted for throughout this study:

1. Participants may not provide full participation in this study. Participants may not show up at the designated time to take the initial assessment and then again for the retest.
2. The data will be limited to the effort put forth by the participant. Participants may over look either the initial assessment, retest, or both assessments. Equal effort on both assessment may not be obtained by

each participant which can consequently affect the reliability of the assessment.

CHAPTER II: REVIEW OF LITERATURE

A review of the literature is provided in this chapter. The information in this section includes: Concussions, testing paradigm, reliability, and BrainFx 360.

Concussions

Various organizations have attempted to define a concussion injury and its many components (American Academy of Neurology, 2013; Centers for Disease Control & Prevention, 2015; Guskiewicz, et al., 2004; McCrory, et al., 2012). The current definition, defined at the 4th International Conference on Concussion in Sport in Zurich, is "a complex pathophysiological process affecting the brain, induced by biomechanical forces" (McCrory, et al., 2012, p. 250). This definition was established and agreed upon among a panel of some of the experts in concussions today.

Epidemiology. Concussions remain a hot topic as the most widely publicized neurological disorder (Conidi, 2011). The frequency of concussions is between 1.6 and 3.8 million injuries per year (Langlois, Rutland-Brown, & Wald, 2006). Concussions are six times more likely to occur during organized sport in children ages 6 to 16 years old (Browne & Lam, 2006). A rate of 3.66 concussions per 100 players per season occur in high school football (Powell & Barber-Foss, 1999). Furthermore, 53% of high school athletes have reported a history of a concussion and 36% of collegiate athletes have reported a history of multiple concussions in their athletic career (Field, et al., 2003). On average, athletic trainers (AT) care for seven concussions per year (Ferrara, McCrea, Peterson, & Guskiewicz, 2001).

Mechanism of Injury. Concussions are caused by one or two forces against the skull and brain, causing injury to the area of the brain underlying the skull (Daneshvar, Nowinski, McKee, & Cantu, 2011; Guskiewicz, et al., 2004; McCrory, et al., 2012; Starkey, Brown, & Ryan, 2010). The mechanism of injury known as a coup injury refers to a forceful blow to the resting, movable head, where the tissue damage caused by sudden momentum changes occurs beneath the point of impact. Oppositely, a countercoup mechanism is when the site of tissue damage is on the other side of the impact point, such as an athlete contacting the ground. Most diffuse injuries involve an acceleration-deceleration motion, either within a linear plane or in a rotational direction or both. The key elements of the mechanism of injury are the velocity of the head before impact, the time over which the force is applied, and the magnitude of the force. No evidence exists to suggest that either a coup or contrecoup mechanism is more serious or presents differently than the other (Guskiewicz et al., 2004).

Sport Mechanism. There are multiple mechanisms of injury for concussive injuries, due to the wide variety of locations, severity, and forces evident during sport-related concussions (Broglio & Guskiewicz, 2009; Gessel et al., 2007). A direct blow to an athlete's head is not required for a concussion injury to occur; direct or indirect impact to an athlete's head, neck, face, or elsewhere can also result in a head injury (Daneshvar, et al., 2011). This can include both the coup and 7ountercoup mechanisms. Axial loading is another common cause of injury in all sports, but is especially evident in football (Conidi, 2011; Mihalik, Bell, Marshall, & Guskiewicz, 2007). In addition, 18.81% of all football head impacts were to the top of the head, referred to as axial loading (Mihalik, et al., 2007). Helmet to helmet hits, helmet to face mask, and blindside hits to the body which cause flexion and rotation of the neck, have all been demonstrated to induce concussions (Conidi, 2011).

Signs and Symptoms. Signs and symptoms of concussions vary from mild to severe, and sometimes, life threatening. The most common concussion symptoms include headache, dizziness and confusion (Gessel, et al., 2007). It has been reported that 83% of concussed athletes reported a headache, 65% of concussed athletes reported dizziness and 57% reported confusion (Delaney, Lacroid, Leclerc, & Johnston, 2002; Guskiewicz, et al., 2003; Guskiewicz, Weaver, Padua, & Garret, 2000; McCrory, Ariens, & Berkovic, 2000). More recently, it was reported that a headache occurred in 88% of all sports-related concussions (Conidi, 2012). Other signs and symptoms of concussions include lightheadedness, nausea, vomiting, photophobia, blurred vision, noise sensitivity, tinnitus, aphasia, nystagmus, antegrade and/or retrograde amnesia, feeling slowed down, fatigue or drowsiness, sleeping troubles, difficulty concentrating, and inability to maintain balance (Conidi, 2011; Daneshvar, et al., 2011; Guskiewicz, et al., 2004; McCrory, et al., 2012). Only 10% of concussed athletes exhibited loss of consciousness (McCrory, et al., 2012). The actual severity of many concussions goes unrecognized as signs and symptoms don’t always appear immediately in an athlete, sometimes taking as long as a couple days to surface (Leuke, 2011). Typically, signs and symptoms evolve immediately following injury and are usually short lived (McCrory, et al., 2012).

Consequences. Concussions can cause short-term and long-term disabilities if not recognized properly and effectively. Every individual is different and the brain will heal in its own time so it is vital that each case is specific to the individual (Edwards & Bodle, 2014). A younger age and a prior history of concussions predispose individuals to prolonged symptoms and a longer recovery period (Guskiewicz, et al., 2003; McCrory, et al., 2012; Reddy & Collins, 2009).

Short-term Effects. Following a concussion injury, neurological and cognitive symptoms usually continue for hours to days (Edwards & Bodle, 2014; Guskiewicz, et al., 2003; McCrory, et al., 2012). In some cases, concussion symptoms do not always appear or seem to be as severe immediately following impact. Second impact syndrome (SIS) is an uncommon but sometimes fatal outcome of returning to play too soon after an initial concussion (Cantu & Voy, 1995). When a concussion occurs, an athlete’s brain is in a vulnerable state and another impact to the head before the brain has adequate time to heal can result in death (Cantu & Voy, 1995) Short-term effects of a concussion injury include the clinical signs and symptoms that were previously discussed.

Medium-term Effects. An athlete may experience more persistent concussion symptoms (Silverberg & Iverson, 2011). Concussion symptoms that occur days to weeks following the initial impact include sleep disturbances, persistent headaches, photophobia, poor attention, difficulty with concentration and memory, irritability, anxiety and depression. These are known as post-concussive symptoms and make up what is known as post-concussive syndrome. These symptoms can last weeks to months depending on an athlete (Silverberg & Iverson, 2011).

Long-term Effects. Chronic traumatic encephalopathy (CTE) is thought to be a neurodegenerative process that occurs due to repeated concussions (Gavett, Stern, Cantu, Nowinski, & McKee, 2010; McKee, et al., 2009; Omalu, et al., 2005). Repeated concussions are linked to cognitive and psychiatric disturbances later in life. The symptoms suggested to accompany CTE include aggression, depression, suicidal behavior, poor impulse control, Parkinson's, and dementia (Gavett, et al., 2010; McKee, et al., 2009; Omalu, et al., 2005). Consequences of concussions causing long-term effects are negatively affecting athletes later in life once their athletic careers have ended.

Testing Paradigm

Because it is impossible to prevent concussions from occurring during sports, researchers continue to find new and various ways to manage concussions. Neuropsychological testing batteries have been designed in order to compare post injury performance with preseason baseline performances (Collie, et al., 2003). It is imperative that preseason baselines are completed in order to take full advantage of the clinical utility of the assessment. A baseline test provides data that shows the ability of the individual before injury has occurred. Post injury data can then be compared with that to make clinical decisions regarding an athlete (Grindel, Lovell, & Collins, 2001).

Post injury assessments that are performed without baseline data are instead compared with normative data (Grindel, et al., 2001). Normative data doesn’t always reflect the ability of a single individual which can negatively alter results and may cause an athlete to return to play before the brain has fully recovered. An athletes abilities may be above that of normative data which could cause post injury test results to fall within normal limits allowing an athlete to return to their sport. This is the reasoning for why assessment tests have been developed to allow for pre and post injury tests (Grindel, et al., 2001).

Concussion Assessment Testing. Over the years, assessment testing for concussions has become increasingly popular and widely used among sport organizations (Randolph, McCrea, & Barr, 2005). Numerous concussion assessment testing programs, both non-computerized and computerized, have been established in order to detect and manage concussions (Randolph, et al., 2005).

***Non-computerized Tests*.** Non-computerized tests were designed in order for clinicians to perform quick sideline assessments (Randolph, et al., 2005). Two of the most common of these tests are the Standardized Assessment of Concussion (SAC) and the Balance Error Scoring System (BESS) (Randolph, et al., 2005).

Standardized Assessment of Concussion. The Standardized Assessment of Concussion (SAC) was developed as a quick and reliable mental status exam for the field practitioner (McCrea, Kelly, Kluge, Ackley & Randolph, 1997). It is the ideal test for administration on the sideline; and requires only 5 to 6 minutes to complete. SAC consists of four sections that evaluate the areas of orientation, immediate memory, concentration, and delayed recall. Performance on the cognitive categories is added and a total possible score acquired is 30 (McCrea, et al., 1997).

SAC is widely used among clinicians and while it has some positives, it also has numerous flaws among its validity and reliability. When SAC is administered immediately following injury, a 94% sensitivity and 76% specificity are noted (Broglio & Guskiewicz, 2009). The previous research portrayed a sensitivity range between .72 and .78 and SACs validity and utility had been questioned (Ragan, Herrman, Kang, & Mack, 2009). Item analysis was used to evaluate the validity of SAC baseline scores. The questions were too found to be too easy and many questions were deemed unacceptable (Ragan, et al., 2009).

Balance Error Scoring System. Balance can be most effectively tested with the Balance Error Scoring System test (BESS) (Riemann, Guskiewicz, & Shields, 1999). BESS was developed as an objective postural control measure that can also be completed on the sideline immediately following injury. The BESS test is conducted under 6 different stance conditions: a double-leg stance, single-leg stance, and heel-to-toe tandem stance all on a firm surface, then all on a foam surface (i.e. airex pad). Each stance is evaluated for 20 seconds, while the athlete places his or her hands on the hips with the eyes closed. During each 20 second interval, errors are counted and recorded (Riemann, et al., 1999). This test yields sensitivity to concussion at 34% and specificity at 91% (Broglio & Guskiewicz, 2009).

It can be possible that SAC and BESS scores are normal in the post-injury evaluation and symptoms can resolve within 20 minutes; however the athlete should still be withheld from activity (Broglio & Guskiewicz, 2009). Emerging evidence has revealed that symptoms may continue evolving in the subsequent hours following injury and that concussed athletes whose symptoms resolved within 25 minutes of injury have displayed impaired neurocognitive function 36 hours following head trauma (Broglio & Guskiewicz, 2009).

Computerized Tests. Standardization of test administration and scoring is one of the most beneficial advantages of neurocognitive computerized assessments (Woodhouse, et al., 2013). The following test batteries have been recommended to be useful in detecting sport related concussions (Randolph, et al., 2005). The three most common computerized tests reported include Automated Neuropsychological Assessment Metrics (ANAM), CogSport, and Immediate Post-concussion Assessment and Cognitive Testing (ImPACT) (Randolph, et al., 2005).

Automated Neuropsychological Assessment Metrics. The Automated Neuropsychological Assessment Metrics (ANAM) was created by the Department of Defense (Friedl, Grate, Proctor, Ness, & Lukey, 2007). ANAM was originally developed for use among military personnel in order to detect concussions and other TBIs (Friedl, et al., 2007). However, more recently evidence has shown promising potential to be used within the clinical population as well. These populations include multiple sclerosis, migraine headaches, systemic lupus erythematosus, Parkinson's disease, and Alzheimer's disease (Woodhouse, et al., 2013).

It has been found that the ANAM General Neuropsychological Screening Battery (ANAM GNS) correctly classified participants 87.9% of the time (Woodhouse, et al., 2013). The assessment battery displayed a sensitivity of 81% and a specificity of 89.1%. Supporting evidence illustrates that the assessment is able to predict cognitive impairment and properly classify the participants (Woodhouse, et al., 2013).

The individual measures of ANAM show low to moderate test-retest reliability and internal consistency (Cernich, Reeves, Sun, & Bleiberg, 2007; Resch, McCrea & Cullum, 2013b). ANAM reliability coefficients range from .38 to .87 (Cernich, et al., 2007). Dependent upon test-retest intervals, the test-retest reliability coefficients range from .14 to .86 (Resch, et al., 2013b).

CogSport. The CogSport test battery is an approximately 20 minute computerized test that involves playing cards (Collie, et al., 2003). The playing cards consist of four cognitive tasks: Detection, Identification, One-Back and One Card Learning. These tasks assess an individual's reaction time, memory and learning as well as performance accuracy and speed (Collie, et al., 2003).

Validity and reliability of CogSport has been called into question by researchers. The validity of the card tasks is fairly low and only focus predominantly on learning efficiency and problem solving (Mielke, et al., 2014). The reliability values for accuracy of psychomotor, decision making, working memory and learning tasks are extremely low (Collie, et al., 2003). The values show psychomotor accuracy at .2, decision making accuracy at -.08, working memory accuracy at .24 and learning accuracy at .45 (Collie, et al., 2003). Test retest reliability coefficients range from .45 to .9 (Resch, et al., 2013b).

ImPACT. Immediate Post-concussion Assessment and Cognitive Testing (ImPACT) is currently one of the most common tests used for concussion assessments (Broglio, Macciocchi, & Ferrara, 2007). The ImPACT test is a computer-based assessment of cognitive functioning including verbal memory, visual memory, visual-motor speed, and reaction time (Lovell, et al., 2003). The test also measures general concussion symptoms and takes a history from the test taker prior to completion (Lovell, et al., 2003). The reliability of ImPACT ranges from .54 to .76 (Broglio, et al., 2007). The scores from tests such as these offer a benchmark from which the athlete must improve on as their recovery is tracked daily (Lovell, et al., 2003).

ImPACT's test-retest reliability coefficients range from .23 to .88 (Resch, et al., 2013b). When observing the subtests of ImPACT, verbal memory had the weakest interclass correlation (ICC) at .29. The published results that assessed validity found correlation coefficients that ranged from .20 to .88. The sensitivity of ImPACT ranged from 79.2% to 94.6% and the specificity ranged from 89.4% to 97.3% (Resch, et al., 2013b).

Reliability

Reliability is the consistency of measurements (Baumgartner, 2006). It is the ability of a testing procedure or instrument to regularly measure a characteristic when repeated on an individual or group. Reliability is an attribute of a score. It is not a characteristic of a test but the interaction between the test and participant (Baumgartner, 2006).

Types of Reliability. There are various measures of reliability. Measures of reliability include test-retest reliability, inter-rater reliability, parallel forms reliability, and internal consistency (Baumgartner, 2006; DeVon, et al., 2007). One of the most common measures of reliability is test-retest reliability (DeVon, et al., 2007).

Test-retest Reliability. Test-retest reliability is the degree to which the results are consistent over a period of time (Baumgartner, 2006; DeVon, et al., 2007; Resch, et al. 2013b). Test-retest reliability entails the same test given to the same test participants on two separate occasions where the scores are then correlated. The ICC of the scores is known as the test-retest reliability coefficient, or the coefficient of stability. Coefficient of stability ranges from 0 to 1 where 1 is perfect reliability and 0 is unacceptable reliability. Perfect reliability means that the participants' scores were perfectly correlated whereas unacceptable reliability means that the participants' scores on both tests were completely unrelated and the test is not reliable. For clinical use, the suggested desired value for appropriate clinical decision making is a coefficient greater than .7 for motor components and greater than .8 for psychosocial components (Baumgartner, 2006; Resch, et al., 2013b).

Inter-rater Reliability. Inter-rater reliability is also known as objectivity (Baumgartner, 2006). This type of reliability refers to the degree to which two different individuals administer a test and obtain similar or the same outcome

(Baumgartner, 2006). It's been suggested that the advancements in the use of technology could be at fault for decreasing the inter-rater reliability.

Technology advancements such as computer operating system, wireless internet connectivity and computer hardware may launch error in computer based testing programs (Resch, et al., 2013b). If the computers operating system isn't up to date, the computer may process more slowly affecting timed activities or tasks. If wireless internet is lost during a test, the test may have to be repeated. Lastly, the computer's hardware may not be compatible with the test or certain activities and/ or tasks within the test (Resch, et al., 2013b).

Parallel Forms Reliability. Parallel forms reliability refers to measures of error due to differences in test forms (DeVon, et *al*., 2007). Sometimes instruments are created with two or more different versions which do not produce scores consistent with each other. Alternate versions of the same instrument can prevent individuals from memorizing information the first time and using it to better scores or outcomes during the retest. However, if the two versions do not test the same concepts in the same manner with equal means the results will be negatively altered and overall, inconclusive (DeVon, et al., 2007).

Internal Consistency. Internal consistency is considered the easiest form of reliability (Baumgartner, 2006; DeVon, et al., 2007). Internal consistency refers to measures of error due to idiosyncrasies of the test items. Cronbach's alpha is generally the measure used for internal consistency or reliability of a psychometric instrument. It is considered the most repeatedly used statistic and most commonly used by researchers (Baumgartner, 2006; DeVon, et al., 2007).

Sources of Inconsistencies. Four sources of inconsistencies among reliability exist (Baumgartner, Jackson, Mahar & Rowe, 2016). These include the test taker, the test itself, the testing conditions, and the test scoring. It is impossible to control the test taker; the individual could have had a bad day, they could be fatigued or uninterested in the test, or they could be sandbagging (Resch, et al., 2013b). Sandbagging refers to an individual purposefully not doing their best in attempt to establish a minimally valid baseline (Resch, et al., 2013b). Sometimes the questions on the test can be unclear to the test taker (Baumgartner, et al., 2016). If questions and/or the directions on how to complete a task are unclear to the test taker, this becomes an inconsistency in the test itself. Distractions during the test can also exist, and some may be inevitable to dismiss. Distractions can include noise, other movements within the participant's eye sight, or being uncomfortable. These become inconsistencies in the testing conditions. The inconsistency in test scoring is that the scores may be applying different standards when evaluating the test takers response (Baumgartner, et al., 2016).

Reliability is an essential and important component in testing. Acceptable reliability is needed in order to obtain valid results on an assessment. An unreliable test can result in unknown invalid results which may then be used in clinical decision making.

BrainFx

BrainFx was created by two occupational therapists in Ontario, Canada (T. Milner, personal communication, February 11, 2015). The program was originally launched in October of 2013. BrainFx was created as a clinical and digital assessment tool for healthcare professionals. The overall goal of BrainFx is to allow healthcare professionals the capability to measure the effects of mild to moderate brain disorders on an individual's ability to function in real life. The cognitive measures of the test provide over 30 skills including, but not limited to: attention, memory and executive functioning (T. Milner, personal communication, February 11, 2015).

BrainFx was designed with the purpose to provide visibility to the effects of mild to moderate brain disorders (T. Milner, personal communication, February 11, 2015). BrainFx is committed to real world function, quality, evidence, continued neuroscience research and non-stop learning to better serve healthcare professionals. The BrainFx design focuses on intermediate to complex cognitive skills, assesses using real life activities, integrates an individual's medical history, symptoms, functional participation and quality of life and obtains a collateral report as well as a subjective and performance report (T. Milner, personal communication, February 11, 2015).

Current BrainFx Research. York University has voluntarily paired with BrainFx to take on trials and studies in order to answer the proposed question: Can mild to moderate brain dysfunction be detected earlier, easier and with greater sensitivity (Sergio, 2014)? The research is promising and shows that when cross-validated, mild to moderate brain injuries were predicted by the activities 95.5% of the time when compared with healthy, controlled subjects. Fifteen of the activities included in the assessment were statistically significant.

The initial study used a small sample size and continued research involving an increase in sample size will continue for further validation (Sergio, 2014). Currently, no reported reliability has been established.

Conclusion

To date, there is not a gold standard for concussion assessment testing (Resch, et al., 2013a). Neurocognitive test batteries depict many false positives. Many clinicians combine SAC and BESS, ANAM, CogSport, ImPACT or any other neurocognitive testing battery used with a clinical exam and symptom checklist in order to manage a concussion and make effective and appropriate decisions (Resch, et al., 2013a).

The purpose of this research study is to determine the test-retest reliability of the BrainFx 360 performance assessment. Good reliability can help establish the existence of an effective concussion assessment testing program for healthcare professionals to use.

CHAPTER III: METHODS

This study examined the test-retest reliability of the BrainFx 360 performance assessment as a concussion assessment testing program. This chapter will describe the design of the study, participants involved, instrumentation, procedures and data analyses.

Design

The design of this study used a single cohort repeated-measures design to evaluate the test-retest reliability of the BrainFx 360 performance assessment.

Participants

Thirty participants were recruited for this study. Thirty to fifty participants are recommended in order to obtain a normal distribution in scores. Participants were healthy adults, 18 to 30 years old, and were initially recruited from a large university in the south. For this particular study, healthy is defined as an individual who has not sustained a concussion in the last six months and who reported no other health disorders, history of learning disability, seizure disorder, attention deficit disorder, or other mental/physical disability that would affect his or her motor performance.

Instruments

The instrument used in this study is the BrainFx 360 assessment. The BrainFx 360 assessment includes a detailed client report and companion report as well as the performance assessment. However, for this particular study those reports will be excluded. The assessment is preloaded on a 10 inch Android tablet and uses accessories which include a tablet stand, wireless keyboard, noise cancelling headphones and a stylus. The assessment kit is a standard kit used by BrainFx with over fifty tasks (Table 1 displays tasks and description). Wireless internet access is needed at the beginning and end of the assessment. The tablet requires mandatory software updates that the CBA will be notified of in advance and will have to complete by a specified time.

Table 1
Tasks included within the BrainFx 360 performance assessment

Task Number	Task Name	Description
1-4	Feeling at time of assessment	Questions regarding fatigue, sleep, mood and pain
5	Vision screen	Reads sentence with the smallest font that they can see
6	Reading screen	
7	Hand dominance	Questions regarding hand dominance
8	Touch objects†	Touch objects that appear on the screen as fast as possible
9	Color palettes†	Distinguish between colors
10	Anxiety level	Questions regarding anxiety level
11	Hearing sounds part 1	
13	Visual perceptual screening	Visual perceptual questions
14	Matching†	Find difference between two pictures
15	Recall items	Recall items heard
16	Time of day	Question regarding time of day
17	Math questions	Answers math questions as quickly as possible
18	Task for later	Follow instructions
19	Puzzles†	View pictures and rebuild
20	Another task for later	Shown a picture to remember
21	Making change	Money counting activity
22	Recall after a delay	Recall items
23	Another task for later	
24	Route finding†	Trace the most direct route
25	Candy jar†	Move candies as fast as possible
26	Meet your team	Meet all people in red shirts at the party during the time allotted
27	Words in a category	Think of as many relevant words as possible
28	Category from words	Find the commonality amongst words
29	Remembering my appointment	Remember appointment details
30	Sequencing†	Sequence pictures and sentences
31	Remember tasks	
32	Players on the field†	Remember location of players
33	Emotions	Select pictures to recognize emotions
34	Categories†	Move objects to the most appropriate category
35	Time elapsed	
36	Anxiety level	Questions regarding anxiety level
37	Interpreting pictures	Interpret pictures out loud
38	Schedule my day†	Schedule activities into agenda
39	Activities with distraction†	Complete previously completed activities but with distraction
40	Remembering appointment	Recall details of appointment

Table 1 (cont.).
Tasks included within the BrainFx 360 performance assessment

Task Number	Task Name	Description
41	Recognizing safety hazards†	Identify hazardous pictures as quickly as possible
42	Recalling my team	Remember pictures and names previously presented
43	Modified stroop task	
44	Online banking	Online banking activity
45	A watched pot†	
46	Listening to a lecture	Listen to a lecture and recall as many details as possible
47	Prioritizing†	Prioritize activities
48	People on a train	Keep track of number of people
49	The conversation	Questions regarding a conversation listened to
51	Remember task for end	

Note. † denotes tasks that have a motor component

Procedures

The initial recruitment process included a detailed e-mail sent to students at a large university in the south asking for their participation in this study (see Appendix A). Prior to administration of the performance assessment, the Certified by BrainFx Administrator (CBA) gave a detailed explanation of the assessment procedure. Participants were then asked to read and sign a consent form agreeing to partake in this study (see Appendix B). Participants also completed a partial form extracted from the BrainFx client report in order to obtain a short history (See Appendix C). The CBA also assisted and was available throughout the assessment for any additional cues, questions or concerns. The assessment took approximately one hour dependent upon the participant. Administration of the retest of the performance assessment was taken 7 to 14 days after the initial assessment (Baumgartner, 2006; Ohl, Crook, MacSaveny & McLaughlin, 2015). Seven to fourteen days is a sufficient length of time in order to decrease the effects of learning and familiarization of tasks and testing procedures. During the retest, the same set up, design and detail were included. This assessment also took approximately one hour to complete depending upon the participant.

Data Analysis

The data obtained from this descriptive research was analyzed looking for similar scores on both the initial and retest assessments for each participant. Test-retest reliability for each task was calculated using ICC. All analyses were done with SPSS 21.

CHAPTER IV: RESULTS

This chapter contains the results of this study. The results are presented in two major segments describing the descriptive statistics and the reliability of overall performance, categories and the subsections. This study intended to examine the test-retest reliability of the BrainFx 360 Performance Assessment.

Descriptive Statistics

The descriptive statistics provide information for the outcome measures, which included the mean and standard deviation, minimum, maximum and range of overall performance, each category and subtest for both Test 1 and Test 2. The descriptive data are represented in Table 2.

Descriptives of Participants. Fifteen participants participated in this study. The fifteen participants were comprised of nine males and six females. The age of participants ranged from age 20 to 27 and the mean age was 22.9 years old. All participants were free from the exclusion criteria.

Table 2

Descriptive Statistics

	Test 1				Test 2			
	M *(SD)*	Min	Max	Range	M *(SD)*	Min	Max	Range
Overall performance	69.1 *(5.7)*	54	77	23	72.1 *(6.8)*	54	80	26
Sensory & Physical Skill Performance	46.0 *(3.7)*	40	52	12	47.5 *(3.4)*	40	52	12
Visual skills	73.5 *(9.4)*	31	58	27	76.3 *(8.2)*	62	89	27
Fine motor coordination	78.3 *(9.0)*	61	92	31	80.7 *(8.6)*	61	94	33
Social & Behavioral Skill Performance	81.5 *(18.4)*	36	98	62	81.3 *(18.0)*	36	99	63
Impulsivity	72.9 *(25.5)*	30	97	67	72.5 *(22.7)*	34	99	65
Emotion recognition	90.3 *(25.7)*	27	100	73	90.3 *(25.7)*	27	100	73
Foundational Cognitive Skill Performance	76.1 *(8.3)*	62	87	25	80.3 *(9.7)*	62	91	29
Memory - Immediate for auditory	95.9 *(11.1)*	63	100	37	96.7 *(8.8)*	75	100	25
Memory - Immediate for visual	83.4 *(8.7)*	66	94	28	84.3 *(9.5)*	66	100	34
Memory - Immediate for complex, visual, novel	60.3 *(19.5)*	28	96	68	63.3 *(22.8)*	28	96	68
Temporal awareness	64.4 *(18.6)*	30	96	66	77.0 *(17.7)*	39	97	58
Intermediate Skill Performance	72.5 *(8.0)*	57	85	28	75.6 *(8.9)*	57	90	33
Attention - Selective to visual distraction	66.1 *(15.7)*	35	91	56	70.0 *(13.7)*	49	89	40
Attention - Selective to audio distraction	50.9 *(8.2)*	36	69	33	51.0 *(7.7)*	33	61	28
Memory - Delay auditory & written	77.7 *(25.0)*	24	100	76	83.6 *(17.7)*	47	100	53
Memory - Delay written & cued	79.2 *(22.1)*	25	100	75	85.3 *(19.4)*	49	100	51
Working memory	73.9 *(28.0)*	35	100	65	76.0 *(26.0)*	35	100	65
Problem solving	56.5 *(16.1)*	25	76	51	60.3 *(23.1)*	5	96	91
Constructive ability	88.3 *(21.6)*	30	100	70	83.9 *(21.6)*	36	100	64
Route finding	97.4 *(5.4)*	87	100	13	96.7 *(7.1)*	77	100	23
Sequencing	63.1 *(13.6)*	42	87	45	71.5 *(15.8)*	42	95	53
Complex Cognitive Skill Performance	69.0 *(5.9)*	61	80	19	76.6 *(5.6)*	68	84	16
Attention divided	68.7 *(22.5)*	33	98	65	87.6 *(16.0)*	48	99	41
Memory - Delay for face & names	67.3 *(12.2)*	47	85	38	76.6 *(11.1)*	55	92	37
Memory - Prospective auditory 2 steps	73.9 *(7.2)*	72	100	28	86.3 *(13.9)*	72	100	28
Mental flexibility	63.3 *(25.1)*	16	98	82	74.4 *(20.4)*	25	96	71
Abstract reasoning	64.2 *(9.3)*	47	78	31	67.1 *(8.3)*	55	84	29
Judgement for safety	71.5 *(11.9)*	52	90	38	78.7 *(12.7)*	41	94	53
Foresight for safety	68.1 *(22.8)*	20	99	79	75.3 *(23.5)*	20	100	80
Comprehension & humor inferences with distraction	71.1 *(12.9)*	45	89	44	71.1 *(15.4)*	43	98	55
Executive functioning & combined skills	72.3 *(5.0)*	65	80	15	73.1 *(5.6)*	63	80	17

Note. M = mean; *SD* = standard deviation; Min refers to the minimum score and Max refers to the maximum score; Range of possible score is 0 to 100, with 100 being the best possible score

Reliability of BrainFx 360 Performance Assessment

The reliability of the BrainFx 360 performance assessment was examined. The overall performance score for both tests had good reliability at .85. A single measure of the overall performance score had an acceptable reliability of .73. The reliability of all categories and subsections are represented in Table 3.

Table 3

Reliability of BrainFx's overall performance, categories and subsections

	Intraclass Correlation Coefficients	
	Single Measures	Average Measures
Overall performance	.73	.85▪
Sensory & Physical Skill Performance	.72	.84▪
Visual skills†	.73	.84▪
Fine motor coordination†	.68	.81▪
Social & Behavioral Skill Performance	.69	.82▪
Impulsivity	.94	.97▪
Emotion recognition	.45	.62
Foundational Cognitive Skill Performance	.66	.79
Memory – Immediate for auditory	.53	.69
Memory – Immediate for visual†	.79	.88▪
Memory – Immediate for complex, visual, novel	.73	.84▪
Temporal awareness	.46	.63
Intermediate Skill Performance	.75	.86▪
Attention – Selective to visual distraction†	.73	.84▪
Attention – Selective to audio distraction	-.03	-.06
Memory – Delay auditory & written	.33	.50
Memory – Delay written & cued	.48	.65
Working memory	.75	.86▪
Problem solving	.64	.78
Constructive ability†	.31	.47
Route finding†	.11	.19
Sequencing†	.59	.75▪
Complex Cognitive Skill Performance	-.21	-.54
Attention divided†	.01	.03
Memory – Delay for face & names	.23	.37
Memory – Prospective auditory 2 steps	-.05	-.10
Mental flexibility	.26	.42
Abstract reasoning†	.18	.31
Judgement for safety	-.32	-.93
Foresight for safety	.82	.90▪
Comprehension & humor inferences with distraction	.05	.10
Executive functioning & combined skills†	.37	.54

Note. † denotes subsections that have a motor component; ▪ denotes a reliability greater than .7 for those subsections with a motor component and greater than .8 for psychosocial; 1.0 is perfect reliability

CHAPTER V: DISCUSSION

The purpose of this study was to evaluate the test-retest reliability of the BrainFx 360 Performance Assessment. This section will address and interpret the findings and discuss their impact. Limitations and future directions will also be included.

Reliability of BrainFx

Overall performance of the BrainFx 360 performance assessment displayed good reliability. The BrainFx 360 performance assessment is broken up into five categories that include subsections. The sensory and physical skill performance category, the social and behavioral skill performance category, the foundational cognitive skill performance category and the intermediate skill performance category all had acceptable composite reliability. The sensory and physical skill performance category was two for two in the subsections that also had acceptable reliability greater than .7 for those subsections with a motor component and greater than .8 for those with a psychosocial component. The social and behavioral skill performance category was one for two. The foundational cognitive skill performance category was two for four and the intermediate skill performance category was four for nine. The complex cognitive skill performance category was one for nine and the only category that's composite reliability was unacceptable.

Comparing Reliability. When the reliability of the BrainFx 360 performance assessment subsections are compared to other assessment subsections it shows to have better reliability. Five of BrainFx's subsections displayed good reliability, especially when compared to the comparable subsections with ANAM, CogSport and ImPACT.

ANAM and CogSport both have subsections that assess working memory; however, the reliability is low to moderate. In ANAM, the subsection is called the Sternberg memory procedure which is comparable with working memory. The reliability coefficient of working memory in CogSport is .24 and .48 for ANAM (Cernich, et al., 2007; Collie, et al., 2003). BrainFx's reliability coefficient for working memory is .86. This task involves keeping track of individuals getting on and off a train. The participant must enter the final count of individuals that are on the train once the task is completed.

CogSport's subsection decision making is comparable with BrainFx's problem solving subsection. CogSport's decision making subsection has an extremely low observed ICC of -.08 (Collie, et al., 2003). CogSport consists of playing cards. There are only so many tasks that can be done to assess decision making with playing cards. BrainFx's subsection includes a task with math questions and making change from a cash register and has an ICC of .78.

CogSport and ImPACT both have subsections comparable to the fine motor coordination subsection of BrainFx. CogSport's reliability of this subsection, psychomotor accuracy, is low with an ICC of .20 (Collie, et al., 2003). The reliability of the visual motor speed subsection within ImPACT is borderline with an ICC of .61 (Broglio, et al., 2007). BrainFx assesses fine motor coordination using a unique task of sliding and pinching candies into a jar using the touch screen tablet and has an ICC of .81.

Visual and verbal memory subsections for BrainFx were much better than that of ImPACT's. ImPACT's visual memory has a reliability coefficient of .32 whereas BrainFx's comparable subsection of memory, immediate for visual has a reliability coefficient of .88 (Broglio, et al., 2007). Verbal memory was the weakest ICC observed among ImPACT's subsection with an ICC of .29 (Broglio, et al., 2007). ImPACT's verbal memory subtest is comparable to BrainFx's memory, immediate for complex, visual, novel which has an ICC of .84. BrainFx's subsections that assess visual and verbal memory include recalling details from a one minute lecture and recalling the location of players on a field. These tasks are more engaging to the participant than recalling shapes and words.

When the reliability of the subsections of BrainFx are compared with other assessments subsections, BrainFx shows to have better reliability.

Potential Issues

There were a few subsections within the BrainFx 360 performance assessment that had unacceptable reliability. Whether these task directions are actually unclear or the participant is not fully reading and understanding the directions before he or she begins the task is unknown. Sometimes on the initial assessment, a participant skipped an entire task but will then complete the task during the retest assessment. This may be due to a better understanding of directions the second time around. These seven tasks are unique to the BrainFx 360 performance assessment. The following tasks discussed below include category from words, rebuild pictures, route finding, a watched pot, recall sound, recognizing safety hazards and the conversation.

Category from Words. Category from words is a task within the subsection attention, selective to audio distraction which has an ICC of -.06. This subsection included tasks which involved math questions with noise distraction, the difference between math questions with and without noise distraction, items in a category with distraction, the difference between items in a category with and without noise distraction, category from a list of words with distraction and the difference between category from a list of words with and without distraction. Many participants had difficulty with the category from a list of words. The categories are not consistent in their level of difficulty. A participant may get an easier category first and a more difficult category later on in the assessment when there is background noise as distraction or vice versa. Abstract reasoning has an ICC of .31 and was also a subsection that included the category from words task.

Rebuild Pictures. In the rebuilding pictures task, the participant would look at a pictures for a few seconds before it broke up into nine pieces that they had to put back together within the time allotted. The participants, using their index finger, were to slide the nine puzzle pieces back into place. Sometimes the final piece of the puzzle would not slide into place, instead returning to the outside of the puzzle and the participant had to complete the task with the final piece missing from the picture. The rebuild pictures task is under the subsection constructive ability which has an ICC of .47. Not allowing the last puzzle piece to slide into place is an issue that could be at fault for the low reliability of this subsection. It affected the participant's score as well as the reliability of the subtest.

Route Finding. Route finding included a town map where the participant would have to trace the most direct route from one place to another, sometimes making stops in between. The reliability of this subsection and task is .19. Most participants scored a perfect score on the first, second or both times taking this task. The route finding task is too easy and is not an accurate task for assessing concussive injuries. Route finding is not a reliable task within the BrainFx 360 performance assessment.

A Watched Pot. A watched pot is a task under the subsection attention divided which has an ICC of .03. A watched pot includes matching of items while watching a pot on the stove top. Anytime the pot boils the participant must slide the pot to the sink and then continue matching items until the pot boils again. Many participants didn't fully read or understand the directions and were confused on what needed to be done for this task. On the initial test some participants would only slide the pot to the sink when it boils while others would only match the items ignoring the other task. On the retest, extra cues were needed to complete the task successfully or the participant would remember to read the directions more carefully before beginning the task.

Recall Sound. The majority of participants completely missed the recall sound task. This task includes a noise that they will hear later in the assessment. When they hear that specific noise, they are to double click on the icon and type a sentence. Most listen to the sound and hit next to go on to the next task. Some have listened to the sound and started typing, however nothing comes up. While others have looked at the CBA and stated the sentence they were to remember out loud. This task is under the subsection memory, prospective, auditory two steps which has an ICC of -.10.

Recognizing Safety Hazards. The subsection judgement for safety had the worst reliability observed with an ICC of -.93. This subsection included a task where the participant needed to assess what to do in response to a hazard presented. Some of the hazards included a blender with the top off, a person climbing a tree, a piece of wood going through a table saw with a person's thumb very close to the blade, a person choking, and a cutting board, hand, and knife. The task asked whether this was inconvenience or extra work, a minor injury, or death or severe injury. This task is subjective and dependent upon the participant different responses are obtained.

The Conversation. The conversation included two individuals who run into each other at a party and haven't seen each other in years. They discuss what is new in their lives as well as look back on the old days. In the background is noise heard from the rest of the party that is distracting while listening to the conversation. This task is under the subsection comprehension and humor inferences with distraction which has an ICC of .10. The task doesn't seem too difficult, but is one of the last tasks on the assessment and it seemed the interest of the participant was decreasing by the time they needed to listen to a conversation. This is the third to last task in the assessment and most participants did not provide their full attention while listening to this task.

The subsections which included these specific tasks displayed poor reliability. It is important that these tasks are altered or thrown out in order to increase not only the reliability of each subsection but of the overall performance of the assessment. Altering these tasks to include easy, simple and clear direction may better the tasks performance.

Clinical Implications

As shown in this study, the BrainFx 360 performance assessment has the ability to be a reliable test for concussion injuries. The findings of this study have the potential to help alter the assessment to make it more reliable. For example, throwing out some of the tasks which displayed low reliability and altering those tasks with low to moderate reliability will probably increase the reliability of the subsections and the overall performance reliability. A consolidated version included concussion specific tasks with good reliability should be created. Good reliability can help establish the existence of an effective concussion assessment testing program for healthcare professionals to use.

This may also decrease the time it would take to complete the assessment. A shorter, more reliable assessment would be more efficient to healthcare providers. A shorter assessment would be more accepted among healthcare professionals to use, especially in a team or school setting where larger groups of athletes need to be tested. Because there is currently not a gold standard for concussion assessment testing, healthcare professionals are open and welcoming to new research and tests available (Resch, et al., 2013a).

Currently, healthcare professionals are using the easiest and simplest concussions assessment testing that is available whether the reliability is borderline or acceptable. The BrainFx 360 performance assessment is not a self-administered assessment which may deter most healthcare professionals away from using this assessment for sport screening. In the clinical setting, it is more time efficient to test a group of athletes at the same time rather than individually. Currently, BrainFx requires the CBA to be available and assisting one client through the entire hour long assessment. The administration of BrainFx should consider self-administration.

Limitations

This study is not without limitations. One limitation is the small sample size that was gathered. With more time and greater resources a larger sample size can be used in order to obtain a normal distribution of scores and more information regarding the reliability of the BrainFx 360 performance assessment. Another limitation is that there is no control over the test order during the assessment. It is possible that some of the tasks near the end displayed poor reliability due to their placement. A final limitation is the responsiveness of the tablet. The reaction time seemed slower and sometimes a client needed to tap the tablet more than once to continue.

Future Direction

Future research of the BrainFx 360 performance assessment might consider testing the reliability of the balance portion of the assessment. Another interesting area of research would be to assess the motivation and effort levels of the clients during the initial assessment and compared with the retest. Creating an assessment with a randomized test order may also display better results when assessing test-retest reliability.

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APPENDICES

APPENDIX A

PARTICIPANT RECRUITMENT E-MAIL

To whom it may concern,

I am writing to let you know about an opportunity to participate in a research study regarding the reliability of the BrainFx 360 Performance Assessment. BrainFx has designed a computerized neurocognitive test in order to detect mild to moderate brain injuries more efficiently. This study is being conducted by Chelsea Searles at Middle Tennessee State University. Participation in this study will involve two meetings with the researcher lasting approximately one hour each. In the first meeting, you will complete the initial assessment and then you will return 7-14 days later to complete the second assessment.

You may be eligible for this study if you are a healthy, college aged student. For this particular study, healthy is defined as an individual who has not sustained a concussion within the last six months and is not taking any medications that would affect motor performance.

It is important to know that this letter is not to tell you to join this study. It is your decision. Your participation is voluntary. Whether or not you participate in this study will have no effect on your relationship with Middle Tennessee State University as a student.

If you are interested in learning more or participating in this study, please contact Chelsea Searles either by e-mail at cms8t@mtmail.mtsu.edu or by phone at (203) 695-5115. You may also visit BrainFx's website at www.brainfx.com.

You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you, but you may receive another e-mail which you can simply disregard.

Thank you for your consideration.

Chelsea Searles, ATC, LAT
Smyrna High School Athletic Trainer
(203) 695-5115

APPENDIX B

INFORMED CONSENT

Reliability Study Consent Form

Title of Research: Test-retest Reliability of the BrainFx 360 Performance Assessment
Researcher: Chelsea Searles, ATC, LAT

You are being asked to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. You should receive a copy of this document to take with you.

Explanation of Study

You are invited to participate in a research study to test the reliability of the BrainFx 360 Performance Assessment. We ask that you read this form and ask any questions you may have before agreeing to allow your participation in the study.

The study is being conducted by Chelsea Searles at Middle Tennessee State University.

The purpose of this study is to determine the test-retest reliability of the BrainFx 360 performance assessment. Specifically, this study will compare the initial assessment scores with the retest scores in order to measure the reliability of the BrainFx 360 performance assessment. The researcher, a Certified by BrainFx administrator (CBA), will administer both tests, provide cues if needed during the assessments, answer any questions or concerns and collect data.

If you agree to be in the study, you will do the following things:

Participate in Baseline Assessment:

Prior to the initial assessment, you will be provided a detailed explanation of the assessment and how to complete it. The CBA will also be available for any cues, questions or concerns during the assessment. The CBA will continually help with the set up of the tablet and accessories for each task throughout the assessment.

Participate in a Retest Assessment:

The retest assessment will be similar to the baseline and initial assessment. The CBA will, again, provide you with a detailed explanation of the assessment and how to complete it. The CBA will also be available for any cues, questions or concerns during the assessment. The CBA will continually help with the set up of the tablet and accessories for each task throughout the assessment.

Your participation in the study will last two weeks where you will need to be available to the investigator for approximately one hour each week.

Risks and Discomforts
There are no additional risks by participating in this study. There may be other risks that we cannot predict.

Also, at any point you do not want to continue participation in the research study, you can stop participating, at any time. Doing so will not affect the participant's status with Middle Tennessee State University or the investigator.

Benefits
While there is no direct benefit to you for participating in this research study, the overall benefits we hope to gain from this study are establishing a concussion testing program to better detect mild to moderate brains injuries.

Confidentiality and Records
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Institutional Review Board or its designees, or the study sponsor.

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

* Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
* Representatives of Middle Tennessee State University (MTSU), including the Institutional Review Board, a committee that oversees the research at MTSU;

Contact Information
If you have any questions regarding this study, please contact
<u>Middle Tennessee State University Contacts:</u>

Chelsea Searles	*cms8t@mtmail.mtsu.edu*	***(203) 695-5115***
Brian Ragan	*brian.ragan@mtsu.edu*	***(615) 898-2812***

<u>BrainFx Contact:</u>
Tracy Milner, CEO
tmilner@brainfx.com
1-844-4BRAINFX

If you have any questions regarding your rights as a research participant, please contact the Research Compliance Office, Middle Tennessee State University, compliance@mtsu.edu (615)494-8918.

By signing below, you are agreeing that:

- you have read this consent form and have been given the opportunity to ask questions and have them answered
- you have been informed of any potential risks and they have been explained to your satisfaction.
- you are 18 years of age or older
- your participation in this research is completely voluntary
- you may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you and you will not lose any benefits to which you are otherwise entitled.

Signature___________________________________ Date____________

Printed Name_____________________________________

APPENDIX C

PARTICIPANT HISTORY FORM

Biographical Information

Name: ___________________________________

Gender: Male Female

Age: ____

BrainFx

Neurological Event/Disease

Have you ever experienced any of the following:

Concussion/Traumatic Brain Injury? Yes No

If yes, please provide details:

How many? ____

When? __/__/____

If sport related, which sport? __________________________

If sport related, which position were you playing? ________________

How did it happen? ____

____

Were you wearing protective equipment? Yes No

If yes, please list ____

Did you lose consciousness? Yes No Not Sure

If yes, how long? ____minutes

Acquired Brain Injury? Yes No

If yes, please provide details:

Description? ____

____

Persistent symptoms? Yes No

Stroke? Yes No

If yes, please provide details:

Description? ____

____

Persistent symptoms? Yes No

Dementia? Yes No

If yes, please provide details:

Description? ____

____

Persistent symptoms? Yes No

Other Neurological Condition(s) that affects you (cognitively, emotionally, physically)

Have you ever had another neurological condition(s)? Yes No

When did the symptoms start? __/__/____

Description? ____

____

Persistent symptoms? Yes No

Medical History

Disease or Disorder

Name	Year Diagnosed	Currently Resolved?	
______________________	________	Yes	No
______________________	________	Yes	No
______________________	________	Yes	No
______________________	________	Yes	No

Medications

Medication	Dose	Frequency	Purpose of Drug
______________	________	__________	__________
______________	________	__________	__________
______________	________	__________	__________
______________	________	__________	__________

APPENDIX D

IRB APPROVAL LETTER

4/2/2015

Investigator(s): Chelsea Searles
Department: Health and Human Performance
Investigator(s) Email Address: cms8t@mtmail.mtsu.edu; brian.ragan@mtsu.edu

Protocol Title: Test retest reliability of the BrainFx 360 Performance Assessment

Protocol Number: #15-252

Dear Investigator(s),

Your study has been designated to be exempt. The exemption is pursuant to 45 CFR 46.101(b)(2) Educational Tests, Surveys, Interviews, or Observations.

We will contact you annually on the status of your project. If it is completed, we will close it out of our system. You do not need to complete a progress report and you will not need to complete a final report. It is important to note that your study is approved for the life of the project and does not have an expiration date.

The following changes must be reported to the Office of Compliance before they are initiated:

- Adding new subject population
- Adding a new investigator
- Adding new procedures (e.g., new survey; new questions to your survey)
- A change in funding source
- Any change that makes the study no longer eligible for exemption.

The following changes do not need to be reported to the Office of Compliance:

- Editorial or administrative revisions to the consent or other study documents
- Increasing or decreasing the number of subjects from your proposed population

If you encounter any serious unanticipated problems to participants, or if you have any questions as you conduct your research, please do not hesitate to contact us.

Sincerely,

Lauren K. Qualls, Graduate Assistant
Office of Compliance
615-494-8918

MTSU Compliance Office
010A Sam Ingram Bldg.
1301 E. Main St.
Murfreesboro, TN 37129

APPENDIX E

IRB APPROVAL LETTER ADDENDUM I

4/28/2015

Investigator(s): Chelsea Searles, Brian Ragan
Department: Health and Human Performance
Protocol Title: Test-retest Reliability of the BrainFx 360 Performance Assessment
Protocol Number: #15-252

Dear Investigator(s):

I have reviewed your research proposal identified above and your requested changes. I approve of the following change:

- Participant age range extended to 30 years old

Please note that any unanticipated harms to participants or adverse events must be reported to the Office of Compliance at (615)494-8918 or compliance@mtsu.edu. Any change to the protocol must be submitted to the IRB before implementing this change.

According to MTSU Policy, a researcher is definied as anyone who works with data or has contact with participants. Anyone meeting this definition needs to be listed on the protocol and needs to complete the online training. If you add researchers to an approved project, please forward an updated list of researchers to the Office of Compliance ***before*** they begin to work on the project.

Sincerely,

Office of Compliance
Middle Tennessee State University

MTSU Compliance Office
010A Sam Ingram Bldg.
1301 E. Main St.
Murfreesboro, TN 37129

APPENDIX F

IRB APPROVAL LETTER ADDENDUM II

MIDDLE TENNESSEE STATE UNIVERSITY

5/26/2015

Investigator(s): Chelsea Searles and Brian G. Ragan
Department: Health and Human Performance
Protocol Title: Test-retest reliability of the brainFX 360 Performance Assessment
Protocol Number: #15-252

Dear Investigator(s):

I have reviewed your research proposal identified above and your requested changes. I approve of the following change:

> Replacement of "MTSU student population" with "age group 18-30" in regard to the target population for the study

Please note that any unanticipated harms to participants or adverse events must be reported to the Office of Compliance at (615)494-8918 or compliance@mtsu.edu. Any change to the protocol must be submitted to the IRB before implementing this change.

According to MTSU Policy, a researcher is definied as anyone who works with data or has contact with participants. Anyone meeting this definition needs to be listed on the protocol and needs to complete the online training. If you add researchers to an approved project, please forward an updated list of researchers to the Office of Compliance ***before*** they begin to work on the project.

Sincerely,

Office of Compliance
Middle Tennessee State University

Template Revised March 2014

MTSU Compliance Office
010A Sam Ingram Bldg.
1301 E. Main St.
Murfreesboro, TN 37129