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Is the Geriatric ImPACT iPad Test a Valid Measurement of Cognitive Function in Older Adults?

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Is the Geriatric ImPACT™ iPad Test a Valid Measurement of Cognitive Function in Older Adults?

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Abstract

The number of older adults will rapidly increase within the next generation (Brookmeyer, Johnson, Ziegler-Graham, & Arrighi, 2007). Alzheimer's disease risk increases with age, especially after age 60 (NIA, n.d.). Aging leads to a decrease in functional independence, and this side effect is exacerbated by cognitive decline (Johnson, Lui, & Yaffe, 2007). Executive function is a predictor of Alzheimer's disease onset and progression (Zhang, Han, Verhaeghen, & Nilsson, 2007). The Geriatric ImPACT™ test is a potential new and more convenient testing methods than traditional methods used. The purpose of this research is to validate the Geriatric ImPACT™ test by comparing the scores to those of traditionally used paper and pencil tests.

The paper and pencil tests showed correlation with the Geriatric ImPACT™, indicating that the Geriatric ImPACT™ tests the same cognitive domains of the traditional testing battery. This test is validated and is more convenient to use than the paper and pencil tests. Future research is needed to confirm this and should use a larger sample size, including participants with diagnosed cognitive decline.

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Chapter I

Introduction

In less than 40 years, the number of individuals affected by Alzheimer's disease will quadruple (Brookmeyer et al., 2007), taking the total affected to more than 13.5 million people (Sperling et al., 2011). According to the National Institute on Aging (NIA), Alzheimer's symptoms generally present in individuals later in life, after about 60 years old (NIA, n.d.) . After age 65 an individual's likelihood of developing the disease doubles every five years. Thus an 80-year-old would be six times more likely to have the disease over a 65-year-old (NIA, n.d.). This is particularly alarming since the number of individuals over the age of 80 years is projected to increase by a factor of 3.7 by 2050 (Brookmeyer et al., 2007). A decline in functional independence is a common occurrence in older adults, especially with Alzheimer's disease and dementia, leading to negative prognoses and the dependence upon others to complete basic tasks of living (Johnson, Lui, & Yaffe, 2007). With the number of older adults increasing rapidly, quality of life and the ability to maintain independence will presumably decrease.

Executive function is the portion of cognitive processing that is responsible for the planning, beginning, and adapting of a behavior (Farina, Tabet, & Rusted, 2014). Brennan, Welsh, and Fisher (1997) showed that executive function declines with individuals who are aging normally, without diagnosed neurological disease or major impairment. This decline has been attributed to a general slowing in the processing of information in the working memory, not an insufficiency in the ability to control executive functions (Fisk & Warr, 1996). Decline in executive function may be an important predictor of Alzheimer's diagnosis and used to pinpoint the conversion from normal aging to a more serious disease state, according to Zhang et al.

(2007). Some of the factors used to predict cognitive impairment and executive function decline may be modifiable (Yaffe et al., 2009), and cognitive impairment can be differentiated from the memory loss that accompanies normal aging (Basak, Boot, Voss, & Kramer, 2008). Executive function decline in itself is disruptive, and can also cause a decrease in quality of life. A reduction in quality of life not only puts emotional and financial stress on an individual and their family, but on the healthcare industry as a whole. Functional impairment can lead to decreased quality of life, which ultimately can lead to increased healthcare costs via repeated hospitalization or long-term care facility (Hertzog, Kramer, Wilson, & Lindenberger, 2008).

It is important to understand the measurement of cognitive and executive function in order to understand the level of care that older adults need. Cognitive impairment can lead to loss in executive function, along with difficulty performing activities of daily living. Functional dependence causes older adults to need help with bathing, medication, eating, transportation, laundry, and many other necessities. Because of the rising population of older adults, and the care that they will need in the cases of functional impairment, society should be concerned with testing cognition levels at regular intervals in order to monitor the progression of cognitive decline. According to Kuslanksy et al. (2004), diagnosing memory disorders may be postponed in primary care due to lack of time. This presents a need for a convenient, easily administered cognitive test. Also, treatment of cognitive disorders is more successful when administered in the beginning stages before widespread damage occurs (Kuslansky et al., 2004). As with many other diseases, early detection is important. The sooner treatment can begin, the less likely rapid, widespread damage becomes. Early testing and diagnosis of cognitive impairment may be able to help delay the debilitating and costly effects of such diseases.

The Geriatric ImPACT™ iPad test presents a potential cognitive testing method that is convenient and time-efficient. There are several potential advantages to using a computerized test for cognitive screening. First is the ease of use (Nakayama, Covassin, Schatz, Nogle, & Kovan, 2014). The cognitive screening tool contained in the iPad app can reduce testing time compared to a paper and pencil battery consisting of multiple tests. It is available any time the test administrator's iPad is on hand and therefore requires little advance planning. The geriatric version of ImPACT™ adds another level of convenience in data collection; test results are stored within the app and may be emailed to the administrator for ease of access. This iPad app also presents the possibility of cost reduction for cognitive testing. While the iPad and the app may require initial investment, each paper and pencil test requires multiple expenses, such as instruction manuals, score sheets, response forms, stimulus cards, staff members, stopwatches, and pencils. The iPad app automatically scores the test, without the need for additional staff hours, which may further increase the cost of paper and pencil measures (Bauer et al., 2012).

The second major advantage is the automatic generation of alternate test forms (Nakayama et al., 2014). When using the iPad app, a different version of the test is presented each time. To accomplish this with paper and pencil tests, different forms must be ordered for each test in the given battery. The app also helps to reduce human error with timed tests (Bauer et al., 2012). Paper and pencil tests require the administrator to determine starting and stopping time, while the iPad app does so automatically when the participant begins and ends a portion of the test.

Finally, the iPad app reduces the number of staff members needed for cognitive testing (Nakayama et al., 2014). While the ImPACT™ software is not intended to be an independent diagnostic measure for cognitive impairment (Nakayama et al., 2014), the availability of the iPad app does allow this tool to be accessible without the presence of a neuropsychologist (Bauer et al., 2012).

According to Czaja et al. (2006), computer anxiety and self-efficacy are limiting factors for older adults to technology use. These would need to be overcome if an iPad app were used for cognitive testing. This may need to be mediated by the presence of a test administrator to explain test instructions as needed or help with the iPad operation.

Purpose of the Study

The purpose of this study is to validate the Geriatric Immediate Post-Concussion Assessment and Cognitive Test ImPACT™ iPad application. There are single standard tests that are used in clinical settings, such as MMSE, Trail Making, etc., but testing multiple cognitive domains is helpful in diagnosing dementia (Small, Herlitz, Fratiglioni, Almkvist, & Bäckman, 1997). The Geriatric ImPACT™ presents a test battery to test multiple cognitive domains in a convenient, portable, and time- and cost-efficient manner.

Hypothesis

The Geriatric ImPACT™ iPad app is based upon a validated battery of tests that measure cognitive and executive function, visuospatial processing, selective attention, response inhibition, and verbal fluency (Spreen & Strauss, 1998). Therefore, it is hypothesized that Geriatric ImPACT™ will have at least a moderate correlation to the paper tests that measure the same cognitive domains.

Operational Definitions

The following definitions will be used in this study:

- Activities of daily living – routine behaviors that take place each day, such as laundry, gardening, driving, and eating.
- Alzheimer's disease – clinical dementia, beyond typical aging, marked by developing memory loss, with other behavioral and cognitive impairments that limit activities of daily living (Dubois et al., 2010).
- Cognition – the mental ability to comprehend and recall (Merriam-Webster's online dictionary, n.d.); comprised of the domains of language, concentration, memory, executive functioning, and visuospatial skills (Helm-Estabrooks, 2002).
- Dementia – deficit in cognition, marked by loss of function in activities of daily living (Breitner, 2006), commonly caused by Alzheimer's disease (Blennow, de Leon, & Zetterberg, 2006).
- Executive functions – the mental processes that dictate goal-oriented behaviors, especially when a behavior occurs for the first time (de Frias, Dixon, & Strauss, 2006).
- Mild cognitive impairment (MCI) – memory loss more severe than that attributed to typical aging, but not at the level of Alzheimer's disease (Zhang et al., 2007).
- Older adults – adults aged 65 and older, or those 50-64 years old with diagnosed conditions or physical limitations that decrease functioning (Pescatello, Arena, Riebe, & Thompson, 2014)
- Phonemic verbal fluency – the ability to list words beginning with the same letter (Oriá, Costa, Lima, Patrick, & Guerrant, 2009).
- Semantic verbal fluency – the ability to list words in a specific category (Oriá et al., 2009).

- Visuospatial – understanding the position of objects, such as finding an object or the route to a specific location (Kemps & Newson, 2006).

Assumptions

It is assumed that the participants will follow the directions for each test properly, including the use of the iPad.

Limitations

The sampling procedure for this study produces a limitation in that it is a convenience sample, which makes generalizing the findings to the general older adult population difficult. The individuals in this group live in an affluent retirement community.

Another limitation to the study may be vision issues. Many older adults have difficulty seeing small print, which could be an issue with the paper and pencil tests. Participants should be encouraged to either wear their normal glasses or bring reading glasses with them. Also, indoor lighting may cause a glare on the iPad screen, which could lead to further complication. Familiarization with the iPad will be completed before testing begins in order to counter act this limitation.

Delimitations

A convenience sample of 70 residents from Butterfield Trail Village Retirement Community was proposed for this study. The sample size was determined by a G*Power analysis (Faul, Erdfelder, Lang, & Buchner, 2007). The measures taken were the Trail Making Test Parts A and B, Mini-Mental State Examination, D-KEFS Color-Word Interference Test, clock drawing test, D-KEFS Verbal Fluency Test, and Geriatric ImPACT™ iPad app.

Chapter II

Review of Literature

Introduction

Executive function – the ability to create, begin, and evaluate and modify behavior (Farina et al., 2014) – is an important factor in considering the ability of older adults to maintain independence and complete activities of daily living. Tasks that require executive function include dressing, preparing meals, and traveling to and from home to the grocery store and doctor's appointments. The inability to complete these independently requires a caregiver or other modification of living conditions that subtracts from independence.

Decline in executive function may be used as diagnostic criteria for dementia (Zhang et al., 2007); however, Fisk and Warr (1996) showed that decline occurs as a function of age, even in the absence of chronic disease. This review discusses paper and pencil measures and their past usage. It also discusses the Geriatric ImPACT™ test and its potential importance as a screening tool for changes in cognition and executive function.

Cognitive Function

Successful cognition can promote quality of life into old age (Hertzog et al., 2008). Cognitive function includes the ability to learn, comprehend, remember, speak, and perform goal-oriented behavior (Helm-Estabrooks, 2002). Older adults may still be able to function and/or live independently with a decline in cognitive ability (Lezak, Howieson, & Loring, 2004). For example, older adults may become temporarily confused about what day of the week it is but eventually figure it out. They may forget an appointment that they remember later, or misplace something but eventually remember where it is (Alzheimer's Association, 2009). However, a slight decline in cognition may signal the beginning stages of a more serious condition, indicating the need to monitor cognitive changes (Kuslansky et al., 2004).

Executive Function

Executive function comprises the cognitive processes that oversee and develop behavior. This is especially important during new experiences (de Frias et al., 2006). The ability to perform deliberate, independent actions is due to executive function ability. Impaired executive function may hinder quality of life by not only disrupting an individual's own activities, but also the ability to form and maintain social relationships (Lezak et al., 2004).

Brennan, Welsh, and Fisher (1997) showed that executive function declines as age increases. The Tower of Hanoi task was employed to measure both task efficiency and error correction. The scores of the younger elderly participants (average age 65 years) were between those of the older elderly (average age 75 years) and younger adults (average age 19 years), implying a decline with aging (Brennan et al., 1997). Fisk and Warr (1996) attributed this decline to a general slowing down, not a specific impairment. They proposed that executive control is reduced because of a slowed perceptual speed, affecting how quickly information is processed in the working memory.

Executive function affects activities of daily living, and it is the key to maintaining independence in older adults (Johnson, Lui, & Yaffe, 2007). Because of the decline in executive function seen with aging, strategies to minimize this loss become crucial (Farina et al., 2014). Testing measures for executive function are needed to understand its responsibility in cognitive decline with aging (Fisk & Warr, 1996) and to assess and monitor changes that may occur.

Testing Measures

Trail-Making Test. The Trail-Making test is used as a measure of executive function (Coppin et al., 2006; Johnson et al., 2007; Zhang et al., 2007). There are two parts to the test: part A requires the participant to connect 25 numbers in order, while part B involves connecting 25 alternating letters and numbers in order (Spreen & Strauss, 1998). Part B can predict the ability to complete activities of daily living (Bell-McGinty, Podell, Franzen, Baird, & Williams, 2002), and low scores on part B imply that the participant is more likely to develop functional dependence (Johnson et al., 2007). Both parts of the Trail-Making Test were correlated with other neuropsychological measures, including IQ testing and the Wechsler Adult Intelligence Scale, and were found to be valid neuropsychological assessments (Corrigan & Hinkeldey, 1987). The Trail-Making test is scored by the number of seconds taken by the participant for each part (Spreen & Strauss, 1998).

Mini-Mental State Examination (MMSE). The Mini-Mental State Examination contains 11 questions and requires 5-10 minutes to complete. It focuses on the mental abilities that govern thinking, learning, and memory processes (Folstein, Folstein, & McHugh, 1975). MMSE is a test of cognitive function. Older adults who have normal MMSE scores may still show executive control impairment (Coppin et al., 2006). Therefore, MMSE does not detect decline in executive function well (Royall, Palmer, Chiodo, & Polk, 2004). In research conducted by Coppin et al. (2006), older adults who showed evidence of cognitive decline through MMSE scores may have maintained the ability to function independently. This coincides with Lezak et al. (2004) that decline in cognitive function may not impair executive function, but executive function decline often signals a decline in cognition. Cognition is a part of executive function in that executive function encompasses complex tasks and involves multiple cognitive processes working together. MMSE detects cognitive changes, but if executive function is the variable to be measured, other tests may be necessary. The maximum score for MMSE is 30 points. When the MMSE was developed, the researchers found that the mean score for participants with dementia was 9.7, while the mean score for the participants without cognitive or affective disorders was 27.6 (Folstein et al., 1975).

Color-Word Interference Test. The D-KEFS Color-Word Interference Test is based on the Stroop color test and consists of four conditions. The participant simply names the color of ink squares in condition 1. Condition 2 requires the participant to read a color name printed in black ink. Condition 3 requires the participant to identify the color of ink, ignoring the word itself. Condition 4 is a switching task in which the participant will switch between identifying the ink color that does not match the word and reading the word itself (Delis, Kaplan, & Kramer, 2001a). Color-word interference measures selective attention (Spreen & Strauss, 1998) and response inhibition (Koss, Ober, Delis, & Friedland, 1984). The test is scored by the number of seconds taken to complete each condition (Delis et al., 2001a).

Clock Drawing Test. Clock drawing is a convenient test that measures cognitive decline (Shulman, Shedletskya, & Silver, 1986). This test requires the participant to draw a clock face, complete with numbers, and the hour and minute hand pointing to a specified time (Spreen & Strauss, 1998). Scoring occurs on a 10-point scale, with 7-10 being normal, 6 is considered marginal, and 5 or less occur commonly in Alzheimer’s patients (Spreen & Strauss, 1998). The clock drawing test is an effective screen for cognitive impairment, and becomes a powerful tool when paired with the MMSE (Brodaty & Moore, 1997; Shulman et al., 1986).

Verbal Fluency Test. Letter fluency involves naming as many words as possible beginning with the letters F, A, and S. Words beginning with these letters are listed for one minute each, for a total of three minutes. Category fluency requires naming as many words in a given category – animals, in this case – as possible within one minute. Names of people, places, or numbers are considered errors (Delis et al., 2001a). In the Bronx Aging Study, individuals with diagnosed dementia were more likely to have poor word fluency ($p < .00001$) (Aronson et al., 1990). Masur, Sliwinski, Lipton, Blau, and Crystal (1994) suggested that category fluency is an indicator even before the discovery of clinical symptoms. In their study, absence of dementia was correctly predicted by the test battery for 88% of patients, and 85% of those classified at highest risk developed dementia (Masur et al., 1994). Spreen and Strauss (1998) posed that letter fluency may be an easier test for the participant than category fluency simply because of learned spelling ability. In a sample of 1300 individuals 16-95 years old without cognitive decline, letter and category fluency were moderately correlated ($r = .52$) (Tombaugh, Kozak, & Rees, 1999). Interrater reliability for letter fluency in older adults is .70 (Spreen & Strauss, 1998). Scoring is calculated with the total number of letters or words correct for each section (Delis et al., 2001a).

Geriatric ImPACT™ iPad app. ImPACT™ is a widely used computerized screening tool for mild traumatic brain injury (Maerlender et al., 2010). The geriatric edition is an early version iPad app. It consists of seven tests, including shopping list, design rotation, traffic light, memory touch, picture match, color match, and clock speed. Also included in the app is a demographic section, containing participant information such as marital status, years of education, and health history.

Chapter III

Methodology

Research Design

This study used the comparative research approach to compare validated cognitive measures to a new cognitive assessment. Convergent construct validity was used to determine whether the testing measures were correlated by considering the degree to which the Geriatric ImPACT™ iPad test scores paralleled those of the traditional paper and pencil tests (Maerlender et al., 2010).

Participants

This study proposed to measure 70 older adults (Faul et al., 2007) aged 65 and older who live independently at the Butterfield Trail Village Retirement Community. Recruitment took place with an interest sign-up sheet located at the front desk, accessible to all residents. Informational flyers were placed in popular locations around the main building, along with a flyer in each resident's mailbox. The research was also discussed at the monthly village-wide town meeting and in all exercise classes. Participation was strictly voluntary, and informed consent was obtained from each participant. After recruitment and exclusion, 47 participants completed all cognitive testing measures.

Exclusion criteria included residents with a diagnosed neurological condition, such as dementia or Alzheimer's disease or MMSE score below 24 (Coppin et al., 2006; Royall et al., 2004). Individuals with severe hearing or vision impairment that rendered them unable to complete all testing measures were also excluded.

Testing Measures

Trail Making Test. The Trail Making Test measures executive function by asking participants to connect numbered circles in order from smallest to largest. Part A requires that only numbered circles are ordered, while part B requires that both letters and numbers be put in order. Time to complete the test increases with age and is sensitive to the function of the brain (Corrigan & Hinkeldey, 1987). Scoring is measured in seconds required for each part of the test (Spreen & Strauss, 1998). Inter-rater reliability for part A is .94 and for part B is .90 (Fals-Stewart, 1992). The ratio of part B to part A may also be taken as a measure of executive function (Spreen & Strauss, 1998), and the difference between parts B and A may be taken as well (Sánchez-Cubillo et al., 2009).

Mini-Mental State Examination (MMSE). The MMSE is a validated and widely used measure of cognition. It consists of 11 questions measuring mental function, but not executive function. The first portion is verbal and measures orientation, such as date and time, immediate memory, and concentration. Calculation, following instructions, and comprehension are measured by the second half of the test (Folstein et al., 1975).

This test is reliable for 24-hour or 28-day retest by either single or multiple researchers. When given twice, 24 hours apart by the same tester, the correlation by a Pearson coefficient was .89. When given by two different examiners, the Pearson *r* was .83 (Folstein et al., 1975). Scores below 24 out of 30 were used as exclusion criteria for cognitive dysfunction (Coppin et al., 2006; Royall et al., 2004).

D-KEFS Color-Word Interference Test. The Stroop Color test is a test of executive functioning that requires participants to read a word and either match the color of ink or eliminate the unneeded data (Vidoni et al., 2012). For this project, the D-KEFS Color-Word Interference Test was used. The internal consistency value for the D-KEFS Color-Word Interference Test ranged from 0.77-0.81 for ages 60-89. Test-retest reliability is 0.50 for adults aged 50-89 (Delis et al., 2001b). Scores for this test included the raw time score for each of the four conditions and total error scores for each of the four conditions. These scoring methods are described in more detail in Table 1.

Clock Drawing Test. The clock drawing test is a cognitive measure that corresponds to the MMSE and aids in monitoring cognitive decline (Shulman, 2000). According to Brodaty and Moore (1997), clock drawing is an effective supplement to the MMSE in detecting early stages of dementia. The test involves the participant drawing a specific time on a circle drawn by the participant (Shulman, 2000). The reliability between administrators, both clinicians and non-clinicians, was .97 for normal elderly participants and those with Alzheimer's disease (Spreen & Strauss, 1998). There were two different times used for testing: 20 to 4 (Spreen & Strauss, 1998) and 10 after 11 (Shulman, 2000). These times were randomized for participants, with 53% using 20 to 4 and 47% using 10 after 11.

D-KEFS Verbal Fluency Test. Animal naming is a popular test of semantic verbal fluency in which participants are asked to name as many animals as they can think of in 60 seconds. Using this test in combination with the Controlled Oral Word Association (COWA) test can help determine which type of language competency is affected the most by cognitive decline. Animal naming is a simple and quick test that is useful in diagnosing dementia (Tombaugh et al., 1999).

The COWA test is related to the animal naming test, but as a measure of phonemic verbal fluency. In contrast to the animal naming test, it is more useful in measuring loss of cognition. COWA is commonly administered by asking participants to name all the words they can think of, other than proper nouns, beginning with the letters “F”, “A”, and “S” for one minute each (Tombaugh et al., 1999).

The D-KEFS Verbal Fluency Test was used in this research and consisted of three conditions: letter fluency, category fluency, and category switching. There were two forms used for this test, standard and alternate, that were randomized for participants. The standard form was given to 43% of participants, while 57% of the participants completed the alternate form. The standard form used the letters “F”, “A”, and “S” for letter fluency, animals and boys’ names for the two trials of category fluency, and fruits and furniture for the switching task. The alternate form used “B”, “H”, and “R” for letter fluency, clothing items and girls’ names for categories, and vegetables and musical instruments for the switching task (Delis et al., 2001a). The test-retest reliability coefficients are as follows for the 50-89 year-old age group: 0.88 for condition 1, 0.82 for condition 2, and 0.51 for condition 3 (Delis et al., 2001b).

Geriatric ImPACT™ iPad app. The Geriatric ImPACT™ test was validated through this study. It is both time- and cost-efficient and is user-friendly. It consists of seven tests, including shopping list with delayed free recall and recognition, design rotation, traffic light, memory touch, picture match, color match, and clock speed. This battery of tests should measure cognition, executive function, selective attention, response inhibition, visuospatial processing, and verbal fluency like the related paper-and-pencil tests.

The Geriatric ImPACT™ test does not compute a total composite score for the results of all seven tests. Instead, it scores multiple measures within each test. For a detailed description of Geriatric ImPACT™ scores see Table 2.

Table 1

Scoring Measures for Paper and Pencil Cognitive Tests

Paper test	Score	Description	Cognitive Domain
Trail Making	Part A	Time to complete part A.	Executive Function
	Part B	Time to complete part B.	
	Difference	Difference of part A time taken from part B time.	
	Ratio	Ratio of part B score to part A score.	
MMSE	Total	Total score out of possible 30.	Cognitive Function
D-KEFS Color-Word Interference	Condition 1 Raw	Time to identify all blocks of color presented.	Selective Attention
	Condition 2 Raw	Time to read all color names presented.	
	Condition 3 Raw	Time to identify printed color of all words given.	
	Condition 4 Raw	Time to identify either color name or color of ink of all words given.	
	Condition 1 Errors	Total number of both corrected and uncorrected errors for condition 1.	Response Inhibition
	Condition 2 Errors	Total number of both corrected and uncorrected errors for condition 2.	
	Condition 3 Errors	Total number of both corrected and uncorrected errors for condition 3.	
	Condition 4 Errors	Total number of both corrected and uncorrected errors for condition 4.	
Clock Drawing	Total	Score out of 10 possible points.	Visuospatial
D-KEFS Verbal Fluency	Letter Fluency Correct Responses	Number of correct responses for condition 1.	Verbal Fluency
	Category Fluency Correct Responses	Number of correct responses for condition 2.	
	Category Switching Correct Responses	Number of correct responses for condition 3.	
	First Interval Correct Responses	Number of correct responses for the first interval of all conditions.	
	Second Interval Correct Responses	Number of correct responses for the second interval of all conditions.	
	Third Interval Correct Responses	Number of correct responses for the third interval of all conditions.	
	Fourth Interval Correct Responses	Number of correct responses for the fourth interval of all conditions.	
	Repetition Errors	Total number of repeated words across all conditions.	Response Inhibition
	Set-Loss Errors	Total number of words named that did not fit the given category across all conditions.	

	Total Responses	Total number of responses across all conditions.	Verbal Fluency

Table 2

Scoring Measures for Geriatric ImPACT^{TM} test

	Score	Description	Cognitive Domain
Shopping List	Number/ Percent Correct	Number/ percent of correct answers immediately recalled and typed from the given list of five random words.	Cognitive Function
	Number/ Percent Correct - Free Recall	Number/ percent of correct answers recalled and typed from the given list of five random words after all other tests were completed.	Cognitive Function, Verbal Fluency
	Number/ Percent Correct - Recognition	Number/ percent of words correctly identified from given choices as belonging to the original list of five words.	Cognitive Function
Design Rotation	Number Correct	The number of designs correctly matched out of 10 given designs.	Visuospatial
	Average Time	Average time to match designs.	Selective Attention
Traffic Light	Number Correct	Number of times the corresponding button was correctly pressed out of 10 shown lights.	Response Inhibition
	Average Time	Average time taken to press the corresponding button.	Selective Attention
	Errors	Number of times an incorrect button was pressed for the given traffic light.	Response Inhibition
	Omissions	Number of times no button was pressed for the given traffic light.	
Memory Touch	Number Correct	Number of correct touches from memory of the shown pattern.	Executive Function
	Sequences Correct	Number of complete sequences correctly touched from memory.	
	Highest Sequence	Highest number of dots touched in the correct pattern.	
Picture Match	Average Time	Average time needed to match all pictures from the three sets given.	Selective Attention
	Average Taps	Average number of taps used to match all pictures from the three sets given.	Response Inhibition
Color Match	Number Correct	Number of ink colors and color names correctly matched.	Response Inhibition
	Average Time Correct	Average time spent on correct answers.	Selective Attention
	Errors	Number of times the screen was tapped when the ink colors and color names did not match.	Response Inhibition
Clock Speed	Number Correct	Number of clocks correctly identified as matching the given digital time.	Response Inhibition, Visuospatial
	Average Time	Average time needed to identify each matching time and clock.	Selective Attention

Procedures

There was one session of familiarization work with the iPad to be used for testing in order to reduce any potential anxiety. Practice sessions occurred before testing began to allow participants to experience and understand the touch screen, how to type information into the demographic fields, and how to position the iPad to avoid screen glare. Participants typed three words ("fish", "card", and "space") that were chosen by the administrator for their spelling and typing ease. They also used the pen function to learn to touch the screen with their fingertips. An easel case was used to position the iPad upright in order to avoid glare. Participants used only their dominant hand for touching the screen and both hands when typing.

Each participant completed both the Geriatric ImPACT™ test and the battery of paper and pencil tests. All tests were administered before 12:00pm for scheduling convenience for participants and researchers and to avoid afternoon fatigue. The tests were administered by a graduate student in Kinesiology. The same administrator gave all tests to all participants. The paper battery testing order was: Trail Making parts A and B, MMSE, D-KEFS Color-Word Interference Test, the clock drawing test, D-KEFS Verbal Fluency Test. Whether participants completed the paper tests or the Geriatric ImPACT™ test first was randomized. The paper tests were completed first by 47% of the participants, leaving 53% to complete iPad testing first. According to Folstein, Folstein, and McHugh (1975), the compliance of older adults to cognitive testing may decline after a 30-minute session. Other studies have allowed for all testing to be completed within one or two sessions, with breaks taken as needed by the participants (Fisk & Warr, 1996; Maerlender et al., 2010). In order to minimize both fatigue and potential practice effects, the testing measures used in this study were given in two separate sessions, with paper and pencil tests one day and the Geriatric ImPACT^{TM} iPad app given the following day, or vise versa depending upon randomization.

Data Analysis

Because the scoring measures between the traditional cognitive tests and the iPad app are different, a Pearson correlation was performed to determine the association of the scores achieved for each test. Statistical significance was set at $\alpha = .05$. Correlation was calculated between tests within similar cognitive domains. The scores for each test and their respective domains are outlined in Tables 1 and 2.

Multiple regression analysis was performed between scores from the seven Geriatric ImPACT^{TM} tests and each paper and pencil test. The Geriatric ImPACT^{TM} scores used were those that showed the most significant correlations and included: Color Speed Average Time, Design Rotation Number Correct, Memory Touch Highest Sequence, Traffic Light Number Correct, Shopping List Number Correct, Color Match Average Time Correct, and Picture Match Average Time. These scoring methods are described in detail in Table 2. Part correlations were also calculated to determine which Geriatric ImPACT^{TM} test score that had the greatest relation to each individual paper test.

Internal Validity Threats

Potential threats to internal validity for this study included, testing competence, contamination, attrition, and selection bias. Contamination could become a factor. Some participants were likely close friends, neighbors, or spouses. Participants were asked not to discuss the testing questions or answers until testing was completed. Attrition was a possibility, but could be avoided with effective scheduling. There were nine individuals who did not complete all cognitive testing measures. Many of the tests given are simple and time-efficient. Selection bias was present in this study because of the convenience of sampling residents at Butterfield Trail Village.

External Validity Threats

A practice effect was possible because the Geriatric ImPACT™ tests are similar to the paper and pencil tests. However, the tests were formatted differently, which helped to minimize this threat.

Chapter IV

Results

The demographic characteristics of participants who completed all cognitive testing measures are listed in Table 3. The mean age was 79 ± 5.68 years. There were more females than males in this study; the ratio of males to females of all residents at Butterfield Trail Village is approximately one to three. The majority of the participants held at least a Bachelor's degree and had a yearly income greater than $50,000.

Table 3

Demographic Characteristics of Participants

Demographic Characteristics	Total Sample (N=47)
Age, mean (SD)	79 (5.68)
Sex	
Male, N (%)	9 (19.10)
Female, N (%)	38 (80.90)
Marital Status	
Married, N (%)	24 (51.10)
Widowed, N (%)	16 (34.00)
Divorced, N (%)	7 (14.90)
Education	
High School, N (%)	3 (6.40)
Some College, N (%)	8 (17.00)
Bachelor's Degree, N (%)	15 (31.90)
Master's Degree, N (%)	16 (34.00)
Doctorate Degree, N (%)	5 (10.60)
Yearly Income	
Less than $50,000	3 (6.40)
$50,001-75,000	6 (12.80)
$75,001-100,000	6 (12.80)
Greater than $100,000	8 (17.00)
Missing Data	23 (48.90)

The resulting correlations from the paper and iPad cognitive test scores were grouped into five different cognitive domains: executive function, cognitive function, selective attention, response inhibition, and visuospatial. These domains and scores are shown in Tables 4-9.

Executive Function

Table 4 shows the tests that measured executive function. The Geriatric ImPACT™ Memory Touch test showed participants a sequence of two to eight lights on a 3x3 grid of circles. The participants were expected to touch the same dots in the same sequence as the one shown. Trail Making involved connecting numbers (Part A) in sequential order and switching between numbers and letters while connecting them in order (Part B). Both tests required visual scanning and processing, along with memory and higher-order cognitive processes to complete.

Table 4

Correlations between Executive Function Scores

		Memory Touch			Trail Making			
		Number Correct	Sequences Correct	Highest Sequence	Part A	Part B	Difference	Ratio
Memory Touch	Number Correct	--						
	Sequences Correct	.32*	--					
	Highest Sequence	.32*	.80**	--				
Trail Making	Part A	-.17	-.29	-.27	--			
	Part B	-.16	-.35*	-.41*	.55**	--		
	Difference	-.07	-.14	-.28	.12	.92**	--	
	Ratio	-.01	-.03	-.19	-.32*	.59**	.87**	--

Note. Memory Touch is a component of Geriatric ImPACT™.
** p <0.01 level (2-tailed). *p< 0.05 level (2-tailed). ImPACT™

Cognitive Function

The Shopping List test and the MMSE both measured cognitive function. Results are shown in Table 5. The Shopping List test consisted of five random words that appeared on the screen of the iPad. After all five words were shown, the participant was asked to either type them into the spaces provided in any order, or to repeat them to someone else to type in. There was also a delayed recall element; after all other tests were finished, the same spaces appeared for the participant to type in the words he or she remembered. The recognition task occurs at the end of the test, after an average time of 14.5 minutes, and ten different words appeared on the screen. The test asked whether it was one of the words listed, and the participant is expected to press either the “YES” or “NO” button.

Table 5

Correlations between Cognitive Function Scores

		Shopping List		
	MMSE	Number/ Percent Correct	Number/ Percent Correct - Free Recall	Number/ Percent Correct - Recognition
MMSE	--			
Number/ Percent Correct	.48**	--		
Number/ Percent Correct - Free Recall	.47**	.82**	--	
Number/ Percent Correct - Recognition	.28	.46**	.67**	--

Note. Shopping List is a component of Geriatric ImPACT™.
** p <0.01 level (2-tailed). *p< 0.05 level (2-tailed).

Selective Attention

Selective attention, as shown in Table 6, consisted of the Design Rotation, Color Match, and Picture Match Geriatric ImPACT™ tests and the Color-Word Interference paper test. The Design Rotation test showed participants a particular figure with four choices of figures underneath. All the figures were similar to the one given and may have only had a slightly different rotation, but participants were instructed to choose only the shape that exactly matched the given design. The average time to identify each matching figure was used for the selective attention domain.

Color Match showed participants squares containing the name of a color: red, blue, or green. The ink color in which it was printed may or may not have matched the color name. Participants were instructed to touch the screen when the printed color matched its name. Average time was used to determine relationships with other tests measuring selective attention.

The Picture Match test showed participants a screen with what looked like the backs of playing cards. When the cards were tapped, they flipped to reveal a picture. When all pictures were matched, a new screen appeared. This occurred three times, and the average time to complete all three was computed.

Condition four of the Color-Word Interference test, or the inhibition/switching task, required participants to identify the color of the printed ink for some words, but if it was enclosed in a box, the word was to be read. Time taken to complete the test was scored and used as a measure of selective attention (Delis et al., 2001a).

Table 6

Correlations between Selective Attention Time Scores

	Color-Word Interference							
	Condition 1 Raw	Condition 2 Raw	Condition 3 Raw	Condition 4 Raw	Design Rotation Average Time	Traffic Light Average Time	Picture Match Average Time	Color Match Average Time Correct
Condition 2 Raw	-.60**	--						
Condition 3 Raw	.67**	.55**	--					
Condition 4 Raw	.63**	.50**	.55**	--				
Design Rotation Average Time	.24	.05	.27	.32*	--			
Traffic Light Average Time	-.06	.09	-.05	-.10	-.01	--		
Picture Match Average Time	.46**	.34*	.48**	.23	.09	-.06	--	
Color Match Average Time Correct	.33*	.32*	.44**	.45**	.21	.01	.19	--
Clock Speed Average Time	.54**	.36*	.50**	.42**	.17	.08	.42**	.41**

Note. Picture Match, Color Match, and Clock Speed are Geriatric ImPACT™ components.
** *p* <0.01 level (2-tailed). **p*< 0.05 level (2-tailed).
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Response Inhibition

Table 7 shows correlations for tests that measured response inhibition. These included the Traffic Light, Picture Match, Color Match, and Clock Speed Geriatric ImPACT^{TM} tests and the Color-Word Interference and Verbal Fluency paper tests. The Traffic Light test gives the instructions that the participant is to press the "STOP" button when a red light is shown, the "GO" button when the green light is shown, and to do nothing when the yellow light is shown. Geriatric ImPACT^{TM} measured the number of traffic lights that are correctly pressed and the number of errors and omissions.

The Picture Match test scored the average number of taps needed to match pairs of pictures across all three trials. Participants needed to remember where the pictures were that they had previously seen and avoid tapping those multiple times to keep the number low. Clock Speed showed the participant a digital time and asked for it to be matched to the correct one of four analog clocks shown. The number correct required participants to ignore the clocks showing incorrect times and focus only on the one that matched the given time. Color Match scored both the number correct and the number of errors. Participants were required to only touch the screen when the printed ink color matched the color word shown. They had to ignore the other choices that did not match.

Table 7

Correlations between Response Inhibition Error Scores

		Color-Word Interference				Verbal Fluency		Traffic Light			Picture Match	Color Match	
		Condition 1 Errors	Condition 2 Errors	Condition 3 Errors	Condition 4 Errors	Set-Loss Errors	Repetition Errors	Number Correct	Errors	Omissions	Average Taps	Number Correct	Errors
Color-Word Interference	Condition 2 Errors	-.02	--										
	Condition 3 Errors	.22	-.05	--									
	Condition 4 Errors	.38**	-.08	.48**	--								
Verbal Fluency	Set-Loss Errors	.01	.14	.01	.19	--							
	Repetition Errors	.19	.03	-.03	-.03	.09	--						
Traffic Light	Number Correct	-.06	.07	-.34*	-.21	.12	-.03	--					
	Errors	.06	-.07	.34*	.21	-.12	.03	-1.00**	--				
	Omissions	.02	-.06	.32*	.16	-.20	.01	-.99**	.99**	--			
Picture Match	Average Taps	.21	-.11	.06	-.10	-.24	.16	-.08	.50	.90	--		
Color Match	Number Correct	-.18	-.26	-.15	-.15	.11	-.11	.20	-.20	-.19	-.36*	--	
	Errors	-.15	.23	-.08	-.14	-.10	.26	.05	-.05	-.40	-.06	-.33*	--
Clock Speed	Number Correct	-.15	-.17	-.02	-.19	.09	-.09	-.19	.19	.17	.18	-.10	.16

Note. Picture Match, Color Match, and Clock Speed are Geriatric ImPACT^{TM} components.
** p <0.01 level (2-tailed). *p< 0.05 level (2-tailed).

Visuospatial

Clock Speed number correct, Design Rotation number correct, and the score for the Clock Drawing paper test analyzed visuospatial processing. Clock Drawing required the participant to draw a clock, complete with face, all numbers, and the hour and minute hand for the given time (Spreen & Strauss, 1998). These correlations are shown in Table 8.

Table 8

Correlations between Visuospatial Scores

	Clock Drawing Total	Design Rotation Number Correct	Clock Speed Number Correct
Clock Drawing Total	--		
Design Rotation Number Correct	-.07	--	
Clock Speed Number Correct	-.15	.08	--

Note. Design Rotation and Clock Speed are Geriatric ImPACT™ components.
** *p* <0.01 level (2-tailed). **p*< 0.05 level (2-tailed).

Verbal Fluency

The relationships between verbal fluency scores are shown in Table 9. These included correct responses for each of the three conditions and four intervals of the Verbal Fluency paper test, along with the total number of responses. The Shopping List Geriatric ImPACT™ free recall number and percent correct were also included.

Table 9

Correlations between Verbal Fluency Scores

	Letter Fluency Correct Responses	Category Fluency Correct Responses	Category Switching Correct Responses	Total First Interval Correct Responses	Total Second Interval Correct Responses	Total Third Interval Correct Responses	Total Fourth Interval Correct Responses	Total Responses
Category Fluency Correct Responses	.09	--						
Category Switching Correct Responses	.33*	.05	--					
Total First Interval Correct Responses	.57**	.19	.48**	--				
Total Second Interval Correct Responses	.77**	.23	.49**	.56**	--			
Total Third Interval Correct Responses	.67**	.06	.38**	.51**	.66**	--		
Total Fourth Interval Correct Responses	.69**	-.04	.50**	.43**	.60**	.61**	--	
Total Responses	.83**	.15	.55**	.70**	.80**	.81**	.74**	--
Shopping List Number/Percent Correct - Free Recall	.22	-.09	.22	.39**	.34*	.40**	.11	.34*

Note. Shopping List is a component of Geriatric ImPACT™.
** p <0.01 level (2-tailed). *p< 0.05 level (2-tailed).

Multiple Regression Analysis

Multiple regression analysis is used to predict a dependent variable from multiple independent variables (Glass & Hopkins, 1996). In these analyses, shown in Table 10, the dependent variables were the following paper test scores: MMSE, Trail Making Test part B, Color-Word Interference Test – Condition 3 raw score, Verbal Fluency Test – Condition 1 raw score, and the score for the Clock Drawing Test. The independent variables were the following Geriatric ImPACT™ test scores: Clock Speed Average Time, Design Rotation Number Correct, Memory Touch Highest Sequence, Traffic Light Number Correct, Shopping List Number Correct, Color Match Average Time, and Picture Match Average Time.

Table 10

Multiple Regression Analyses

Paper Test	R Square
MMSE	.34
Trail Making Part B	.37
Color-Word Condition 3 Raw	.43
Verbal Fluency Condition 1 Raw	.37
Clock Drawing	.14

Note. Geriatric ImPACT™ test scores used were Shopping List Number Correct, Design Rotation Number Correct, Traffic Light Number Correct, Memory Touch Highest Sequence, Picture Match Average Time, Color Match Average Time Correct, and Clock Speed Average Time.

Part Correlation Analysis

Part correlation is the correlation of two variables when the variance accounted for by the predictor has been removed (Glass & Hopkins, 1996). The independent and dependent variables for these analyses were identical to those used for the multiple regression analyses. The results are shown in Table 11.

Table 11

Part Correlation Analyses

Predictors (paper test scores)	Outcomes (Geriatric ImPACT™)	Part Correlation
MMSE	Shopping List Number Correct	.29
Trail Making Part B	Picture Match Average Time	.27
Color-Word Condition 3 Raw	Picture Match Average Time	.31
Verbal Fluency Condition 1 Raw	Memory Touch Highest Sequence	.26
Clock Drawing	Picture Match Average Time	-.18

Note. Geriatric ImPACT™ test scores used were Shopping List Number Correct, Design Rotation Number Correct, Traffic Light Number Correct, Memory Touch Highest Sequence, Picture Match Average Time, Color Match Average Time Correct, and Clock Speed Average Time.

Chapter V

Discussion

The Geriatric ImPACT™ iPad test was shown to be a valid test that was more convenient than the traditional paper and pencil test battery. The ImPACT™ test required less material, took less time to administer, and required no training to administer. This study showed statistically significant correlations between the Geriatric ImPACT™ test and the comparative paper and pencil tests. This is encouraging, given the small sample size of only 47 participants.

Executive Function

As shown in Table 4, no significant correlations were found between Memory Touch Number Correct and paper tests. There was a modest inverse relationship between the time taken to complete part B of the Trail Making test and the highest Memory Touch sequence achieved. There was also a small inverse relationship between Trail Making part B completion time and the highest sequence achieved during Memory Touch. These are logical relationships because having higher visual scanning ability and processing time would imply that more lights could be found, remembered, and repeated correctly during Memory Touch and that Trail Making could be completed faster. Visual scanning is a skill required during part A of the Trail Making test, the portion of the test that is reflected by Memory Touch (Coppin et al., 2006; Corrigan & Hinkeldey, 1987).

Cognitive Function

Since the verbal memory portion of the MMSE contains both an immediate and delayed recall task, it is encouraging that it was moderately correlated with the Shopping List test. There was a moderate positive correlation between the MMSE and the number of words correct for both the immediate and delayed free recall portion of the Shopping List test. These results are shown in Table 5.

Small et al. (1997) showed that MMSE, letter fluency, and free recall were related in predicting risk of Alzheimer's disease. Dementia severity as measured by MMSE had a statistically significant relationship to both letter and category fluency in a meta-analysis conducted by Henry, Crawford, and Phillips (2004).

Selective Attention

As shown in Table 6, the average time to complete Picture Match, Color Match, and Clock Speed within Geriatric ImPACT™ were modestly correlated with the time it took to complete conditions 1-3 of the Color-Word Interference paper test. All of these tasks required the participant to pay attention to all possible answers and select only the ones needed, while ignoring unnecessary information. This is an essential part of the Color-Word Interference task, according to Koss et al. (1984).

Condition 4 of the Color-Word paper test also had modest positive correlations with Color Match and Clock Speed average time. It also showed a small positive relationship with Design Rotation. Condition 4 required participants to randomly switch between naming the color of ink the words were printed in and reading the actual word. Design Rotation required similar skills. While there was not a switching task involved in Design Rotation, both tasks required the participant to ignore the information that was not needed and focus on the one choice that was correct.

Response Inhibition Errors

The most significant error correlations were found between Condition 3 of the Color-Word Interference paper test and Verbal Fluency and Traffic Light of the Geriatric ImPACT™. There was a small inverse relationship between Condition 3 errors and Verbal Fluency Number Correct. There was also a small positive relationship between Condition 3 errors and the errors and omissions committed during the Traffic Light Geriatric ImPACT™ test. These results are shown in Table 7.

Visuospatial

As shown in Table 8, there were no significant correlations within the visuospatial domain. There was a small, non-significant inverse relationship between the total score for the Clock Drawing paper test and the number correct for both the Design Rotation and Clock Speed Geriatric ImPACT™ tests. This result is puzzling because these results should not be inverse; however, the relationship was very small.

Verbal Fluency

Table 9 shows that the Shopping List Geriatric ImPACT™ test was somewhat correlated with all three intervals of the Verbal Fluency paper test. These were the four 15-second intervals that made up the 60-second time span in which the participant named as many words as possible that fit the condition (Delis et al., 2001a). It is also logical that the number of total responses for Verbal Fluency was positively correlated with the Shopping List task. The more words that the participant listed seemed to relate to the number that they would remember for the Shopping List. The two different forms of the Verbal Fluency test may have been a limiting factor. While the two forms are considered equal, there may be differences in the number of words named simply due to vocabulary volume for each letter or category (Spreen & Strauss, 1998).

Multiple Regression and Part Correlation Analyses

Multiple regression and part correlation analyses are shown in Tables 10 and 11, respectively. Multiple regression analysis allowed the comparison of several scores from the Geriatric ImPACT™ to each of the paper tests to see an overall relationship. The Geriatric ImPACT™ scores allow for the prediction of the variance of each paper test using the multiple regression analysis. The part correlation showed which Geriatric ImPACT™ score was most related to each paper test. The MMSE paper test showed a .290 part correlation with the number correct achieved on the Shopping List portion of the Geriatric ImPACT™ test. The Shopping List test required the participant to remember a random set of words given at the beginning of the test; the MMSE includes a portion in which a list of 3 words must be remembered and repeated. The average time to complete the Picture Match portion of the Geriatric ImPACT™ had a .265 part correlation with part B of the Trail Making paper test. These were both time scores, and the tests required similar skills. Picture Match Average Time also showed a .312 part correlation with condition 3 of the Color-Word Interference paper test. These part correlations imply that the portion of the Geriatric ImPACT™ that showed the highest part correlation was most closely related to the paper test used as the dependent variable.

General Discussion

The Geriatric ImPACT™ iPad test was validated because it showed a correlation with similar, validated paper and pencil cognitive tests. It was also more convenient than the paper tests because it required only the iPad whereas the paper tests required five individual paper tests for the battery. The average time for the Geriatric ImPACT™ iPad test was 14.5 minutes, while the paper tests consistently lasted between 30-45 minutes. Future research should include a larger sample size. There should also be efforts made to compare the testing measures in populations with diagnosed cognitive impairment. The classification criteria for cognitive disorders has been measured with paper and pencil tests and even with a computerized battery (Ritchie, Artero, & Touchon, 2001), but not yet for the Geriatric ImPACT™ iPad test. The sensitivity and specificity of the online version of the original ImPACT™ test has been measured for concussions and should be measured for the geriatric version if it is to be used as a diagnostic tool (Schatz & Sandel, 2013).

This study had several potential limitations. The small sample size used in this study was composed of healthy, high-functioning adults. The technology itself could also have been a factor. Several participants owned an iPad and were comfortable using it during testing. However, those who did not own an iPad or a similar device (other tablet or iPhone), were a bit intimidated by it initially. There were 19 participants who did not own an iPad, 10 who did own an iPad, two who owned another brand of tablet, and two who owned an iPhone. For the 19 who were unfamiliar with an iPad, their anxiety disappeared after the familiarization session. Some of them still asked for the administrator to complete the typing portions, usually due to lack of self-efficacy. Vision issues may have also been a limitation. The iPad was positioned to avoid screen glare, but the office in which testing took place has several windows. During the morning hours, the sunlight created a problem for some participants. Seating was rearranged to combat this problem as best as possible. Some participants also had trouble looking at the screen due to bifocal lenses.

Any testing measure used should have the ability to evolve and adapt with technology, participant needs, and administrator training. For example, the Clock Drawing paper test may become obsolete within the next 10-20 years due to the use of digital clocks (Shulman, 2000). While this is not an immediate concern, it will need to be accounted for within the Geriatric ImPACT™ test as well.

Conclusion

The Geriatric ImPACT™ test has the potential to become a cognitive test battery that is widely used and is more convenient and cost-effective than current traditional measures. Further testing is needed to substantiate this.

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Appendix

UNIVERSITY OF ARKANSAS

Office of Research Compliance
Institutional Review Board

February 12, 2015

MEMORANDUM

TO:	Michelle Gray Kristen Holmes Heather O'Dell
FROM:	Ro Windwalker IRB Coordinator
RE:	New Protocol Approval
IRB Protocol #:	15-01-438
Protocol Title:	*Examining the Relationship between Neurocognitive Performance and Functional Fitness Levels among Older Adults*
Review Type:	☐ EXEMPT ☒ EXPEDITED ☐ FULL IRB
Approved Project Period:	Start Date: 02/06/2015 Expiration Date: 02/05/2016

Your protocol has been approved by the IRB. Protocols are approved for a maximum period of one year. If you wish to continue the project past the approved project period (see above), you must submit a request, using the form *Continuing Review for IRB Approved Projects*, prior to the expiration date. This form is available from the IRB Coordinator or on the Research Compliance website (https://vpred.uark.edu/units/rscp/index.php). As a courtesy, you will be sent a reminder two months in advance of that date. However, failure to receive a reminder does not negate your obligation to make the request in sufficient time for review and approval. Federal regulations prohibit retroactive approval of continuation. Failure to receive approval to continue the project prior to the expiration date will result in Termination of the protocol approval. The IRB Coordinator can give you guidance on submission times.

This protocol has been approved for 130 participants. If you wish to make *any* modifications in the approved protocol, including enrolling more than this number, you must seek approval *prior to* implementing those changes. All modifications should be requested in writing (email is acceptable) and must provide sufficient detail to assess the impact of the change.

If you have questions or need any assistance from the IRB, please contact me at 109 MLKG Building, 5-2208, or irb@uark.edu.

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