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Informing Cognitive Screening in the Young Adult Population

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INFORMING COGNITIVE SCREENING IN THE YOUNG ADULT POPULATION

by

Samantha L. McDaniel

A dissertation submitted to the Graduate College
in partial fulfillment of the requirements
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INFORMING COGNITIVE SCREENING IN THE YOUNG ADULT POPULATION

Samantha L. McDaniel, Ph.D.

Western Michigan University, 2021

The clock drawing test (CDT) is a cognitive screening measure with sound psychometric properties which has been well researched over the past century. The CDT is a popular tool for many healthcare professionals to administer independently or as part of a more thorough cognitive evaluation. Given the drastic technological and social developments over the years since the CDT was developed as well as the persistent research focus on older adult populations, a gap in the CDT literature presented for young adults, who may have difficulty drawing an analog clock. Identifying cognitive impairment can improve health outcomes. The young adult population requires an effective and accurate cognitive screening tool due to the incidence of traumatic brain injury including concussion, the need for pre-sports season physicals, and eventual maturation to older adulthood. Inaccurate CDT outcomes could result in unnecessary further testing, increased hospital length of stay, and avoidable emotional stress for the patient and family.

The first study explores CDT performance in young adults who self-identify as having normal cognition. Using the Shulman method of scoring, a significant proportion of the participants received a “failing” score on the CDT. Visuospatial skills were preserved in this population which suggests a lack of knowledge of analog clock times or language. The second study focuses on the clinical setting and compares CDT scores between young and older adult

hospital inpatients. These data confirmed findings from the first study and determined a significant variance from young to older adults when categorized by overall cognitive severity ratings. The third study investigates the effect on cognitive severity rating in participants with a diagnosis of concussion or craniotomy who missed points on the CDT. Findings suggested a significant difference in cognitive severity rating between young and older adults for those participants with a diagnosis of concussion, again likely related to challenges in drawing an analog clock within the younger adult population.

As generational evolution is inevitable, it is vital to assess the current and future role of the CDT in cognitive screening for young adults. This three-paper dissertation offers further insight into the CDT ability of young adults with relevant recommendations and future research implications for interdisciplinary cognitive screening practice with this population.

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CHAPTER I

INTRODUCTION

Cognitive impairment can be debilitating for the individual as well as their support system; Early identification is essential for adequate diagnosis, intervention, and support (Morley et al., 2016). All ages of adults are susceptible to cognitive deficits; The cause for most younger adults (i.e., ages 18-30) is traumatic brain injury (TBI) and for most older adults (i.e., ages 65+) is dementia (Hackenberg & Unterberg, 2016; NIA, 2021). In 2014, the leading cause of hospitalizations from TBI for adolescents and young adults (i.e., ages 14-44) was motor vehicle collisions (Centers for Disease Control and Prevention, 2019). The Centers for Disease Control and Prevention (2019) also found that motor vehicle collisions were the second most common cause of brain injury with the average age of 18.2 years in 2014.

Cognitive screening is an effective way of determining further assessment and intervention needs for individuals who are at risk for cognitive deficits (Morley et al., 2016). The clock drawing test (CDT) is a screening method that has a rich history in the clinical setting and has been thoroughly researched since its initiation in 1915 (Hazan et al., 2018). Much of this research has focused on older adults and, in particular, the identification of dementia. This has led to a gap in the literature for the current young adult population (i.e., 18–30-year-olds).

The young adult population, as previously mentioned, are still at significant risk for cognitive impairment and are in need of accurate cognitive screening. Also, as this young adult population ages, accurate cognitive screening is necessary to identify other disorders more commonly associated with the older adult population (e.g., dementia). The current young adult population does not use analog clocks as commonly as older adults (Fultonberg, 2017; Slome,

2015). Many children and young adults do not wear watches, and very few of the individuals who do wear a watch have an analog clock screen (Fultonberg, 2017). The ability to complete the CDT relies on exposure to analog clocks, and it is not clear whether young people currently growing up in a digital world have sufficient exposure to analog clocks to enable them to perform the task accurately, independent of cognitive status.

The Clock Drawing Test

The CDT is a robust assessment of cognition relative to the time and effort involved for administration and can evaluate the following cognitive domains: selective and sustained attention, verbal working memory, visual memory and reconstruction, visuospatial skills and executive function (Dion et al., 2020; Mainland & Shulman, 2017). Following the Mini Mental State Examination (MMSE), the CDT is the second most widely used test for evaluating cognition (Khan, 2016). The CDT has been found to be fast and easy to administer, non-invasive and non-offensive which has contributed to its acceptance and widespread use (Mainland & Shulman, 2017; Nyborn et al., 2013; Parker & Philp, 2004; Souillard-Mandar et al., 2016).

There is no standardized approach to administration or scoring of the CDT and may include copying an analog clock, filling in an analog clock from a pre-drawn circle, reading an analog clock time, or free-drawing an analog clock, including numbers and clock hands (Hazan et al., 2018). Although Scanlan et al. (2002) found that untrained raters could accurately screen cognition with the CDT, the CDT is mostly used by healthcare providers such as neurologists, psychologists, speech-language pathologists, nurses, geriatricians, occupational therapists, and family practice physicians among others.

Various scoring methods have been developed over the years, with the Shulman method remaining the most widely used as a stand-alone scoring method (Mainland, Amodeo, & Shulman, 2013). The Shulman method consists of a pre-drawn circle with a diameter of approximately four inches. The instructions presented are, “This circle represents a clock face. Please put in the numbers so that it looks like a clock and then set the time to ten minutes past eleven.” Five points are given for a “perfect” clock, four points for a clock containing minor visuospatial errors, three points for acceptable visuospatial organization but inaccurate representation of the requested time, two points for moderate visuospatial disorganization of numbers, one point for a severe level of visuospatial disorganization, and zero points for the inability to make any reasonable attempt.

The CDT is used to screen cognition for adults of all ages; however, the literature more recently has focused on the geriatric population. Although young adults are not as susceptible to neurodegenerative (e.g., dementia, Parkinson’s) or ischemic (e.g., stroke) disease, as they age, they will grow increasingly at risk for various disorders affecting cognition. This young adult population also remains at risk for brain injury due to trauma, which may require cognitive screening (Centers for Disease Control and Prevention, 2019). The CDT has demonstrated the highest diagnostic accuracy in detecting dementia for combined sensitivity (76.6%) and specificity (87.4%) when compared to the similar brief screening tools of overlapping infinity loops and the wire cube (Charernboon, 2017). Other cognitive screening measures (e.g., MMSE, Montreal Cognitive Assessment) have demonstrated higher sensitivity and specificity for identifying mild cognitive impairment and dementia; however, these assessments take significantly longer than the CDT to administer (Lin et al. 2013; Patnode et al., 2020).

The CDT literature on various diagnoses with possible cognitive changes is vast and is present with schizophrenia (Bozikas et al., 2004), metabolic syndrome (Viscogliosi et al., 2016), traumatic brain injury (De Guise et al., 2011), Parkinson's disease with dementia or Parkinson's disease with MCI (Saka & Elibol, 2009), Huntington's disease (Terwindt et al., 2016), and right and left hemisphere stroke (Cooke et al., 2010; Suhr et al., 1998). Although the literature is conflicted, there are data suggesting the CDT can identify particular types of dementia (Duro et al., 2018; Mantioli & Caramelli, 2010; Tan et al., 2015). A predictive nature for independence and long-term outcomes was also proposed when the CDT was administered to individuals in the acute stroke phase (Champod et al., 2019).

Cognitive Screening and Assessment Measures

The CDT may be administered as a stand-alone tool or may be one of several tasks on an assessment instrument. Examples of assessments where the CDT is embedded include the following: Cognitive-Linguistic Quick Test (CLQT), Mini-Cog, Montreal Cognitive Assessment (MoCA), Saint Louis University Mental Status Examination (SLUMS), Self-Administered Gerocognitive Exam (SAGE). Various delivery and scoring methods are utilized amongst these assessments.

The CLQT was written by Helm-Estabrooks in 2001 and requires the patient to fill in a pre-drawn circle with a 13-point scoring system. CLQT instructions request, "Draw a clock. Put in all the numbers. Set the hands to 10 minutes after 11. Be careful. Be neat." The Mini-Cog is a three-minute assessment that includes the CDT (Mini-Cog, n.d.). Administration of the CDT for the Mini-Cog includes the following instructions, "Please draw a clock in the circle. Put all the numbers in the circle. Now set the hand to show 10 past 11." A score of two is given for a

normal clock (i.e., correct number and hand placement) and a score of zero is given for anything less. Nasreddine et al. (2005) created the CDT of the MoCA with a free-drawn clock and a three-point scoring system (one point for contour, one point for numbers, and one point for clock hand placement). The MoCA uses the following instructions for the CDT portion, “Draw a clock. Put in all the numbers and set the time to 10 past 11.” Different versions request different times (version 8.1: “10 past 11,” version 8.2: “10 past nine,” version 8.3: “five past 10”). According to Tariq et al. (2006), the SLUMS CDT administration includes a pre-drawn circle with the instructions, “This is a clock face. Please put in the hour markers and the time at 10 minutes to 11 o’clock.” Two points are given for all clock numbers present and correct and two points for accurate hour markers. The SAGE includes a free-drawn CDT for which the instructions read, “Draw a large face of a clock and place in the numbers. Position the hands for five minutes after 11 o’clock. On your clock, label ‘L’ for the long hand and ‘S’ for the short hand” (Scharre, 2021). There are four components that are scored: clock face, clock numbers, hand positions, and hand size. A total score of two points is given for all four components correct, one point is given for three of four components correct and zero points are given for two or less components correct.

Cognitive Impairment in the Acute Care Hospital Setting

Cognitive impairment present in a hospital setting may be the result of an acute brain injury (e.g., stroke, concussion) or a baseline condition (e.g., cognitive delay, dementia). Individuals with cognitive impairment have twice as many hospital stays than neurotypicals and, on average, require a stay that is more than four times as long during those inpatient hospitalizations (Alzheimer’s Association, 2019). Delirium is common in patients admitted to

the hospital and may lead to short- or long-term cognitive impairments (Fogg et al., 2018). The presence of a cognitive impairment increases hospital length of stay (Davoren et al., 2015) and identification of cognitive impairments, including etiologies in a hospital setting leads to improved health outcomes (Perry et al., 2018). Focusing on appropriate identification of cognitive impairment is important given the fact that many causes of cognitive impairment are reversible if recognized early.

Although much of the focus in the literature remains on older adults (i.e., 65+) and the need for identification and intervention related to cognitive changes, younger adults are still at risk for acquired cognitive impairment (e.g., traumatic brain injury, concussion; Centers for Disease Control and Prevention, 2016). From 2006-2014, motor vehicle collisions were the second most common cause of hospitalization for traumatic brain injury with the average age of patient at 22.3 years (Centers for Disease Control and Prevention, 2019). It was found that almost one fifth of adolescents in the United States aged 12-18 have been diagnosed with a concussion (Veliz et al., 2017). The incidence of TBI in America was greatest amongst individuals aged 16-25 years with an average of about 300 per 100,000 (Bruns & Hauser, 2003). Therefore, it is imperative that cognitive screening in this young adult population be valid and reliable. A young adult who is unable to draw an analog clock prior to a brain injury, will most certainly not be able to do so after this insult. A false positive (i.e., indicating below normal) result on a brief cognitive screening may result in further unnecessary testing, which could waste medical resources and provider time, as well as cause unwarranted concern by the involved patient and family.

Speech-Language Pathology Procedures for Cognitive Evaluation

Included in their scope of practice, Speech-language pathologists (SLPs) in a medical setting are frequently consulted to evaluate cognitive-communication and provide relevant recommendations (Pathology and Laboratory Medicine, 2017). Often a standardized cognitive screening or assessment will be administered to any patient for whom the primary or consulting provider may have a cognitive concern. Some examples of diagnoses that might qualify for these SLP referrals include stroke, traumatic brain injury, post craniotomy, brain tumor, and concussion. A cognitive screening measure is an efficient way to determine the intervention that may be appropriate.

A practicing SLP requires a graduate degree from an accredited university (ASHA, n.d.). Clinical requirements of SLP graduate students include 375 hours of direct patient contact, followed by nine months of a clinical fellowship under supervision of a certified SLP (ASHA, n.d.). Just about half of undergraduate and graduate students are between the ages of 20-21 (Education Data, 2020). This indicates that many SLP graduate students, clinical fellows, and newly certified SLPs are included in the young adult population. Understanding the knowledge of analog clocks in young adults is important to determine the accuracy of administration and scoring of the CDT, which is required of SLP graduate students and new clinicians.

Unique Aspects of the Current Young Adult Population

Today's young adult population (i.e., ages 18-30) has arguably grown up in a different environment, socially and technologically, from the adult population living at the conception of the CDT (i.e., 1915) and from today's older adult population (Holland, 2016). Analog clock use

is not as common with the current young adult population (Fultonberg, 2017; Slome, 2015). The ability to complete the CDT relies on exposure to analog clocks. It is less common for college students to consistently wear a watch (Slome, 2015). Digital technology is now ubiquitous in most countries and areas where the CDT is used (e.g., United States, Canada, Europe, Australia). Over one fifth of Americans wear a smartwatch (Vogels, 2020) and timekeeping is not always the key utility for such devices. Those young adults who wear watches, may have the option to also use the technology as fitness trackers, jewelry, sleep trackers, email inboxes, calorie counters, heart rate and blood pressure monitors, among other functions (Alt, 2020).

Tappen (2019) found that the existence of analog clocks in public spaces is becoming less common. Clock reading and elapsed time competence are necessary by completion of the 3rd grade as dictated by current education standards (CCSSI, 2020). Beyond 3rd grade, children have difficulty coordinating time units (Earnest, 2017). Friedman and Laycock (2006) found that 5th grade students had difficulty responding to minute-hand questions and some of these students were only able to respond to hour-hand questions for analog time. These researchers also found that analog time reading develops at a later age than digital time reading. These findings in combination seem to suggest that although analog clock reading continues to be taught in early education, due to reduced exposure and use, students seem to lose some knowledge pertaining to this analog time skill.

Significance of the Research

Although the CDT is most widely used with the older adult population, it is administered to all ages of adults and as the young adult population of today ages, they would benefit from an accurate and reliable screening method for cognitive disorders that are more common in older

adults (e.g., mild cognitive impairment, dementia). In order to guide accurate medical practice of cognitive function and appropriately distribute resources in a clinical setting, it is imperative to determine the validity of the CDT within the young adult population. Along with accurate ability to complete the CDT comes the concern of accurate ability to score the CDT within this population. Many student clinicians and young healthcare providers are charged with administering and scoring the CDT and need to reliably ascertain normal from disordered, which first requires the ability to complete this task independently.

Summary

Identification of cognitive disorders is dependent upon cognitive screening until reliable biomarkers have been established (Larner, 2017). Valid and reliable cognitive screening tools have the potential to identify pathological changes in cognition which can play an important role in rehabilitative success (Liu & Lou, 2019). Larner (2017) and the Research Committee of the American Neuropsychiatric Association (1997) state that the optimal cognitive screening measure should be able to be administered by a clinician at any level of training. For this reason, cognitive screening is a universal tool used by a variety of disciplines and aids in referrals across disciplines for a better integrative and interdisciplinary health approach.

The CDT has been widely used and researched for its unique ability to briefly screen a variety of aspects of cognition in adults (Dion et al., 2020; Mainland & Shulman, 2017). Much of the CDT literature has concentrated on older adults, given the greater prevalence of neurodegenerative and ischemic disease, placing this population at increased risk for cognitive changes. The young adult population remains in need of an accurate cognitive screening tool due to the incidence of traumatic brain injury and, as they age, requiring cognitive screening for

various acquired disorders affecting cognition, such as dementia. In summary, altering the research focus from the older to the younger adult population is imperative in order to determine the generational and cultural biases of the CDT and whether this young adult population can draw an analog clock. This research will benefit a variety of disciplines with clinicians who perform cognitive screening (e.g., nursing, primary care physicians, neurologists, neuropsychologists, speech-language pathologists, occupational therapists, geriatricians).

Purpose

This three-paper dissertation is comprised of studies to address the gaps in literature by investigating the accuracy of the CDT for the young adult population which is underrepresented in existing studies. The purpose of this three-paper dissertation is to help determine the accuracy of the CDT for young adults. The research completed in this dissertation is aimed at answering the following questions:

- Paper 1: Are young adults, who self-identify as having normal cognition, able to accurately draw an analog clock?
- Paper 2: When controlling for cognitive severity, is there a difference in CDT performance between and within young and older adults in a clinical setting?
- Paper 3: Depending on diagnosis, is there a difference between young and older adults on whether the CDT score affects the overall cognitive severity rating on the MoCA?

Glossary Terms

- Acute care: For the purposes of this dissertation and research, this term is used to refer to an inpatient hospitalization, including intensive/critical care, progressive care, orthopedic, general medical and surgical, and neurological beds/floors.
- Analog clock: The display of time using a clock face with hands on a fixed numbered dial.
- Clock drawing test (CDT): “A widely used cognitive screening tool that is simple and quick to administer and has been well accepted by both clinicians and patients” (Mainland & Shulman, 2017, p.80)
- Cognition: “The ability to learn, solve problems, remember, and appropriately use stored information” (Morley et al., 2015, p. 732)
- Cognitive-communication: The exchanging of ideas or information in conjunction with the cognitive functions of attention, memory, orientation, language, visuo-spatial skills, abstract reasoning, and executive function
- Cognitive impairment: “When a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life. Cognitive impairment ranges from mild to severe. With mild impairment, people may begin to notice changes in cognitive functions, but still be able to do their everyday activities. Severe levels of impairment can lead to losing the ability to understand the meaning or importance of something and the ability to talk or write, resulting in the inability to live independently” (CDC, 2011, p. 1)
- Cognitive screening: “Short, efficient, and well-researched modalities designed to evaluate multiple cognitive domains” (Gonzalez Kelso & Tadi, 2020)

- Concussion: “A traumatic brain injury that affects your brain function. Effects are usually temporary but can include headaches and problems with concentration, memory, balance and coordination” (Mayo Clinic, 2020, p. 1)
- Delirium: “A common neuropsychiatric syndrome that is characterized by a change in awareness and cognition, develops in a short period of time, and has the tendency to fluctuate” (Adamis et al., 2016, p. 981)
- Dementia: “A significant impairment in cognitive functioning, and is defined as a decline in memory and at least one other cognitive domain serious enough to interfere with daily life and not accounted for by other medical conditions” (Zagaria, 2013)
- Digital clock: The display of time using numerals or symbols.
- Older Adult: For the purposes of this dissertation and research, this term will refer to individuals aged 65 years and older. The research conducted in chapters III and IV both use an older adult participant group, which is comprised of individuals aged 55-85 years due to the evaluation methods conducted.
- Smart watch: A wearable computer with the ability to tell time
- Speech-language pathologist (SLP): “Experts in communication. SLPs treat many types of communication and swallowing problems. These include problems with speech sounds, language, literacy, social communication, voice, fluency, cognitive-communication, feeding and swallowing” (ASHA, n.d.)
- Traumatic brain injury: “Can alteration in brain function manifest as confusion, altered level of consciousness, seizure, coma, or focal sensory or motor neurologic deficit resulting from blunt or penetrating force to the head” (Bruns & Hauser, 2003, p. 2)

- Young Adult: For the purposes of this dissertation and research, this term will refer to individuals aged 18-30 years.

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CHAPTER II

CLOCK DRAWING TEST PERFORMANCE OF YOUNG ADULTS BASED ON A ONE-SHOT CASE STUDY

Introduction

The clock drawing test (CDT) has a rich research history. A PubMed search for “clock drawing test” yields 1067 results from 1989-2020. As life expectancy increases, the research community has concentrated resources on primarily investigating cognitive changes in neurodegenerative disease, such as dementia, in older age individuals. CDT research has followed suit and mainly focused on screening for cognitive impairment in the older adult population (65+ years) and those with neurodegenerative disorders (Mainland & Shulman, 2017). Young adults remain at risk for cognitive impairment with trauma as the leading cause of brain injury (Centers for Disease Control and Prevention, 2019). There are limited data available regarding the use of the CDT with younger populations who may have less exposure to analog clocks due to fewer analog clocks in public spaces and reduced use of analog watches (Fultonberg, 2017; Tappen, 2019).

Background

Clinical use of the CDT is described as early as 1915 with its popularity of use, as demonstrated through the research, beginning in the 1980s (Hazan et al., 2018). The CDT may look different depending on the version used, as there is no standardized approach. It may include copying an analog clock, filling in an analog clock face, reading an analog clock time, or free-drawing an analog clock (Hazan et al., 2018). Given the timing of its initiation (i.e., early

20th century) and its continued clinical use as a cognitive screening tool, the CDT will have one of the longest lifespans among medical tests (Shulman, 2000).

The CDT has been found to be quick and simple to administer, non-invasive and non-offensive which has contributed to its popularity (Mainland & Shulman, 2017; Nyborn et al., 2013; Parker & Philp, 2004; Souillard-Mandar et al., 2016). Mainland & Shulman (2017) describe the CDT as a robust assessment of cognition relative to the time and effort involved for administration. Properties of cognition assessed in the CDT include selective and sustained attention, verbal working memory, visual memory and reconstruction, visuospatial skills and executive function (Dion et al., 2020; Mainland & Shulman, 2017). Executive function aspects quantified and qualified by the CDT are abstraction, complex motor sequencing, response inhibition and frustration tolerance. Components of numerical knowledge and language, including auditory comprehension, are also incorporated (Mainland & Shulman, 2017). The overlapping infinity loops and the wire cube are two additional, relatively common cognitive screening tests that identify abnormalities in visuospatial skills and executive function (Chareernboon, 2017). Compared to these tools, the CDT has demonstrated the highest diagnostic accuracy for combined sensitivity (76.6%) and specificity (87.4%) in detecting dementia (Chareernboon, 2017). Other screening tools, such as the Mini Mental State Examination (MMSE) have demonstrated better sensitivity and specificity for detecting certain disorders (e.g., mild cognitive impairment, dementia), but take longer to administer and may be copyrighted (Lin et al. 2013; Patnode et al., 2020).

Given the longevity of the original CDT and changes in the technological (e.g., digital formats) and social environments (e.g., setting timers for appointments), various scoring systems have been developed over the years. Shulman (2000) specifies 13 original scoring systems and

Mainland & Shulman (2017) describe 19 total scoring systems for the CDT. New scoring systems continue to emerge (e.g., Gromisch et al., 2019). The CDT varies by task, e.g., free drawing or pre-drawn circles, drawing or copying a clock, specific time settings, and scoring criteria. The various CDT versions have total scores that range from three to 30 based on the visuospatial, executive, quantitative, and, especially, qualitative aspects of the drawing that are assessed. The CDT may be administered as a stand-alone tool or may be one of several tasks on an assessment instrument, e.g., the Montreal Cognitive Assessment (MoCA). Researchers more recently have been attempting to update and increase qualitative analysis for the CDT by creating a digital CDT, in which the analog clock is drawn on a digital device (Müller et al., 2019; Souillard-Mandar et al., 2016). The digital CDT assesses geometric, spatial, and temporal properties of the drawing with the use of a digital pen and allows the clinician to capture the entire sequence of behaviors, instead of simply the end product. Buckley et al. (2020) were also interested in easier transfer to an electronic medical record, as this is the current gold standard of preserving medical data.

Valid and reliable cognitive screening tools have the potential to identify pathological changes in cognition. The young adult population, as previously mentioned, are still at significant risk for cognitive impairment and are in need of accurate cognitive screening. Also, as this young adult population ages, accurate cognitive screening is necessary to identify other disorders more commonly associated with the older adult population (e.g., dementia). The changes to the original CDT made over the years, resulting in different versions, have improved diagnostic accuracy and aided in identification and longitudinal monitoring of various disorders present in older adults (e.g., dementia; Lerner, 2012). However, as noted above, there is still no standardization of versions and scoring systems which can lead to differences in CDT scores

(e.g., Santana et al., 2013). For example, in a systematic review and meta-analysis of 18 studies using the CDT for dementia diagnosis, Park et al. (2018) found that the Shulman scoring system yielded a sensitivity and specificity of 82% and 75.7% respectively, while the Sunderland system resulted in 72.6% and 87.9% respectively. Hazan and colleagues (2017) administered the clock drawing portion of the Montreal Cognitive Assessment (MoCA) to individuals who had sustained a TBI. When they scored the drawings using the 3-point MoCA system, 23.2% of participants who had passed three other cognitive assessments failed the CDT, while when a 20-point scoring system was used only 8.5% of those participants failed.

The CDT has been used in studies of a variety of disorders affecting cognitive function in older adults (e.g., Mainland & Shulman, 2017; Pinto & Peters, 2009). These include schizophrenia (Bozikas, Kosmidis, Gamvrula, Hatzigeorgiadou, Kourtis, & Karavatos, 2004), metabolic syndrome (Viscogliosi, Chiriach, Andreozzi, & Ettorre, 2016), traumatic brain injury (De Guise et al., 2011), Parkinson's disease with dementia or Parkinson's disease with MCI (Saka & Elibol, 2009), Huntington's disease (Terwindt, Hubers, Giltay, Van der Mast, & Van Duijn, 2016), and right and left hemisphere stroke (Cooke, Gustafsson, & Tardiani, 2010; Suhr, Grace, Allen, Nadler, & McKenna, 1998). There is some evidence that the CDT might help differentiate various types of dementia, however, the literature reveals mixed results (Duro et al., 2018; Matioli & Caramelli, 2010; Tan et al., 2015). CDT research has demonstrated inconsistent results for individuals with delirium and mild cognitive impairment (MCI). Adamis, Meagher, O'Neill, & McCarthy (2016) found the CDT to be an inaccurate predictor of delirium in hospitalized elderly patients. The predictive power of the CDT in identifying postoperative delirium has yielded more significant results (Fisher & Flowerdew, 1995).

Cognitive function can play an important role in rehabilitative success (Liu & Lou, 2019). The CDT may have predictive capabilities relating to acute illness recovery and length of hospital stay outcomes for certain populations. Hershkovitz et al. (2010) found that post-acute rehabilitation length of stay and CDT scores had an inverse relationship, whereas functional independence outcomes and CDT scores had a positive correlation for patients' status post hip fracture. Champod et al. (2019) found that the CDT administered during the acute stroke phase predicted long-term outcomes, such as independence in performing activities of daily living.

The literature has demonstrated that variables such as gender, age, race, and education and literacy levels may affect CDT score (de Noronha et al., 2018; Kim & Chey, 2010). Mainland & Shulman (2017) suggest females may perform better on the CDT than males, however, Reiner and colleagues (2018) and Santana and colleagues (2013) found that females performed more poorly than males. In addition, the scoring system that is chosen can interact with variables such as age and gender to affect scores (e.g., Santana et al., 2013). Studies with participants aged 25-30 years and older have found a negative correlation between age and CDT performance (Santana et al., 2013; Sugawara et al., 2010). Crowe et al. (2008) found that African Americans presented with lower CDT scores than Caucasian participants and Storey et al. (2002) found that it demonstrated poor specificity for detecting dementia when used with a non-English speaking multicultural population, despite their use of six different scoring systems. However, Parker and Philp (2004) include the CDT in their list of "culture-free" cognitive assessment tools that are appropriate for black people and those from other under-represented groups. Moreover, it has been shown to be valid for use with individuals from around the world and has been translated as a standalone screening or as part of an assessment, such as the MoCA into a variety of different languages, including Portuguese (Teixeira et al., 2014; Santana et al., 2013), Japanese

(Matsuoka et al., 2014), Spanish (Royall et al., 2003), and Chinese (Chen et al., 2018; Zhou et al., 2019). In summary, the CDT has been used in studies of cognitive impairment with a variety of etiologies, in a variety of countries, and in a variety of languages. However, an individual's score may be influenced by a number of variables other than cognitive status. Importantly, with a few exceptions, CDT studies have been focused on older adults. The ability to complete the CDT relies on exposure to analog clocks, and it is not clear whether young people currently growing up in a digital world have sufficient exposure to analog clocks to enable them to perform the task accurately, independent of cognitive status.

Analog Clock Use and Knowledge

Social and learning environments have changed drastically (Holland, 2016), including use of digital technology, since the birth of the CDT in 1915 (Hazan et al., 2018). Smart watches are now being used by 21 percent of Americans (Vogel, 2020). In addition, the uses for watches are arguably different than in the early to mid-20th century. Time keeping is not always the primary purpose for such devices. Watches may now serve as fitness trackers, jewelry, sleep trackers, email inboxes, calorie counters, heart rate and blood pressure monitors, news reporters, phones, stereo systems, weather indicators and forecasters, calendar and appointment reminders, and social media portals among other things (Alt, 2020). As a smartwatch comes with many capabilities, an individual may not always be attending to or using an analog clock function.

Analog clock use is not as common with the current young adult population (Fultonberg, 2017; Slome, 2015). Many children and young adults do not wear watches, and very few of the individuals who do wear a watch have an analog clock screen (Fultonberg, 2017). In 2015, the 29th Annual Proprietary Teen Research Project surveyed 6,200 American teenagers with an

average age of 16.3 years. Accounting for a variety of household incomes, five percent owned a smartwatch, compared to 15 percent who owned a fitness band (Piper Jaffray, 2015). Slome (2015) conducted a survey of 602 millennials from the University of Missouri of whom 34 percent reported they “never” wear a wristwatch and 36 percent reported to wear one “occasionally.” With these data, it could be assumed that cell phones are a much more popular source of telling time for this young adult age group; however, mobile phones often present with a digital clock screen. When asked about cell phone usage in a focus group, one teen stated, “This is my clock. This is my watch (Lenhart et al., 2010).” A digital format for time is the default setting on many electronic devices, such as mobile phones, iPads, tablets, and computers (e.g., Apple products).

Given the current digital environment, an updated verification of CDT validity for the young adult population (ages 18-30) is warranted. Although this population is not growing rapidly like the older adult population (ages 65+), young adults remain at risk for acquired cognitive changes (e.g., traumatic brain injury, concussion) that require a reliable, brief screening tool for proper assessment and intervention (Centers for Disease Control and Prevention, 2016). From 2006-2014, motor vehicle collisions were the second most common cause of hospitalization for traumatic brain injury with the average age of patient at 22.3 years (Centers for Disease Control and Prevention, 2019). It was found that almost one fifth of adolescents in the United States aged 12-18 have been diagnosed with a concussion (Veliz et al., 2017). The incidence of TBI in America was greatest amongst individuals aged 16-25 years with an average of about 300 per 100,000 (Bruns & Hauser, 2003). Also, as young adults age, they will grow more at risk for various conditions affecting cognition (e.g., dementia) and require more regular cognitive screening. As mentioned earlier, the CDT is a highly popular screening tool that is

used for conditions with possible related cognitive changes (e.g., brain injury, concussion), so it is likely that it could be administered to younger individuals who have minimal exposure to analog clocks. If the CDT is not valid for this population, its use with them may result in misinterpretation of the screening and subsequent improper medical management, such as a referral for further cognitive evaluation that is not warranted.

Education standards dictate clock reading and elapsed time mastery by the end of 3rd grade (CCSSI, 2020). A study by Earnest (2017) found children have difficulty coordinating time units beyond 3rd grade. Friedman and Laycock (2006) demonstrated that digital time reading develops at an earlier age than analog time reading. By evaluating children in 1st through 5th grades, these researchers also found that some 5th grade students were only successful at answering questions pertaining to the hour hand on an analog clock. This decreased comprehension at the time of learning, in combination with reduced future exposure to analog clocks, results in an overall limited analog clock knowledge-base. Although students continue to be taught analog clock interpretation in grade school, this skill is not maintained which could be due to scarce application of this skill (Fultonberg, 2017). Public presence of an analog clock for reference is growing more infrequent (Tappen, 2019). In summary, altering the research focus from the older to the neurologically healthy younger adult population is imperative in order to determine whether this population can draw an analog clock.

Research Purpose

This research aims to answer the question of whether young adults, who self-identify as having normal cognition, are able to accurately draw an analog clock. It is hypothesized that the

current young adult, who self-identify as having normal cognition, has inadequate analog clock use and knowledge to demonstrate accurate results on the CDT.

Method

Study Participants

Eighty young adult participants were recruited from outdoor public areas in an urban setting (e.g., parks, walking trails, parking lots) for this study. Table 1.1 details the demographics for the participants. The mean age was 24.2 years ($SD = 3.93$), ranging from 18-30 years. The mean education level was 14.8 years ($SD = 2.26$), ranging from 11-23 years. A convenience sample during COVID-19-restrictions limited the participants to 88.8% Caucasian, 3.8% Hispanic, 2.5% African American, 2.5% Asian, and 2.5% self-identified as more than one race or ethnicity. Exclusion criteria included the self-identification of the presence of a cognitive impairment or a substance abuse disorder, history of a brain injury, seizures or psychiatric illness.

Table 1.1. Participant Demographics

	<i>M</i>	<i>SD</i>
Age (years)	24.2	3.93
Education (years)	14.8	2.26
	<i>n</i>	%
Gender		
Male	36	45
Female	44	55
Ethnicity		
White/Caucasian	71	88.8
Hispanic/Latino	3	3.8
Asian	2	2.5
Black/African American	2	2.5
More than one	2	2.5

Measurements

Participants were asked to complete a brief 5-10-minute assessment containing the CDT, as well as tasks for setting times on pre-drawn analog clock faces and identifying various analog clock times. Participants were asked whether they wore an analog watch as well as their attitude toward aspects of time, such as being on time and being aware of the time. Five pre-drawn circles with a digital time underneath were used to further assess the participants' ability to set analog clock hands. Five completed analog clocks with pre-set numbers and clock hands were used as an identification task, wherein participants were asked to write the corresponding digital time underneath.

Procedures

The CDT was administered first and according to the Shulman method (Mainland, Amodeo, & Shulman, 2013). This method consisted of a pre-drawn circle with a diameter of approximately four inches. The administrator stated, "This circle represents a clock face. Please put in the numbers so that it looks like a clock and then set the time to ten minutes past eleven." Five points were received for a "perfect" clock, four points for a clock containing minor visuospatial errors, three points for acceptable visuospatial organization but inaccurate representation of the requested time, two points for moderate visuospatial disorganization of numbers, one point for a severe level of visuospatial disorganization, and zero points for the inability to make any reasonable attempt. Refer to examples in Figure 1.1. A score of four or five was considered within normal limits (i.e., pass), and therefore, participants were separated into a group that passed and a group that failed the CDT for further analysis.

Statistical Analyses

In order to answer the question of are young adults, who self-identify as having normal cognition, able to accurately draw an analog clock several statistical analyses were performed with the data collected. To compare the observed proportion of participants who passed the clock drawing test to that of the expected proportion, a one proportion z-test was conducted assuming a p-value of 0.05. A Spearman's rank-order correlation was performed to determine the relationship between the clock hand placement and analog clock identification tasks in both the group that passed the clock drawing test ($M = 60$) and the one that failed ($M = 20$). To determine the level of agreement for CDT scores among raters, twenty assessments were randomly selected and scored by a second rater who was familiar with the CDT and scoring methods. The data was entered and analyzed using SPSS for Mac, version 27.

Results

Details pertaining to assessment responses investigating whether young adults can draw and tell time on an analog clock are presented in Table 1.2. In comparing the proportion of CDT success ("passing") between the observed group (0.75) and the expected group (1.0), the difference was statistically significant ($T = -217.938, p < 0.001$). Table 1.3 displays descriptive and inferential statistics for the drawing and identification tasks included in the assessment. There was a moderate, positive correlation between clock hand placement and analog clock time identification in the group that failed the clock drawing test only, which was statistically significant ($r_s(16) = 0.472, p = 0.048$). Cohen's kappa was used to determine an inter-rater reliability for CDT scoring of 0.724. In a secondary analysis, five variables were used to help determine any patterns of CDT scoring. Four variables were condensed into binary indicators

and included gender (male, female), education level (0-12, 12+), wearing an analog watch (yes, no), and perception of timeliness (importance, not important). A fifth variable of race and ethnicity was also included in the calculation. Step-wise logistic regression aided in determining no significant variables to explain scoring discrepancies among the participants. 91.2% of participants reported not wearing an analog watch. Figure 1.1 displays a few examples of errors consistent with a failing score on the CDT. Analog clock drawings A-G each scored three points, indicating acceptable visuospatial organization but inaccurate representation of the requested time. Drawing H scored 1 point, indicating a severe level of visuospatial disorganization.

Table 1.2. Assessment Responses ($n = 80$)

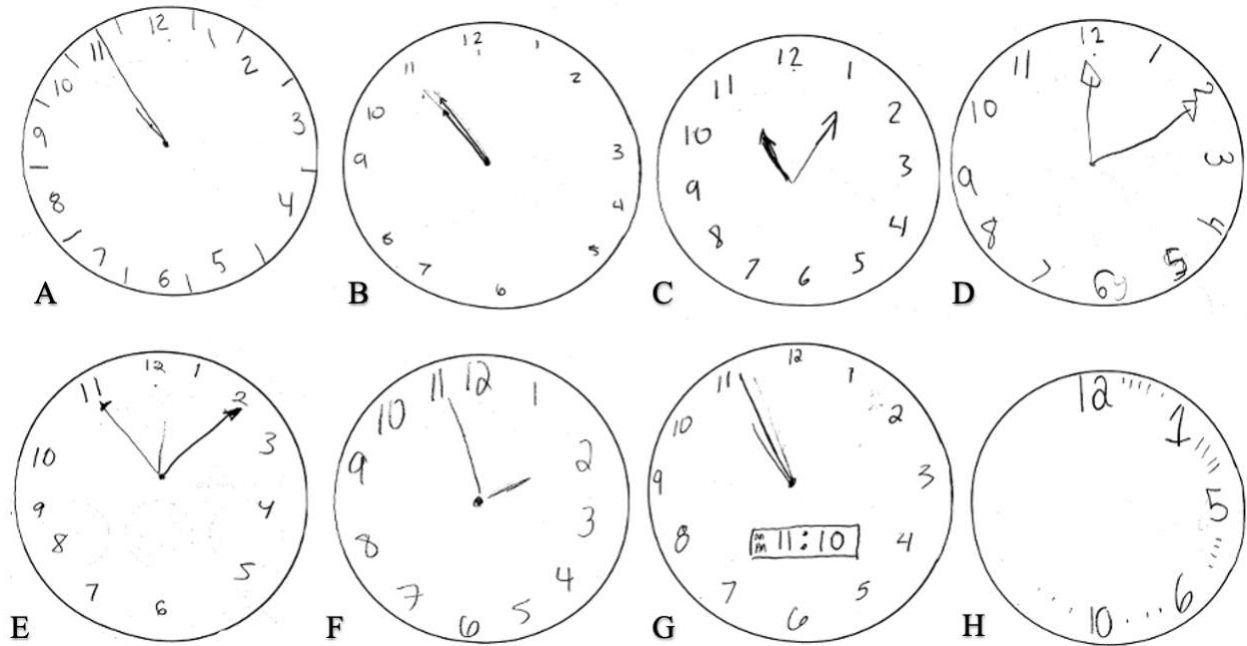
	<i>N</i> (%)	Standardized Test Statistic (<i>p</i>)
CDT with Shulman scoring method		-217.938 ($p < 0.001$)
Total Pass (score 4-5)	60 (75)	
Total Fail (score 0-3)	20 (25)	
Importance of Timeliness		
Yes	70 (88)	
Sort of/No	10 (12)	
Wear Analog Watch		
Yes	7 (8.8)	
No	63 (91.2)	

Table 1.3. Performance and Correlation for Drawing and Identification Tasks ($n = 80$)

	<i>M</i> (<i>SD</i>)	<i>r</i> _s	<i>p</i>
CDT Pass		0.147	0.264
Draw Clock Hands from Digital Representation	4.65 (0.71)		
Identification of Analog Clock Time	4.6 (0.59)		
CDT Fail		0.472*	0.048*
Draw Clock Hands from Digital Representation	2.22 (1.83)		
Identification of Analog Clock Time	3.56 (1.76)		

* $p < 0.05$

Figure 1.1. Examples of CDT Errors



Discussion

Our data suggest that clinicians should be cautious in using the CDT as a single cognitive screening measure in the young adult (i.e., ages 18-30) population who self-identify as having normal cognition. If a neurologically healthy young adult fails the screening due to insufficient exposure to analog clocks, this could lead to improper medical management, such as prolonged hospital stays and unnecessary brain imaging. False positives could also be emotionally distressing to the individual and caregivers. However, the CDT may still be useful for screening some aspects of cognition in the young adult population. Using the Shulman method for scoring, participants in the study received a score of either three (acceptable visuospatial organization, but inaccurate representation of the requested time) or five (“perfect” clock) in 97.5% of attempts. Both of these scores indicate adequate visuospatial organization. Thus, a score of one, two, or

four (all of which include visuospatial errors) may accurately reveal a visuospatial deficit in this age group.

As noted earlier, one reason that young adults who self-identify as having normal cognition might receive a failing score on the CDT is that they have more limited exposure to analog clocks and watches. Given the low percentage of our participants who reported wearing an analog watch (8.8%), as well as the literature suggesting fewer analog clocks are present in public areas, this is a reasonable explanation. However, we cannot assume that all individuals within this age group will not have analog watches. Luxury analog watches have become increasingly popular among Millennials and Gen Zs who can afford them (Gehrlein, 2020; McNish, 2018). Thus, in future studies aimed at developing normative data on the CDT in this population, it might be interesting to study young adults from different socioeconomic groups.

Another reason that some individuals in this age group might fail the CDT is the nature of the verbal instructions for clock time setting. Bock et al. (2003) suggest that time telling linguistic expressions are idiomatic and “frustrate rational analysis.” They also note that expressions differ in different languages, e.g., a British speaker’s half six (6:30) is likely to be unclear to a speaker of American English. Expressions also differ within languages (an American speaker might say either ‘six 20’ or ‘20 past/after six’). Bock and colleagues propose that time telling expressions take two forms. One is relative (ten past two, quarter to four) and the second is absolute (two ten, three forty-five). They note three ways in which these two forms are different. One is that relative expressions denote the relationship between the hour and minute reference points (to, after, etc), while absolute expressions do not. Another difference is that in relative expressions, the reference point changes over the transit around the hour (e.g., ‘20 after’ versus ‘quarter to’). Finally, relative expressions name the minute before the hour, while absolute

expressions name the hour before the minute. Bock et al. asked 144 American and 144 Dutch undergraduate students to read and write the times of analog and digital clocks. While the Dutch students used relative expressions predominantly for both clock types, the American students tended to avoid them, using mainly absolute expressions. Although this study is now 17 years old, it still provides some evidence that the way the instructions are worded on the CDT could play a role in young adults' performance on the test. This is another topic for future research. Also, although both hand placement and clock reading are related to analog clock knowledge, clock hand placement is a memory recall task, compared to the memory recognition task of analog clock time identification. Memory recall can be a more challenging task, given fewer cues or prompts when compared to a recognition task (Rumbaugh & Landau, 2018). A correlation between clock hand placement and analog clock identification tasks was present only in the group that failed the CDT, so further investigation into the ability of this population to both recognize and tell time would be beneficial. Yet another area for future research would be to use different CDT scoring methods, since it has been shown in previous studies to be a factor determining whether someone passes or fails the test (Hazan et al., 2017).

Limitations

There are several limitations to this study. One is that participants who failed may not have devoted sufficient effort to the task. The assessment was completed outdoors and in a public setting with many distractions present. The request for participation in the study was spontaneous and unexpected. Future research could be conducted on young adults with normal cognition in a hospital environment, who have been admitted for an acute illness with little threat to cognitive change (e.g., orthopedic injury) to replicate a setting where the CDT is frequently used. Another limitation includes the convenience sample obtained during public COVID-19

restrictions, reducing the variety of participant backgrounds, especially for race and ethnicity and education level. Yet another limitation is that participants' cognitive status was obtained through self-report. Testing was conducted as privately as possible (i.e., in written form and out of ear shot of others in the area) in order for participants to feel safe to respond truthfully; however, they still might not have been comfortable being honest about their abilities with a stranger. Future studies should include a more complete cognitive assessment for comparison with the CDT results. In addition, some participants could have had problems that might affect CDT performance but did not consider the problem serious enough to report, for example, not doing well in mathematics. Studies have found that children who struggle with mathematics perform significantly more poorly on clock reading as compared to children who do not have problems with math (Andersson, 2008; Burny, Valcke, & Desoete, 2012).

Conclusion

Previous research has shown the CDT to be a long-standing, valid, and reliable measure for screening aspects of cognition in older adults with a variety of etiologies. Younger adults remain in need of an accurate cognitive screening measure; The Centers for Disease Control and Prevention (2019) also found that motor vehicle collisions were the second most common cause of brain injury with the average age of 18.2 in 2014. A current and accurate cognitive screening for younger adults will secure a psychometrically sound measure as this population matures to older adulthood with the increased risk of neurodegenerative and ischemic cognitive change that come with older age. The results of this study reveal that at least some young adults aged 18 to 30 years who self-identify as having normal cognition, cannot accurately draw an analog clock and are not successful in passing the stand-alone CDT using the Shulman scoring method. If the CDT is used with this population, the results should be interpreted with caution. Until more

research can be conducted on neurologically healthy individuals in this age group, clinicians might want to consider alternative cognitive screening tests that have been demonstrated to be valid for younger people, although they might not be as brief, e.g., the MoCA (Pike, Poulson, & Woo, 2017).

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Conflict of Interest

None declared.

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CHAPTER III

THE EFFECT OF AGE ON CLOCK DRAWING TEST PERFORMANCE IN A CLINICAL SETTING

Introduction

Cognitive screening is a quick and easy way to determine further evaluation and intervention needs in individuals with acute or progressive cognitive changes. The geriatric population continues to grow and, with this, brings along the medical challenges that come with older age. Following this trend, much of the research on cognitive screening has been concentrated on the older adult population, focusing on identification of neurodegenerative diseases, such as dementia (Mainland & Shulman, 2017). The clock drawing test (CDT) is a cognitive screening tool that has more than a century of history in clinical use and is widely studied in the literature. The CDT can be administered to all adults, including young adults who remain at risk for cognitive changes with the incidence of traumatic brain injury at 300 in 100,000 for Americans aged 16-25 years (Bruns & Hauser, 2003). The second most common cause for brain injury in adolescents and young adults in 2014 was motor vehicle collisions with the average age of 18.2 years (Centers for Disease Control and Prevention, 2019). Young adults will also require cognitive screening at a higher rate as they age and become at increased risk for various conditions with known cognitive changes (e.g., dementia). Given the technological advances and social transformations that have developed over the last century, there is little recent data to establish the CDT as a reliable and valid cognitive screening instrument for young adults.

A prior study found a discrepancy in some young adults' (i.e., ages 18-30) ability to accurately draw an analog clock. This research was conducted in public areas, whereas the majority of CDT administration is completed in a clinical setting with current patients. To better ensure external validity of these findings, it is important to know whether current young adults admitted as patients in a hospital setting are able to draw an analog clock. As the CDT is a ubiquitous screening for cognition in adults, this should be demonstrated as a valid measure across all adult age groups. Invalid results could lead to inappropriate diagnosis and intervention in a clinical setting.

Another concern for limited analog clock knowledge and drawing ability in ages 18-30, lies in the individuals administering and interpreting these CDTs. The majority of speech-language pathology (and other healthcare) students and new clinicians are in the young adult age group. If there is an inability to draw an analog clock, suggested by a previous research study, this may also limit one's ability to score an analog clock drawing, including number and clock hand placement, which could lead to incorrect and unreliable cognitive screenings across providers.

Background and Significance

The CDT is a robust assessment of cognition relative to the time and effort involved for administration and can evaluate the following cognitive domains: selective and sustained attention, verbal working memory, visual memory and reconstruction, visuospatial skills and executive function (Dion et al., 2020; Mainland & Shulman, 2017). Following the Mini Mental State Examination (MMSE), the CDT is the second most widely used test for evaluating cognition (Khan, 2016). The CDT has been found to be fast and easy to administer, non-invasive

and non-offensive which has contributed to its acceptance and widespread use (Mainland & Shulman, 2017; Nyborn et al., 2013; Parker & Philp, 2004; Souillard-Mandar et al., 2016).

There is no standardized approach to administration or scoring of the CDT and may include copying an analog clock, filling in an analog clock from a pre-drawn circle, reading an analog clock time, or free-drawing an analog clock, including numbers and clock hands (Hazan et al., 2018). Although Scanlan et al. (2002) found that untrained raters could accurately screen cognition with the CDT, the CDT is mostly used by healthcare providers such as neurologists, psychologists, speech-language pathologists, nurses, geriatricians, occupational therapists, and family practice physicians among others.

The CDT has demonstrated the highest diagnostic accuracy in detecting dementia for combined sensitivity (76.6%) and specificity (87.4%) when compared to the similar brief screening tools of overlapping infinity loops and the wire cube (Charernboon, 2017). Other cognitive screening measures (e.g., MMSE, Montreal Cognitive Assessment) have demonstrated higher sensitivity and specificity for identifying mild cognitive impairment and dementia; however, these assessments take significantly longer than the CDT to administer (Lin et al. 2013; Patnode et al., 2020).

The CDT literature on various diagnoses with possible cognitive changes is vast and is present with schizophrenia (Bozikas et al., 2004), metabolic syndrome (Viscogliosi et al., 2016), traumatic brain injury (De Guise et al., 2011), Parkinson's disease with dementia or Parkinson's disease with MCI (Saka & Elibol, 2009), Huntington's disease (Terwindt et al., 2016), and right and left hemisphere stroke (Cooke et al., 2010; Suhr et al., 1998). Although the literature is conflicted, there are data suggesting the CDT can identify particular types of dementia (Duro et al., 2018; Matioli & Caramelli, 2010; Tan et al., 2015). A predictive nature for independence and

long-term outcomes was also proposed when the CDT was administered to individuals in the acute stroke phase (Champod et al., 2019).

The CDT can be administered independently as a cognitive screening measure but is also embedded in many cognitive screening measures and assessments (e.g., Cognitive-Linguistic Quick Test, Mini-Cog, Montreal Cognitive Assessment (MoCA), Saint Louis University Mental Status Examination, Self-Administered Gerocognitive Exam, Short Test of Mental Status). The MoCA is a 30-point cognitive screening assessment that measures visuospatial/executive function, naming, attention, language, memory, abstraction, delayed recall, and orientation (Hobson, 2015; Nasreddine et al, 2005). Training and certification are required for all healthcare providers who chose to administer and score the MoCA (Nasreddine, 2019). The MoCA has the ability to identify mild cognitive impairment and dementia (Hobson, 2015; Pinto et al, 2019). Nasreddine et al. (2005) created the CDT of the MoCA with a free-drawn clock and a three-point scoring system (one point for contour, one point for numbers, and one point for clock hand placement). The MoCA uses the following instructions for the CDT portion, “Draw a clock. Put in all the numbers and set the time to 10 past 11.” Different MoCA versions request different times (version 8.1: “10 past 11,” version 8.2: “10 past nine,” version 8.3: “five past 10”).

Cognitive impairment present in a hospital setting may be the result of an acute brain injury (e.g., stroke, concussion) or a baseline condition (e.g., cognitive delay, dementia). Delirium is common in patients admitted to the hospital and may lead to short- or long-term cognitive impairments (Fogg et al., 2018). The presence of a cognitive impairment increases hospital length of stay (Davoren et al., 2015) and identification of cognitive impairments, including etiologies in a hospital setting leads to improved health outcomes (Perry et al., 2018).

Focusing on appropriate identification of cognitive impairment is important given the fact that many causes of cognitive impairment are reversible if recognized early.

Although much of the focus in the literature remains on older adults (i.e., 65+) and the need for identification and intervention related to cognitive changes, younger adults are still at risk for acquired cognitive impairment (e.g., traumatic brain injury, concussion; Centers for Disease Control and Prevention, 2016). According to the Centers for Disease Control and Prevention (2019) motor vehicle collisions were the second most common cause of hospitalization for traumatic brain injury between 2006 and 2014 with the average age of patient at 22.3 years. Americans aged 16-25 years have the highest rate of TBI with an average incidence around 300 per 100,000 (Bruns & Hauser, 2003). One fifth of adolescents in the United States aged 12-18 have been diagnosed with a concussion (Veliz et al., 2017). Because of these data, as well as the realization that this population will eventually grow older and assume the risks that come with conditions associated with older age, it is imperative that cognitive screening in this young adult population be valid and reliable. A young adult who is unable to draw an analog clock prior to a brain injury, will most certainly not be able to do so after this insult. A false positive (i.e., indicating below normal) result on a brief cognitive screening may result in further unnecessary testing, which could waste medical resources and provider time, as well as cause unwarranted concern by the involved patient and family.

Included in their scope of practice, Speech-language pathologists (SLPs) in a medical setting are frequently consulted to evaluate cognitive-communication and provide relevant recommendations (Pathology and Laboratory Medicine, 2017). Often a standardized cognitive screening or assessment will be administered to any patient for whom the primary or consulting provider may have a cognitive concern (ASHA, 2004). Some examples of diagnoses that might

qualify for these SLP referrals include stroke, traumatic brain injury, post craniotomy, brain tumor, and concussion. A cognitive screening measure is an efficient way to determine the intervention that may be appropriate.

A practicing SLP requires a graduate degree from an accredited university (ASHA, n.d.). Clinical requirements of SLP graduate students include 375 hours of direct patient contact, followed by nine months of a clinical fellowship under supervision of a certified SLP (ASHA, n.d.). Just about half of undergraduate and graduate students are between the ages of 20-21 (Education Data, 2020). This indicates that many SLP graduate students, clinical fellows, and newly certified SLPs are included in the young adult population. Understanding the knowledge of analog clocks in young adults is important to determine the accuracy of administration and scoring of the CDT, which is required of SLP graduate students and new clinicians.

Today's young adult population (i.e., ages 18-30) has arguably grown up in a different environment, socially and technologically, from the adult population living at the conception of the CDT (i.e., 1915) and from today's older adult population (Holland, 2016). Analog clock use is not as common with the current young adult population (Fultonberg, 2017; Slome, 2015). The ability to complete the CDT relies on exposure to analog clocks. It is less common for college students to consistently wear a watch (Slome, 2015). Digital technology is now ubiquitous in most countries and areas where the CDT is used (e.g., United States, Canada, Europe, Australia). Over one fifth of Americans wear a smartwatch (Vogels, 2020) and timekeeping is not always the key utility for such devices. Those young adults who wear watches, may have the option to also use the technology as fitness trackers, jewelry, sleep trackers, email inboxes, calorie counters, heart rate and blood pressure monitors, among other functions (Alt, 2020).

Tappen (2019) found that the existence of analog clocks in public spaces is becoming less common. Clock reading and elapsed time competence are necessary by completion of the 3rd grade as dictated by current education standards (CCSSI, 2020). Beyond 3rd grade, children have difficulty coordinating time units (Earnest, 2017). Friedman and Laycock (2006) found that 5th grade students had difficulty responding to minute-hand questions and some of these students were only able to respond to hour-hand questions for analog time. These researchers also found that analog time reading develops at a later age than digital time reading. These findings in combination seem to suggest that although analog clock reading continues to be taught in early education, due to reduced exposure and use, students seem to lose some knowledge pertaining to this analog time skill.

Purpose of the Study

This study aimed at answering the research question of when controlling for cognitive severity, whether there a difference in CDT performance between and within young (i.e., 18-30 years) and older (i.e., 55-85 years) adults in a clinical setting. Based on the findings from a previous study, it was hypothesized that approximately 75 percent of the young adult population with normal MoCA scores will also have normal clock drawing tests. It was also hypothesized that when compared to the young adults in this study, the older adult population will have significantly better clock drawing test scores.

Methods

Study Participants

Study participants were gained through retrospective chart review at the Metro Health University of Michigan Health Hospital from January 2017 through December 2020. Selected from these data were adult inpatients in the acute care hospital setting. The ages of 18-30 years were selected for the young adult participants, based on findings from a previous study with a similar population. The ages of 55-85 years were chosen for the older adult participants, as these are the current ages that are validated for the MoCA. To gain the greatest diversity, included were all genders, races, and ethnicities. To eliminate scoring inaccuracy, all participants who spoke English as a second language and required an interpreter were excluded from the data. Table 2.1 details the study participants for the young adult and older adult groups, respectively. A total number of 516 participants were gained; 107 individuals completed the young adult participant group and 409 for the older adult participant group.

Table 2.1. Participant Demographics

		<i>M</i>	<i>SD</i>
Young Adult Group	Age (years)	23.9	3.84
		<i>n</i>	%
	Gender		
	Male	68	64
	Female	39	36
	Education		
	≤12 years	56	52
	>12 years	51	48
	Diagnosis		
	Concussion	80	75
	Craniotomy	14	13
Other	13	12	
		<i>M</i>	<i>SD</i>
Older Adult Group	Age (years)	69.2	8.81
		<i>n</i>	%
	Gender		
	Male	211	52
	Female	198	48
	Education		
	≤12 years	226	55
	>12 years	183	45
	Diagnosis		
	Concussion	98	24
	Craniotomy	50	12
Other	261	64	

Measurements

Also required in the criteria for inclusion is a cognitive-communication evaluation performed by a certified speech-language pathologist, specifically administration of the Montreal Cognitive Assessment (MoCA), versions 7.1, 7.2, 7.3, 8.1, 8.2, or 8.3. The overall MoCA score (i.e., out of 30 total points) and the CDT score from within the executive/visuospatial section of the MoCA was collected.

Procedures

Participants were grouped within their corresponding age categories (i.e., young adults, older adults) according to their MoCA score and related cognitive severity. A MoCA score of 26-30 = normal, 18-25 = mild, 10-17 = moderate, and 0-9 = severe. Therefore, there were a total of eight groups to measure within and between group variances.

Statistical Analysis

A two-way analysis of variance was conducted to estimate how the mean of the CDT scores changes according to the categorical variables of age grouping and cognitive severities. The independent variables of age (young adult group: participants 18-30 years; older adult group: participants 55-85 years) and cognitive severity (i.e., normal, mild, moderate, severe) were used. The dependent variable of CDT scores from the Montreal Cognitive Assessment (MoCA) were used (three total points: one point for circle contour, one point for number placement, and one for clock hand placement). A Bonferroni correction was conducted to adjust for probability values due to the use of multiple comparisons.

Results

A comparison of CDT scores between the young adult and older adult groups is presented in Table 2.2. Statistical significance was found when comparing the variance of age ($F = 5.051$, $p = 0.025$) and overall cognitive severity groupings ($F = 46.917$, $p < 0.001$) for CDT scores taken from the MoCA. The interaction effect of age and severity was not statistically significant ($F = 2.076$, $p = 0.127$) and is displayed in graph form in Figure 2.1. Table 2.3 displays the Bonferroni correction result which verified statistically significant variance among most groups, based on

age difference (i.e., young adult vs. older adult). Cognitive severity groups that did not demonstrate statistically significant variance were among moderate and severe levels ($p = 0.675$); All other comparisons were statistically significant ($p < 0.001$).

Figure 2.1. Age and Severity Interaction

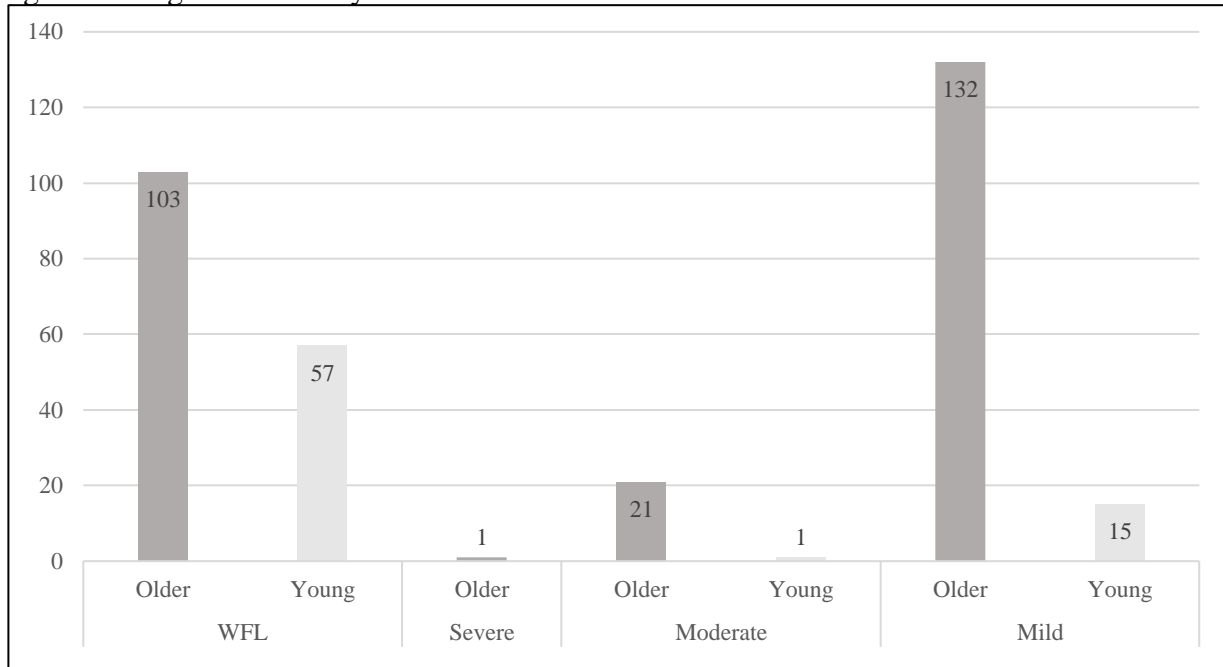


Table 2.2. Comparison of Clock Drawing Test Scores ($n = 516$)

	F	Significance
Age	5.051	0.025*
Severity	46.917	<0.001*
Age x Severity Interaction	2.076	0.127

* $p < 0.05$

Table 2.3. Post-Hoc Test with a Bonferroni Correction ($n = 516$)

	Severity Rating	Mean Difference	Significance
WFL	Mild	0.26	<.001*
	Moderate	0.68	<.001*
	Severe	0.85	<.001*
Mild	WFL	-0.26	<.001*
	Moderate	0.42	<.001*
	Severe	0.59	<.001*
Moderate	WFL	-0.68	<.001*
	Mild	-0.42	<.001*
	Severe	0.17	0.675
Severe	WFL	-0.85	<.001*
	Mild	-0.59	<.001*
	Moderate	-0.17	0.675

* $p < 0.00417$

Discussion

These data suggest a significant difference in the ability to draw an analog clock amongst young (i.e., 18-30 years) and older (i.e., 55-85 years) adults in a clinical setting. In the older adult population, the CDT remains a unique screening tool, providing a wide-ranging glimpse into a variety of cognitive domains within a brief and inoffensive encounter. These data question the CDT accuracy for the young adult population as well as future generations. This screening measure may still be useful for younger adults as a demonstration of progress or decline to one's cognitive skills, and not in relation to the general public. Using the CDT to screen for dementia as these young adults age will likely yield high false positive results along the negative sequelae of unnecessary healthcare costs and emotional stress.

The absolute rationale for the differential performance based on age is unclear. CDT performance is dependent on exposure to analog clocks. As argued earlier, analog clock and watch usage is rarer in current times than when these older adults were young adults. A previous

study suggests only 8 percent of young adults aged 18-30 years report wearing an analog watch. This previous study also suggested that this population presented with intact visuospatial skills in relation to the CDT. The inability of some younger adults to draw analog clock, suggests a reduced general knowledge of analog clocks. Training our young adult healthcare providers to administer this CDT to the older adult population is crucial to maintaining the reliability and validity of this cognitive screening measure.

The MoCA presents one of over 20 different scoring system for the CDT (Hazan et al., 2018). Although, overall, it was found that the simpler the scoring system the better, there may be an administration and scoring method by which young adults and older adults do not differ significantly; This scoring system is likely to be weighted less heavily on clock hand accuracy and more so on visuospatial organization. Further research in this area is indicated.

Limitations

Included in the limitations for this study may be the disproportion of participant groups (approximately 4 older adults:1 young adult). The general hospital population as well as the necessity of cognitive screening produces naturally larger numbers of older adults when compared to young adults. Although this study focused on accuracy of the CDT itself, the complete MoCA was administered as is practice in most acute care facilities. Future research to determine whether CDT failure changes overall severity ratings in young adults more significantly than older adults could aid in assessing the need to alter scoring methods for these tests.

Another limitation considered for this study was the subjective nature of the scoring process of the MoCA. These data were collected from dates prior to the certification requirement

for the MoCA and not all SLPs had completed the certification process. All SLPs who had administered the MoCA during the data collection period were certified for clinical competence in their field and had received professional in-services relating to administration and scoring of the MoCA by an SLP who had completed the MoCA certification process.

Conclusions

Although the CDT has demonstrated excellent reliability and validity amongst adults for over a century, these data suggest that, in current times, some young adults are unable to draw an analog clock; Performing a CDT could lead to inaccurate results and conclusions. Early identification of cognitive deficits can reduce hospital length of stay and provide patients and families with the essential information needed to proceed with adequate intervention. Given the prevalence of traumatic brain injuries in the young adult population, the need for a reliable and valid cognitive screening tool continues to be a critical component of best healthcare practice. Using the CDT unaccompanied as cognitive screener is cautioned with the young adult population. Cognitive screening assessments with the CDT embedded (e.g., MoCA, CLQT) should also be administered and interpreted with caution or with differential scoring for young adults. To withstand “the test of time,” an alternative cognitive screening tool without a generational element, yet with similar psychometric qualities would be welcomed into current practice. Along with a cognitive screening measure, healthcare providers should use their vast clinical knowledge to facilitate identification of severity rating.

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Conflict of Interest

None declared.

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CHAPTER IV

THE EFFECT OF AGE ON CLOCK DRAWING TEST PERFORMANCE AND OVERALL COGNITIVE SEVERITY RATING

Introduction

Cognitive screening is an essential clinical component to inform proper diagnosis and intervention within a medical setting (Morley et al., 2015). All adults can benefit from cognitive screening following diagnosis of an acquired brain injury (ABI) or brain surgery, as there is a possibility for cognitive changes (Sacks, 2020). MacDonald (2017) found a reported 75 percent or higher incidence of cognitive-communication deficits following ABI. Young adults in America remain at risk for these cognitive changes with incidence of concussion at approximately one fifth of individuals aged 12-18 years (Veliz et al., 2017).

Research from previous studies suggest a significant proportion of the young adult population (i.e., ages 18-30) has difficulty completing the task of drawing an analog clock. This clock drawing task is embedded in a variety of cognitive screenings and assessments and can help determine cognitive ability. A speech-language pathology (SLP) cognitive-communication evaluation is ordered during an inpatient hospital stay when there is a possibility of acute brain trauma (e.g., fall, assault, stroke, craniotomy), a persistent cognitive change in the setting of an acute illness (e.g., encephalopathy, delirium), or a concern for safety in the home setting (e.g., dementia, chronic cognitive deficits). If the findings from a previous study completed in a public setting are valid in a clinical setting, some young adults will miss points on the clock drawing test (CDT), despite having normal cognition.

A variety of cognitive screening tools have been validated for use in clinical settings (e.g., CDT, Mini-Cog, Mini-Mental State Examination (MMSE), Montreal Cognitive

Assessment (MoCA), Saint Louis University Mental Status Examination). The standard cognitive evaluation performed at Metro Health University of Michigan Health Hospital is the MoCA; This is a 30-point cognitive screening measure that assesses visuospatial skills, executive functioning, language, attention, memory, abstract reasoning, and orientation (Nasreddine, 2005). Included in the MOCA is a CDT that totals three points: one point for circle contour, one point for number placement, and one point for clock hand placement. Currently, a score on the MoCA that is below normal (i.e., less than a score of 26, indicating a cognitive severity of mild, moderate, or severe) may warrant SLP intervention for further cognitive testing, cognitive-communication therapy, education, and counseling. Cognitive deficits identified in a screening may also warrant referral to other services, such as occupational therapy, neurology, or neuropsychology. Further brain imaging may even be recommended given the MoCA findings. An accurate cognitive assessment is essential to ensure appropriate resource allocation in the medical setting.

Background and Significance

A cognitive-communication evaluation is often completed by a certified speech-language pathologist (SLP) when indicated and ordered by a provider in a medical setting (Pathology and Laboratory Medicine, 2017). Included in this evaluation is often a cognitive screening or assessment as well as relevant recommendations, which is defined within the SLP scope of practice (ASHA, 2016). Some examples of diagnoses that might qualify for these SLP referrals include stroke, traumatic brain injury, post craniotomy, brain tumor, and concussion. A cognitive screening measure is an efficient way to determine the intervention that may be appropriate.

Cognitive screening is essential for early recognition of cognitive impairment which allows for appropriate management, including treatment, education, counseling, and autonomous decision-making (Morley et al., 2015). A variety of cognitive screening measures have been created to fulfill this need (e.g., Cognitive-Linguistic Quick Test, Mini-Cog, Mini-Mental State Examination, Montreal Cognitive Assessment, Short Test of Mental Status). Many of these cognitive screening measures include the clock drawing test (CDT).

The CDT is a widely used, easy to administer, non-invasive, and non-offensive cognitive screening tool (Mainland & Shulman, 2017; Nyborn et al., 2013; Parker & Philp, 2004; Souillard-Mandar et al., 2016). There is no standardized approach and various CDT versions have been created since the initiation, circa 1915, and may include copying, reading, free-drawing, or filling in an analog clock (Hazan et al., 2018). In the brief time the CDT takes to administer, it screens a variety of cognitive functions, including selective and sustained attention, working memory, visual memory and reconstruction, visuospatial skills, and executive function, including abstraction, complex motor sequencing, response inhibition, and frustration tolerance (Dion et al., 2020; Mainland & Shulman, 2017). Some language functions, including numerical knowledge and language, as well as auditory comprehension are also incorporated in the CDT (Mainland & Shulman, 2017).

Much of the CDT literature has been concentrated on identification and differentiation of different types of dementia, which has yielded mixed results for success (Duro et al., 2018; Matioli & Caramelli, 2010; Tan et al., 2015). In addition to dementia, various older adult populations with diagnoses affecting cognitive function have also been studied using the CDT (e.g., Mainland & Shulman, 2017; Pinto & Peters, 2009). Examples of these include schizophrenia (Bozikas et al., 2004), metabolic syndrome (Viscogliosi et al., 2016), traumatic

brain injury (De Guise et al., 2011), Parkinson's disease with dementia or Parkinson's disease with MCI (Saka & Elibol, 2009), Huntington's disease (Terwindt et al., 2016), and right and left hemisphere stroke (Cooke et al., 2010; Suhr et al., 1998).

With this age disparity in the CDT research, young adults have been underrepresented, although still remain in need of accurate cognitive screening due to the possibility of acquired brain injury as well as the knowledge that this population will eventually age and be at risk for various conditions affecting cognition (e.g., dementia). Bruns & Hauser (2003) determined the American incidence of traumatic brain injury (TBI) to be the greatest amongst adolescents and young adults between the ages of 16-25 years with an average of 300 per 100,000 individuals. Between the years of 2006-2014, the second most common cause of hospitalizations for TBI was motor vehicle collisions with the average age of 22.3 years (Centers for Disease Control and Prevention, 2019).

Rehabilitative outcomes can be determined by cognitive function (Liu & Lou, 2019). The literature states that acute illness recovery and length of hospital stay for certain populations may be predicted by CDT performance. Following hip fracture, functional independence outcomes and CDT scores had a positive correlation, whereas post-acute rehabilitation length of stay and CDT scores had an inverse relationship (Hershkovitz et al., 2010). In stroke patients, administration of the CDT predicted long-term outcomes, such as independence in performing activities of daily living (Champod et al., 2019).

Although the CDT is well researched and used widely in clinical settings, the majority of the literature is concentrated on the older adult population, with specific focus on identifying neurodegenerative disease processes (Mainland & Shulman, 2017). As previously stated, the CDT is a unique cognitive screening tool for a variety of populations and has a high diagnostic

value. Given what the vast technological advances and social changes which have occurred within the last century (Holland, 2016), it is unknown whether young adults living in today's world can accurately complete a CDT. Therefore, it is yet to be uncovered whether the CDT, and cognitive screening measures that include the CDT, have the same significance to this young adult population as to those with which have been so thoroughly studied. As discussed earlier, young adults continue to remain at risk for cognitive changes due to brain injury and will age to become older adults who require more frequent cognitive screening due to acquired neurodegenerative or ischemic conditions that affect cognition (e.g., dementia, stroke).

Digital time reading develops at an earlier age than analog time reading (Friedman & Laycock, 2006). Although current standards of elementary education require analog clock reading and elapsed time mastery by the end of the 3rd grade (CCSSI, 2020), research conducted by Earnest (2017) with children older than 3rd grade, demonstrated this population had difficulty coordinating time units. Further research by Friedman and Laycock (2006) found that some 5th grade students were not successful responding to analog clock questions concerning the minute hand.

Previous exposure to analog clocks is essential for CDT success. Analog clock presence in public areas is growing more infrequent and analog clock use is not as common with young adults (Fultonberg, 2017; Slome, 2015). The popularity of smart watches has increased, with 21 percent of Americans now using these devices (Vogels, 2020). Smart watches have options for a digital display and many they also have many other functions beyond time (e.g., fitness and sleep tracking, calorie counting, heart rate and blood pressure monitoring, phone, weather, etc.; Alt, 2020). Alt (2020) also suggests that many children and young adults do not wear watches and

those who do wear watches, do not have an analog clock display. In summary, this information may indicate that young adults have less exposure to analog clocks than previous generations.

The Montreal Cognitive Assessment (MoCA; see Appendix D) is gaining popularity in clinical use and has seen a dramatic increase in the literature. A PubMed search of “Montreal Cognitive Assessment” yields 3,325 results ranging from one publication in 2005 to 792 publications in 2020. The MoCA is a cognitive screening tool that can be administered in 10 minutes, fits on one page, and assesses a variety of cognitive domains (Nasreddine et al., 2005). The sections of the MoCA include a visuospatial/executive portion with a trail making task (one point), copying of a line drawing (one point), and a clock drawing test (3 points). Other sections in the MoCA include naming (three points), attention (six points), language (three points), abstraction (two points), delayed recall (five points), and orientation (six points) for a total of 30 points. The MoCA is currently used by a variety of healthcare providers (e.g., nurses, speech-language pathologists, occupational therapists, neurologists, etc.; Nasreddine, 2019). According to Nasreddine (2019), “Any clinician, health professional, or worker who wishes to administer, score and interpret the MoCA Test should be trained and certified” (FAQ). Currently, the MoCA is validated for ages 55-85 (Nasreddine et al., 2005). Nasreddine (2020) states that research is underway to validate the MoCA for ages 18-99.

A MoCA score of 26 or above indicates cognition within normal limits (Nasreddine et al., 2005). Although research has not yet been established, Nasreddine (2019) recommends the following ranges to be used to grade cognitive severity: 18-25 = mild cognitive impairment, 10-17 = moderate cognitive impairment, and less than 10 = severe cognitive impairment. Educational level is taken into consideration with this cognitive screening measure by adding one point for an individual with 12 years (i.e., high school completion) or less of education.

Compared to a similar 30-point cognitive screening measure, the Mini-Mental State Examination, the MoCA has demonstrated a higher sensitivity to mild cognitive impairment (Nasreddine et al., 2005; Pinto et al., 2019). The MoCA has also demonstrated some predictive ability for driving performance, using the visuospatial/executive section in particular, which is the portion that includes the clock drawing test (Kandasamy et al., 2019; Kwok et al., 2015; Ma'u & Cheung, 2020).

The MoCA BLIND (see Appendix E) was created with the intention of use for individuals with low or no vision (Wittich et al., 2010); This may include patients in the hospital setting who do not have their prescribed corrective lenses in-house. The MoCA BLIND version is the same as the complete version of the MoCA with the exception of elimination of the visuospatial/executive (i.e., one point for trail making, one point for cube copying, and three points for clock drawing) and naming portions (i.e., three points for naming animals). Therefore, scoring for the MoCA BLIND version is out of a total of 22 points with a score of 18 or above suggesting normal cognition (Wittich et al., 2010).

Purpose of the Study

This research was aimed at answering the question of depending on diagnosis, whether there is a difference between young (i.e., 18-30 years) and older (i.e., 55-85 years) adults on whether the CDT score affects the overall cognitive severity rating on the MoCA. Given the findings from previous studies suggesting that some young adults with normal cognition have difficulty accurately drawing an analog clock, it was hypothesized that cognitive severities of young adults will be more negatively impacted by CDT scores than the older adult participant group.

Methods

Study Participants

A retrospective chart review was conducted from the Metro Health University of Michigan Health Hospital during the months of January 2017 through December 2020. All adult inpatients between 18-30 years old (young adult group) and 55-85 years old (older adult group) with a diagnosis of craniotomy or concussion were included. Based on findings from previous studies with a similar population, the ages of 18-30 years were selected for the young adult participants. The ages of 55-85 years are currently validated for the MoCA which aided in determining the age range for the older adult participant group. To ensure adequate participant numbers, craniotomy and concussion were chosen due to the higher frequency of occurrence within the data collection for both age groups. Another common diagnosis for the older adult population was stroke; This was not chosen due to the insufficient data for young adults. Stroke risk increases with age and most strokes occur in individuals 65 years or older (Centers for Disease Control and Prevention, 2021). Included were all genders, races, and ethnicities to ensure adequate diversity for improved external validity. Exclusion criteria included a previous neurocognitive deficit (e.g., brain injury, stroke, dementia, significant psychological diagnosis, etc.) and history of substance (i.e., alcohol or drug) abuse. Table 3.1 displays the participant demographics for this study. A total of 95 participants were gained from this data collection: 40 young adults and 55 older adults.

Table 3.1. Participant Demographics

		<i>M</i>	<i>SD</i>
Young Adult Group	Age (years)	23.67	3.95
		<i>n</i>	%
	Gender		
	Male	26	65
	Female	14	35
	Education		
	≤12 years	18	45
	>12 years	22	55
	Diagnosis		
	Concussion	34	85
Craniotomy	6	15	
		<i>M</i>	<i>SD</i>
Older Adult Group	Age (years)	67.9	9.04
		<i>n</i>	%
	Gender		
	Male	27	49
	Female	28	51
	Education		
	≤12 years	28	51
	>12 years	27	49
	Diagnosis		
	Concussion	33	60
Craniotomy	22	40	

Measurements

During their inpatient stay, participants had undergone a cognitive-communication evaluation performed by a certified speech-language pathologist, specifically administration of the Montreal Cognitive Assessment (MoCA), versions 7.1, 7.2, 7.3, 8.1, 8.2, or 8.3. Inclusion for this study required missing points on the CDT portion from the executive/visuospatial section of the MoCA.

Procedures

An overall MoCA score as well as a BLIND version MoCA score (i.e., executive/visuospatial portion, including the CDT, removed) was gathered for each participant. Each score was converted to a cognitive severity rating. An overall MoCA score of 26-30 = normal, 18-25 = mild, 10-17 = moderate, and 0-9 = severe. A BLIND MoCA score of 18-22 = normal, 13-17 = mild, 7-12 = moderate, and 0-6 = severe (Wittich et al., 2010). Groups will include a young adult concussion (YACo), a young adult craniotomy (YACr), an older adult concussion (OACo), and an older adult craniotomy (OACr) participant group. Overall MoCA score severity rating was compared against the BLIND MoCA score severity rating for each participant.

Statistical Analysis

A chi-square test for independence was conducted using SPSS version 28 to determine whether the distributions of the categorical variables of severity rating differ from one another based on age and diagnosis. A post-hoc Bonferroni correction was conducted to investigate any significant difference between group levels. The independent variables of age (young adult group: participants 18-30 years; older adult group: participants 55-85 years) and diagnosis (post-craniotomy, post-concussion) were used. The dependent binary variable of a change in cognitive severity rating (i.e., yes, no) with missed CDT points (three total points: one point for circle contour, one point for number placement, and one for clock hand placement) was used.

Results

The results of the chi-square test of independence are displayed in Table 3.2. When comparing the difference in change of severity rating from the complete MoCA and the BLIND MoCA versions between the young adult participant group and the older adult participant group, those with the diagnosis of concussion were statistically significant from one another ($\chi^2 = 5.611$, $p = 0.043$). The change in severity rating did not differ between age groups when comparing those with the diagnosis of craniotomy ($\chi^2 = 0.513$, $p = 0.645$) or the combination of diagnoses of concussion and craniotomy ($\chi^2 = 2.162$, $p = 0.164$). Post-hoc Bonferroni correction agreed with the chi-square results, demonstrating significant group differences amongst young and older adults with a diagnosis of concussion ($z = 2.9$, $p = 0.004$). Again, the diagnosis of craniotomy did not demonstrate statistical significance when comparing a negative change in severity rating for younger and older adults ($z = 0.7$, $p = 0.484$). These post-hoc results are detailed in Table 3.3.

Table 3.2. Difference in Severity Rating for Reduced CDT Scores ($n = 95$)

	Chi-Square Value	df	Significance
Concussion	5.611	1	0.043*
Craniotomy	0.513	1	0.645
Overall	2.162	1	0.164

* $p < 0.05$

Table 3.3. Post-Hoc Test with a Bonferroni Correction ($n = 95$)

		z-test		
		Change in Severity Rating	No Change in Severity Rating	Significance
Young Adult	Concussion	2.9		0.004*
			-2.9	0.004*
	Craniotomy	-0.7		0.484
			0.7	0.484
Older Adult	Concussion	-2.9		0.004*
			2.9	0.004*
	Craniotomy	0.7		0.484
			-0.7	0.484

* $p < 0.00625$

Discussion

When compared to older adults (i.e., 55-85 years), young adults (i.e., 18-30 years) with a diagnosis of concussion obtained statistically higher cognitive severity rating scores when the CDT portion of the MoCA was removed. These results, in combination with previous research, suggests the CDT is no longer an accurate cognitive screening measure for this young adult population. Older adults of ages 55-85 years are currently validated for administration of the MoCA (Nasreddine et al., 2005), thus establishing an expected proportion of scores and severity ratings against which the young adult participant group could be compared. Also, removing data from individuals with a previous history of cognitive impairment or substance abuse created an opportunity for clear category distinction when grouping participants.

Using the recommended cognitive severity ratings associated with the complete MoCA and BLIND MoCA versions assisted in categorization for this study. The CDT is absent from the BLIND MoCA and gave an opportunity for a simple scoring adjustment. In following this procedure, also eliminated from the BLIND MoCA scoring were other executive function and visuospatial elements (i.e., alternating trail making and cube copying). The naming portion is

another subtest that is not included in the BLIND MoCA. Removal of these additional subtests could have altered the scoring and should be considered when consuming this research.

The requirement of certification for healthcare workers to administer and score the MoCA is in place to ensure reliability and validity of the assessment. The analysis of cognition should not solely be based on a cognitive screening measure; Speech-language pathologists and other healthcare providers are encouraged to use a variety of informal and formal measures to evaluate these domains. For example, obtaining an accurate history, subjectively assessing pragmatic language, along with other communication skills could assist in appropriate diagnosis and recommendations. Clinical intuition and expertise are powerful tools that should accompany any cognitive screening measure, particularly the CDT when administered to the young adult population until further research can be conducted.

Limitations

The diagnosis of craniotomy did not demonstrate statistically significant results following chi-square and post-hoc Bonferroni testing. Despite four years of data extraction, low numbers of young adult participants were able to be analyzed for this diagnosis. This limitation could have led to inaccurate statistical outcomes. Gaining a broader range of dates or selecting participants from a larger database could support a more accurate analysis for future investigation.

Information concerning the vision for study participants was not collected and therefore is unknown. Given the neurological diagnoses, there is a possibility of some participants having inadequate vision for the CDT. Although patients should have declined the executive/visuospatial portion of the MoCA and opted for the MoCA BLIND in case of vision concerns, some may have chosen to proceed with these subtests. The possibility of vision

impairment with some of the participants is a confounding factor in this research and should be taken into consideration when interpreting the results of this study.

Another limitation may present in the small number of diagnoses studied for this research (i.e., concussion, craniotomy). Potential exploration in this area could focus on a young adult population who frequently receive cognitive screening, such as those in contact sports who require a pre-season sports physical. According to the NCAA (2020), there are approximately 7,200,000 high school student-athletes and 499,000 NCAA student-athletes. Many of these students receive pre-season cognitive screening for a longitudinal measurement of their cognitive function in case of brain injury. In circumstances when pre-season testing does not occur, an inaccurate CDT could suggest acute impairment and may initiate a protocol of additional testing and treatment.

Conclusion

Given recent data from prior studies suggesting the inability of some young adults to draw an analog clock as well as this inaccuracy causing a clinical discrepancy in comparison to older adults, this study was indicated to determine diagnostic inaccuracies related to cognitive severity of the MoCA. The data from this study suggest that in individuals diagnosed with concussion who have incorrectly completed the CDT, younger adults are incorrectly receiving more severe cognitive scores than older adults. These false negative results are leading to misdiagnosis which could cause emotional trauma and unnecessary further medical expenses. It is strongly cautioned to use the CDT in isolation or when embedded in a larger cognitive screening measure (e.g., MoCA, MMSE, CLQT) for the young adult population. An alternative option for cognitive assessment could include more complete cognitive evaluations, those

without inclusion of the CDT, or altering scoring methods (i.e., adding points) for the CDT portion of the cognitive screening. Further research is indicated to determine the adaptation in scoring system required for younger adults. Ongoing and repeated research in this area is also suggested as generational changes persist.

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Conflict of Interest

None declared.

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CHAPTER V

CONCLUSION

Summary

Although the clock drawing test (CDT) has served as an excellent cognitive screening measure with sufficient psychometric properties for a variety of adult populations over the last century (Shulman, 2000), evolving technology and social patterns have created a generation of young adults with an inability to draw an analog clock. Young adults require an accurate cognitive screening measure given the frequency of traumatic brain injury, requirement for pre-season sports physicals, and eventual transition of this generation to become older adults who are at increased risk of cognitive deficits given the potential for cardiovascular and neurodegenerative disease (Bruns & Hauser, 2003; Centers for Disease Control and Prevention, 2016; Veliz et al., 2017). This research serves as an important resource to help fill the gap in the current CDT literature, which mainly focuses on older adults and identification of dementia. Speech-language pathologists (SLPs), as well as other healthcare providers, should stay current with evidence in the cognitive testing domain which, given these findings, may require adjustment for the young adult population.

Study One (Chapter II)

The first study investigated the knowledge surrounding analog clocks for the young adult population (i.e., ages 18-30 years). Participants completed the CDT according to the Shulman scoring system, drew analog clock hands from a digital representation, and wrote digital clock times to a completed analog clock stimulus. Eighty participants, who self-identified as having

normal cognition, were acquired from public areas. Three quarters of the participants were able to pass the CDT according to the Shulman method of scoring, which resulted in statistical significance for the completed one proportion z-test ($T = -217.938, p < 0.001$). In the group that failed the CDT, there was a moderate, positive correlation between clock hand placement and analog clock time identification ($r_s(16) = 0.472, p = 0.048$). In 97.5% of CDT attempts, participants received a score of either three (acceptable visuospatial organization, but inaccurate representation of the requested time) or five (“perfect” clock), both of which indicate adequate visuospatial organization. An inter-rater reliability of 0.724 was achieved as assessed using Cohen’s kappa. The participants were also asked their use of analog watches; 8.8% of whom endorsed wearing an analog watch.

These data suggest that the CDT may no longer be an accurate indicator of intact cognition in the young adult population. A false positive CDT could result in an improper diagnosis and lead to unnecessary diagnostic testing, prolonged hospital length of stay, as well as emotional distress to the patient and loved ones. Administering the CDT using the Shulman scoring method may still be an appropriate screening method for visuospatial organization, as these data suggest this skill remained relatively intact.

The low rate of participants who wear analog watches supports the theory of limited exposure to analog clocks (Alt, 2020; Fultonberg, 2017; Slome, 2015; Vogels, 2020), which may be a reasonable explanation for young adults to exhibit reduced performance on the CDT. Another theory lies in the varying language of English dialects surrounding time concepts, e.g., Ager (n.d.), Murphy (2006), Walter (2018); Most CDT scoring systems use the British English version of time during administration. Verbiage such as “half past five,” “10 after one,” and “quarter to/after nine” is more often used with British English. More commonly in American

English these times would be stated with direct numerals such as, “5:30,” “1:10,” and “9:45/9:15,” respectively.

Study Two (Chapter III)

Building from the data found in the first study, the second study was aimed at determining a difference in CDT performance between young (i.e., ages 18-30 years) and older (i.e., ages 55-85 years) adults within a clinical setting. A clinical setting and an acute care hospital, in particular, was of great interest for this research as this is a site used frequently for cognitive screening. A total of 516 participants were gained through retrospective chart review at the Metro Health University of Michigan Health Hospital from January 2017 through December 2020. Inclusion criteria included inpatients from all genders, races, and ethnicities who received a cognitive-communication evaluation, specifically the Montreal Cognitive Assessment (MoCA) versions 7.1, 7.2, 7.3, 8.1, 8.2, or 8.3, which includes the CDT within the screening. All young adults aged 18-30 years, due to findings from Study One, were included. Ages 55-85 years were selected for the older adult participant group, as these ages are currently validated for the MoCA. Excluded were participants who spoke English as a second language to eliminate scoring inaccuracies created by use of an interpreter. Participants were further grouped into severity ratings, for both young and older adults, recommended by Nasreddine et al. (2005).

Following conduction of a two-way analysis of variance, statistical significance was found when comparing the variance of age ($F = 5.051, p = 0.025$) and overall cognitive severity groupings ($F = 46.917, p < 0.001$) for CDT scores taken from the MoCA. The interaction effect of age and severity was not statistically significant ($F = 2.076, p = 0.127$). Post-hoc Bonferroni correction verified statistically significant variance among most groups, based on age difference

(i.e., young adult vs. older adult). Cognitive severity groups that did not demonstrate statistically significant variance were among moderate and severe levels ($p = 0.675$); All other comparisons were statistically significant ($p < 0.001$).

These data suggest a significant variance in CDT performance between young (i.e., 18-30 years) and older (i.e., 55-85 years) adults in a clinical setting. These findings are integral to ensuring accurate cognitive screening in all populations within an acute care setting. False positive CDT results may prompt avoidable further cognitive testing, referrals, and neuroimaging which could additionally prolong length of hospital stay. Another unfortunate negative sequela of disseminating false positive results could be unwarranted feelings of distress for the patient and family. As stated earlier, further research is warranted to decipher the rationale for the variance in CDT performance between young and older adult populations. Reduced exposure and use of analog clocks (Alt, 2020; Fultonberg, 2017; Slome, 2015; Vogels, 2020), poor retainment of learned analog clock knowledge (Earnest, 2017; Friedman and Laycock, 2006; Fultonberg, 2017), as well as unfamiliarity with the British English dialect terminology for clock times (Ager, n.d.; Murphy, 2006; Walter, 2018) are all considerations that may warrant further investigation.

Study Three (Chapter IV)

Further investigation of CDT accuracy between the young (i.e., ages 18-30 years) and older (i.e., ages 55-85 years) adult populations led data analysis in Study Three to determine whether MoCA severity ratings (and categorizations) were being negatively affected by the variance in CDT performance in this cognitive screening test. This study benefitted from the data collection of Study Two; however, used a more defined exclusion criterion. Also excluded in this

study were participants with a history of cognitive impairment or substance abuse. Participants were also required to have a diagnosis of concussion or craniotomy and have missed at least one point on the 3-point CDT portion of the MoCA. A total of 95 participants met these criteria.

An overall MoCA score severity rating was compared to a MoCA BLIND version severity rating, which excluded the CDT portion of the screener. A chi-square test of independence demonstrated statistically significant results between the younger and older adult participant groups who had a diagnosis of concussion ($\chi^2 = 5.611, p = 0.043$). The change in severity rating did not differ between age groups when comparing those with the diagnosis of craniotomy ($\chi^2 = 0.513, p = 0.645$) or the combination of diagnoses of concussion and craniotomy ($\chi^2 = 2.162, p = 0.164$). Post-hoc Bonferroni correction supported the chi-square results with significance amongst the participants with a diagnosis of concussion ($z = 2.9, p = 0.004$).

These data support findings from Study One and Study Two indicating a discrepancy of CDT accuracy amongst younger and older adults and further suggest that in inpatients with a diagnosis of concussion, the poor CDT performance of young adults places them at increased risk for lower cognitive severity ratings on the MoCA when compared to older adults. Again, justification for the outcome of poor CDT performance in young adults warrants further investigation.

Limitations

Limitations from Study One present from the lack of comparison group, clinical setting, and documented history. The administration was not strictly private, and it was assumed that participants in this study were being honest with their effort of task and endorsement of absent cognitive impairment. The data collected and analyzed for Studies Two and Three from a clinical

setting and with both younger and older adults supported the findings of Study One, which lessened the concern for this limitation.

Another limitation lies in participant numbers. An adequate total number of participants was obtained from data extraction for Studies Two and Three. Due to the higher risk for cognitive impairment in older adults, there was a disproportion of young to older adult participant numbers (i.e., a ratio of 1:4, respectively). It would be ideal to obtain a relatively equal number between the two groups for a more sound comparison. Despite four years of data extraction, the exclusion criteria of Study Three limited the participant numbers, especially for young adults with a diagnosis of craniotomy; This could have impacted the findings for this group. Both diagnoses can result in a variety of neurologic insult for location and severity. A rationale, besides low participant numbers, for the concussion and not craniotomy group to achieve statistical variance is not understood at this time.

A final concern is with administration and interpretation of the CDT within the MoCA for Studies Two and Three. Young adults were included amongst the speech-language pathologists who administered and scored the CDTs. Given the findings for these studies suggesting that young adults present with a lower rate of passing the CDT, it is reasonable to assume that there is a reduced comprehension of analog clocks for this population. Again, all SLPs were certified for clinical competence in their field and had received professional in-services relating to administration and scoring of the MoCA, including the CDT portion.

Implications

This research has interdisciplinary implications as the CDT is used by a variety of healthcare providers to screen cognition among adults. Following screening, various medical

professional referrals for additional testing may take place. The data from these studies suggest the CDT to be an inaccurate tool when administered to young adults aged 18-30 years. If the rationale for poor performance in this population is based on generational changes, the subsequent generations will likely follow suit and require a different cognitive screening tool. Healthcare providers, including registered nurses, primary care and internal medicine physicians, neurologists, neuropsychologists, advanced practice providers, speech-language pathologists, occupational therapists, and physical therapists, among others will require flexibility by adapting their routine with the ever-changing times. This adaptability is a common theme within healthcare practice and should come as no surprise or concern to providers.

Ongoing use of the CDT with older adults is not in question; however, as young adults from this generation age and become older adults, an even greater need for accurate cognitive screening will be indicated. A novel cognitive screening tool with similar psychometric properties to the CDT and that incorporates a wide variety of cognitive domains yet is without generational relations would certainly be welcomed. Another solution in the interim is adding points for the young adult population upon scoring the CDT. Assessments, such as the MoCA and Mini-Mental State Examination, currently add points to the overall score for patients with less formal education, which allows for an accurate severity rating upon final point calculation. Adding points for the young adult population, depending on the CDT scoring system, may alleviate accuracy concerns.

Most healthcare students studying fields of which may use the CDT are young adults themselves. With recommendations for ongoing CDT use in the older adult population, these young adult students may benefit from increased intentional instruction of analog clock language, as well as various CDT scoring systems to maintain reliability and preserve the current

exceptional psychometric properties of this cognitive screening tool. As the older adult population has departed, this additional course content will become unnecessary.

The data from these studies suggest spared visuospatial skills with the CDT and using this cognitive screening tool for visuospatial skills only may be a valid alternative. Use of the CDT for longitudinal self-comparison purposes may also be acceptable. Overall, it is vital for healthcare providers who continue to administer the CDT with young adults to use excellent clinical judgment for interpretation; this includes incorporating a thorough history and physical as well as other relevant clinical findings to produce appropriate impressions and recommendations.

Future Research

A variety of exciting and practical investigative opportunities emerge from this research. As stated earlier, a possible concern regarding reasoning for poorer CDT performance among young adults stems from the difference in time terminology between American and British English (Ager, n.d.; Murphy, 2006; Walter, 2018). To further explore this possibility in the United States, administration of the CDT using American English verbiage (e.g., “11:10” in place of “10 past 11”) is a consideration. Another way to address this same research question would be to conduct a study in a country with a primarily British English-speaking population, using the current CDT protocol. As language may vary, studying a variety of scoring systems with the young adult population may help tease out an accurate version for continuation. Investigating other language, besides English, versions of the CDT could also support this theory of differing language and include cultural implications that may not have yet surfaced with these current studies.

All healthcare providers who administer and score the CDT should be knowledgeable with analog clocks. Determining the reliability of CDT administration among young adult healthcare students appears beneficial given the current concern for reduced analog clock knowledge in this population. Investigating a variety of scoring systems for these young adult healthcare students would likely yield advantageous data and assist in determining the most appropriate educational needs for increased reliability.

Continuing this CDT research agenda is critical in obtaining a reliable and valid cognitive screening measure for the young adult population. As cognitive function may be impacted by a wide range of diagnoses in young adults, investigating each of these patient populations should be considered. The MoCA is one of many other cognitive screening or assessment measures for which the CDT is embedded (e.g., Mini-Cog, Saint Louis University Mental Status Examination, Self-Administered Gerocognitive Exam, Cognitive-Linguistic Quick Test); Further research using these measures is indicated.

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APPENDIX A

Study 1 Human Subjects Institutional Review Board Letter of Approval

WESTERN MICHIGAN UNIVERSITY



Institutional Review Board
FWA00007042
IRB00000254

Date: October 1, 2019

To: Linda Shuster, Principal Investigator
Samantha McDaniel, Student Investigator

From: Amy Naugle, Ph.D., Chair

Re: IRB Project Number 19-09-24

This letter will serve as confirmation that your research project titled “Validating the Clock Drawing Test for the Young Adult Population” has been **approved** under the **exempt** category of review by the Western Michigan University Institutional Review Board (IRB). The conditions and duration of this approval are specified in the policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may **only** be conducted exactly in the form it was approved. You must seek specific board approval for any changes to this project (e.g., **add an investigator, increase number of subjects beyond the number stated in your application, etc.**). Failure to obtain approval for changes will result in a protocol deviation.

In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the IRB for consultation.

The Board wishes you success in the pursuit of your research goals.

A status report is required on or prior to (no more than 30 days) September 30, 2020 and each year thereafter until closing of the study. The IRB will send a request.

When this study closes, submit the required Final Report found at <https://wmich.edu/research/forms>.

Note: All research data must be kept in a secure location on the WMU campus for at least three (3) years after the study closes.

Office of the Vice President for Research
Western Michigan University
1903 W. Michigan Ave., Kalamazoo, MI 49008-5456
PHONE: (269) 387-8293 FAX: (269) 387-8276
WEBSITE: wmich.edu/research/compliance/hsirb

CAMPUS SITE: Room 251 W. Walwood Hall

APPENDIX B

Study 1 Human Subjects Institutional Review Board Approved Consent Document

IRB Approved

OCT 1 2019



WMU IRB Office

**Western Michigan University
Interdisciplinary Health Sciences Ph.D. Program**

Principal Investigator: Dr. Linda I. Shuster, Ph.D., CCC-SLP, ASHA Fellow
Student Investigator: Samantha L. McDaniel, M.S., CCC-SLP

You are invited to participate in this research project titled "*Validating the Clock Drawing Test for the Modern Young Adult Population*"

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. Participation in this study is completely voluntary. You may choose to not answer any question. The purpose of the research is to: update testing for cognition in young adults and will serve as Samantha McDaniel's research project for the requirements of the interdisciplinary health sciences Ph.D. If you take part in the research, you will be asked to answer some questions on a survey. Your replies will be completely anonymous, so do not put your name anywhere on the survey. Your time in the study will take approximately 5-10 minutes to complete the survey. Possible risk and costs to you for taking part in the study may be the inconvenience of time to take the survey and potential benefits of taking part may be knowing that you are helping people in the medical community complete more accurate tests of cognition for young adults. An alternative to taking part in the research study is not to take part in it.

The de-identified (anonymous) information collected for this research may be used by or distributed to investigators for other research without obtaining informed consent from you.

Should you have any questions prior to or during the study, you can contact the principal investigator, Linda Shuster, at Western Michigan University at 269-387-7990 or linda.shuster@wmich.edu or the student investigator, Samantha McDaniel at 989-430-2174 or samantha.l.mcdaniel@wmich.edu. You may also contact the Chair, Institutional Review Board at 269-387-8293 or the Vice President for Research at 269-387-8298.

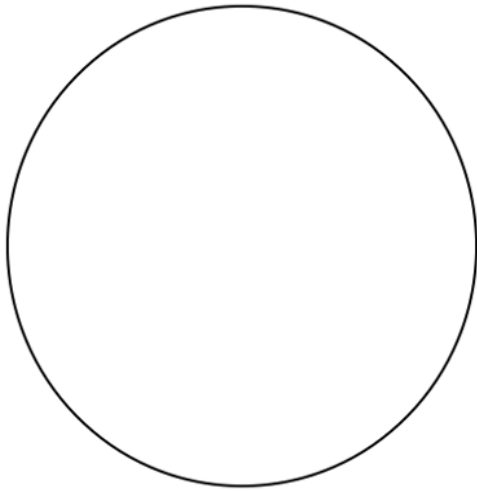
This consent document has been approved for use for one year by the Western Michigan University Institutional Review Board (WMU IRB) as indicated by the stamped date and signature of the board chair in the upper right corner.

Participating in this survey indicates your consent for use of the answers you supply.

APPENDIX C

Study 1 Clock Drawing Test Assessment

(Front)



(Back)

Age: _____

Years of Education: _____

Race/Ethnicity: _____

Do you wear an analog watch? YES NO

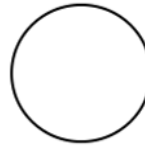
I believe the concept of time is important (being on time for appointments/meetings, being aware of the time).

NO

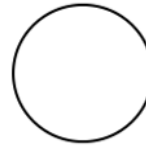
Sort of

YES

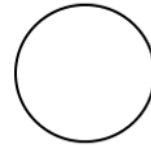
Draw the time shown:



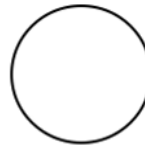
11:10



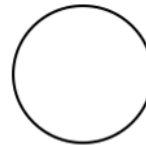
2:45



6:35



9:52



12:27

Please state the time shown:











APPENDIX D

Montreal Cognitive Assessment Version 8.1

APPENDIX E

Montreal Cognitive Assessment Version 8.1 BLIND

MONTREAL COGNITIVE ASSESSMENT (MoCA®)
Version 8.1 BLIND English

NAME:
EDUCATION :
Sex :
Date of birth :
DATE :

MEMORY		FACE	VELVET	CHURCH	DAISY	RED	POINTS	
Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	1st TRIAL						NO POINTS	
	2nd TRIAL							
ATTENTION		Subject has to repeat in the forward order. [] 2 1 8 5 4					___/2	
Read list of digits (1 digit / sec.).		Subject has to repeat in the backward order. [] 7 4 2						
Read list of letters. The subject must tap at each letter A. No points if ≥ 2 errors		[] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B					___/1	
Seria 7 subtraction starting at 100		[] 93	[] 86	[] 79	[] 72	[] 65	___/3	
		4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt						
LANGUAGE		I only know that John is the one to help today. []					___/2	
Repeat:		The cat always hid under the couch when dogs were in the room []						
Fluency: Name maximum number of words in one minute that begin with the letter F.		[] _____ (N ≥ 11words)					___/1	
ABSTRACTION		[] train - bicycle					___/2	
Similarity between e.g. orange - banana = fruit		[] watch - ruler						
DELAYED RECALL		Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	___/5
Memory	(MIS) X3	[]	[]	[]	[]	[]		
Index	X2	Category cue						
Score	X1	Multiple choice cue					NO POINTS	
ORIENTATION		[] Date	[] Month	[] Year	[] Day	[] Place	[] City	___/6
© Z. Nasreddine MD		www.mocatest.org					TOTAL	___/22
Administered by : _____		Add 1 point if ≤ 12 yr edu						

MIS: /15 (Normal ≥ 19/22)

Training and Certification are required to ensure accuracy

APPENDIX F

Studies 2 and 3 Western Michigan University Human Subjects Institutional Review Board Letter
of Approval

WESTERN MICHIGAN UNIVERSITY



Human Subjects Institutional Review Board

Date: May 20, 2021

To: Kieran Fogarty, Principal Investigator
Samantha McDaniel, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: IRB Project Number 21-05-14

This letter will serve as confirmation that your research project titled “The Effect of Age on Clock Drawing Test Performance in a Clinical Setting” has been approved under the exempt category of review by the Western Michigan University Institutional Review Board (IRB). The conditions and duration of this approval are specified in the policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may only be conducted exactly in the form it was approved. You must seek specific board approval for any changes to this project (e.g., *add an investigator, increase number of subjects beyond the number stated in your application, etc.*). Failure to obtain approval for changes will result in a protocol deviation.

In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the IRB for consultation.

The Board wishes you success in the pursuit of your research goals.

A status report is required on or prior to (no more than 30 days) May 19, 2022 and each year thereafter until closing of the study. The IRB will send a request.

When this study closes, submit the required Final Report found at <https://wmich.edu/research/forms>.

Note: All research data must be kept in a secure location on the WMU campus for at least three (3) years after the study closes.

251 W. Walwood Hall, Kalamazoo, MI 49008-5456
PHONE: (269) 387-8293, FAX: (269) 387-8276

APPENDIX G

Studies 2 and 3 Metro Health University of Michigan Health Hospital Human Subjects
Institutional Review Board Letter of Approval

APPROVAL OF RESEARCH

June 29, 2021

Samantha McDaniel, Master of Science
7704 Spring Point Ct. NE
Rockford, MI 49341

TYPE OF REVIEW: **Initial, Non-Committee Review**

IRB#: **2021-015** (please reference this number in all correspondence with the IRB)

PROTOCOL NAME: **The Effect of Age on Clock Drawing Test Performance in a Clinical Setting**

SPONSOR: **Investigator Initiated**

Dear Mrs. McDaniel:

The above referenced protocol and associated materials were reviewed and approved by the IRB via expedited review on June 29, 2021 under category (5) as described in [45 CFR 46.110](#).

The approval period for this research is from **June 29, 2021 to June 28, 2022**.

The IRB reviewed the following documents related to the approval of the research proposal:

- Initial Application signed: June 21, 2021
- Protocol version date: June 21, 2021
- MoCA version 8.1
- Data collection spreadsheet
- Executed Data Use Agreement with WMU
- Authorization Agreement with WMU
- WMU IRB approval letter
- Approved enrollment: 1000

The IRB made the following determinations:

WAIVER OF CONSENT AND ASSENT/HIPAA AUTHORIZATION: A waiver of consent/assent has been approved per 45 CFR 46.116 and a waiver of HIPAA authorization has been approved per 45 CFR 164.512(i)(2)(ii)

Metro Health Institutional Review Board

Metro Health Professional Building

2122 Health Dr. SW, Suite 233 | Wyoming, MI 49519
p 616.252.5026 | irb@metrogr.org | metrohealth.net

Any changes made to the study following this approval, including informed consent changes, require submission in writing to the IRB and approval by the committee. Changes may not be implemented until approved by the IRB except when necessary to eliminate apparent immediate hazards to the subject. Approval of your research means you are responsible for complying with all applicable policies and procedures of the FDA, OHRP, HIPAA, Metro Health, and the Metro Health IRB. Also, please be advised that unanticipated problems involving risk to subjects or others must be *promptly* reported to the IRB.

Please be advised, this approval letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this research. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Use Agreements and Material Transfer Agreements have been signed, department support has been obtained, and any other outstanding items are completed (i.e. CMS device coverage approval letters, material shipment arrangements, etc.)

The IRB requires submission of the Continuing Review Progress Report or Study Completion Notification to the committee prior to the study expiration date. It is recommended that you submit this form 4-6 weeks prior to the expiration date to allow for processing. Your study approval expires on **June 28, 2022 at 11:59 p.m.** and cannot continue until re-approved by the Metro Health IRB. If your study has been completed, terminated, or if you do not wish to continue, please submit the Study Completion Notification before the expiration date.

If you have any questions, please contact the Metro Health IRB at 616-252-5026 or email irb@metrogr.org.

Sincerely,



Cindy Karl, BSN, RN, CCRC, CIP
IRB Designated Reviewer

cc: Samantha McDaniel, Master of Science

Metro Health Institutional Review Board

Metro Health Professional Building
2122 Health Dr. SW, Suite 233 | Wyoming, MI 49519
p 616.252.5026 | irb@metrogr.org | metrohealth.net

APPENDIX H

Studies 2 and 3 Metro Health University of Michigan Health Hospital Data Transfer Agreement

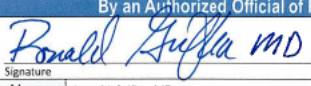
Data Transfer and Use Agreement	
Provider:	Metro Health – University of Michigan Health
Metro Health Representative Name(s):	Samantha McDaniel, M.S., CCC-SLP
Agreement Term	
Start Date:	6/21/21
End Date:	6/21/22
Recipient Institution	Western Michigan University
Recipient Scientist Name:	Kieran Fogarty, Ph.D.
Email:	kieran.fogarty@wmich.edu
Project Title:	The Effect of Age on Clock Drawing Test Performance in a Clinical Setting

Attachment 2 Type (Select Data Type)	
<input checked="" type="checkbox"/> De-identified Data About Human Subjects	<input type="checkbox"/> Personally Identifiable Information – Common Rule Only
<input type="checkbox"/> Limited Data Set	<input type="checkbox"/> Personally Identifiable Information – HIPAA

Terms and Conditions
<ol style="list-style-type: none"> 1) Metro Health shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein. 2) If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1. 3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons"). 4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2. 5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research. 6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information. 7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1. 8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written

notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

- 9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.
- 10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.
- 11) Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.
- 12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project:
 - I. Attachment 1: Project Specific Information
 - II. Attachment 2: Data-specific Terms and Conditions (attachment type chosen on page one (1))
 - III. Attachment 3: Identification of Permitted Collaborators (if any)
- 13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly-authorized representatives of both parties.
- 14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.

By an Authorized Official of Provider		By an Authorized Official of Recipient	
	<i>6/28/2021</i>	Steven J. Weber, Ph.D. <small>Digitally signed by Steven J. Weber, Ph.D. Date: 2021.06.23 11:13:54 -0400</small>	23Jun2021
Signature	Date	Signature	Date
Name: Ronald Grifka, MD		Name: Steven J. Weber, Ph.D.	
Title: Chief Medical Officer		Title: Director, Technology & Commercialization	

Contact Information for Formal Notices			
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