An Examination of Executive Function, Mild Cognitive Impairment and Fall Risk in Community Dwelling Older Adults

Jennifer A. Blackwood
Western Michigan University, jenb_pt@hotmail.com

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AN EXAMINATION OF EXECUTIVE FUNCTION, MILD COGNITIVE IMPAIRMENT AND FALL RISK IN COMMUNITY DWELLING OLDER ADULTS

by

Jennifer Blackwood

A dissertation submitted to the Graduate College in partial fulfillment of the requirements for the degree of Doctor of Philosophy Interdisciplinary Health Sciences Western Michigan University
June 2013

Doctoral Committee:

Kieran Fogarty, Ph.D., Chair
Carla Chase, Ed.D.
Tiffany Shubert, Ph.D.
AN EXAMINATION OF EXECUTIVE FUNCTION, MILD COGNITIVE IMPAIRMENT AND FALL RISK IN COMMUNITY DWELLING OLDER ADULTS

Jennifer Blackwood, Ph.D.

Western Michigan University, 2013

The aim of this three-paper dissertation was to examine the relationship between fall risk, executive function (EF) and mild cognitive impairment (MCI) in community dwelling older adults. Papers one and two describe how mild changes in cognition influence performance on four measures of fall risk, the Five Times Sit to Stand Test (FTSTS), usual gait speed, the Timed Up and Go (TUG) test, and the Activities Specific Balance Confidence Scale (ABC) in a group of community dwelling older adults. The third paper describes if participation in a progressively challenging domain specific computerized cognitive training intervention influenced performance on measures of EF, MCI, and fall risk.

The purpose of the first paper was to investigate the relationship between EF as measured with the Trail Making Test Part B and the four measures of fall risk. The results of this cross-sectional study suggested that EF was significantly associated with usual gait speed in community dwelling older adults which remained after adjusting for age and education. EF was associated with the TUG and usual gait speed in those with MCI.

The objective of the second paper was to describe how performance differed on the four measures of fall risk in those with MCI. No significant differences in mean scores were found on measures of fall risk in those with MCI; however the cognitive resources required during fall risk assessments should be considered in the selection of
measures. In those with MCI, balance confidence was not associated with usual gait speed or with performance on the FTSTS.

The third paper examined how a progressively challenging six week computerized cognitive training program focused on the cognitive domains of attention, set shifting, and visual spatial ability impacted fall risk measure performance. Results indicated that there was no significant difference on measures of fall risk, EF, or MCI following the cognitive training program.
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ACKNOWLEDGMENTS

Completion of this dissertation was not solely the result of the time and effort that I put into it, because it would not have been possible without the support of many who gave me strength throughout the process. I would like to thank, first and foremost, my rock of faith and partner in life, my husband Mike, who patiently supported me during my education including multiple weekends and evenings of writing which required me to be away and resulted in him having to take care of the kids and our home when I was not able. To my children: Colleen, Ryan, and Connor, I thank you for your innocent view on life, for the many loving notes and pictures you created which forced me to focus on my goals, and for the reminders to take time out to play during the process. Thanks to my in-laws, Al and Elaine Blackwood, who lifted the load when life got too tough. To my brothers and sisters and their families: thank-you for your support for not only for me, but also for Mike and the kids during these past few years. Our candid and sometimes philosophical talks on the back deck were therapeutic more than you can imagine.

This dissertation is dedicated in honor of my mom and dad, Mary and Dennis Gleason, who taught me to work hard towards my goals in life. I miss them greatly, but know that they have been guiding me along in the process. It is also dedicated on behalf of my grandmother, Mary Joyce who, through our experiences together, taught me to value and respect older adults. Go raibh Dia leat, Gram.
Acknowledgments—Continued

To my committee chair, Dr. Kieran Fogarty, I truly appreciate working with you these past few years as our frank conversations have helped guide my educational focus, my research, and life in the academy. Thank you to my committee members, Dr. Carla Chase and Dr. Tiffany Shubert for providing feedback when asked, being a sounding board for my ideas and guiding me along to a career of research that will serve the patients that I treat.

This work could not have been completed without the altruistic volunteerism of the older adults in my community who participated as subjects in this study, and I thank them for their participation. Finally, I thank my friends and colleagues; your encouraging support throughout the process has been invaluable and has sustained me in order to reach this goal.

Jennifer Blackwood
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CHAPTER I

INTRODUCTION

Related Purposes of the Three Papers

In the United States, one in three adults age 65 and older falls each year. This results in medical costs of more than $20 billion per year and implications in maintaining function, independence, and longevity.\textsuperscript{1,2} Falling can be attributed to physiological impairments such as muscular weakness, impaired balance, and slowed reaction time,\textsuperscript{3} but can also be associated with cognitive impairments.\textsuperscript{4,5} Older adults with deficits in cognition are twice as likely to fall in comparison to those without cognitive deficits.\textsuperscript{6} Changes in cognition have also been found to be an indicator of greater dependence in performing activities of daily living,\textsuperscript{8} increased risk of hip fracture\textsuperscript{9} and death in older adults.\textsuperscript{10,11}

Cognition is made of multiple domains which include, among others, the domains of attention, memory, visual spatial ability, and executive function.\textsuperscript{12} During functional tasks, like walking, cognitive domains work together to process information including what is required to maintain balance and prevent falling in the older adult.\textsuperscript{12} Deficits in cognition that impact fall risk are not isolated to one specific domain, but are influenced by more than one domain of cognition.\textsuperscript{12} Identifying and addressing the relationship between declines in specific areas of cognition, such as executive function or in those with mild cognitive impairment, and changes in levels of physical function can assist
health care professionals in addressing older adults’ health and safety needs prior to injury or decline.

Multiple screening tools are used in clinical settings to examine risk of falling in the older adult. Likewise, there are many different measures of cognition that exist which range from domain specific assessments to global measures of cognitive decline. As a result, researchers have called for the need to investigate the link between commonly used measures of physical function and the presence of cognitive impairments in older adults in order to best understand and manage the association between decreased cognition and fall risk. A gap in the literature is present in that the relationship between commonly used measures of fall risk and a simple measure of executive function and one assessing mild cognitive impairment has not been reported. Identifying how changes in cognition are associated with changes in physical function is an important step in investigating the relationship between measures of physical function, cognition, and the effectiveness of specific cognitive interventions in older adults.

Older adults with impairments in executive function (EF) have difficulty with integrating, organizing, and maintaining multiple different types of information as presented within their environment during tasks such as walking. Consequently, changes in gait and an increased incidence in falling have been found in those with deficits in EF. Despite this finding, screening for deficits in EF may not be a part of common practice. The first paper of this dissertation investigated the relationship between EF as measured with the Trail Making Test Part B and fall risk using four commonly used clinically relevant fall risk screening tools (the Five Times Sit to Stand test, the Timed Up and Go test, the Activities Specific Balance Confidence scale, and
usual gait speed) in a group of community dwelling older adults. Investigating if a relationship exists between these measures of fall risk and a valid and reliable measure of EF may have an impact on developing early intervention strategies for fall prevention in those with executive dysfunction.

The presence of mild cognitive impairment (MCI) is a growing concern for older adults and their caregivers in the United States. MCI is characterized by having a cognitive decline greater than what is expected for an individual’s age and education level which does not interfere with activities of daily living. Older adults with MCI have impairments in balance and gait, and are at an increased risk of falls, yet a limited number of studies have been completed that examine fall risk in those with MCI. Understanding how fall risk screening tool scores vary with the presence of MCI can allow healthcare professionals to distinguish between normal and abnormal findings prior to the onset of further cognitive decline. Therefore, paper two investigated how the presence of MCI impacts fall risk screening tool performance in a group of community dwelling older adults.

Prevention of the progression of cognitive decline has included interventions that have demonstrated the ability to improve or maintain an older adult’s cognitive state. Cognitive training, a type of nonpharmacologic intervention, has resulted in improvements in cognition with specificity of training directed to the cognitive domains addressed. Some domain specific cognitive training interventions have translated into improvements in function, however, it is unknown if fall risk can be influenced through the completion of a computerized cognitive training program. Paper three adds an additional dimension to the findings of papers one and two. In Paper three, a
progressively challenging cognitive training program targeted to address cognitive domains identified as necessary for safe functional mobility was used to determine if it impacted outcomes on measures of fall risk, EF, and MCI. The findings of these studies can guide healthcare professionals in selecting fall risk measures which are associated with cognitive deficits found in EF and MCI and may provide insight as to the impact a cognitive training intervention that may have on fall risk.

Background information for each of the three papers is provided in Chapter I of this dissertation. Chapters II-IV includes three individual papers with each containing methods, results and discussion sections for three studies. The findings of the three papers are presented in an integrated discussion in the final chapter of the dissertation.

The following section provides background information for the three papers including a review of the literature to help frame the purpose of the three studies within this dissertation. The benefit of completing the three-paper method is that the task of submitting the findings of the study for publication is eased as the dissertation contains three stand-alone papers. A disadvantage for the reader of the three-paper method is that there is redundancy in reading the same sections in each paper. The reader is encouraged to keep in mind that some information may be repeated when read as a whole document.

**Background**

Americans over the age of 65 comprise the largest growing segment of the population. It is estimated that there will be 72 million adults over the age of 65 in 2030, twice the number of older adults in 2009. In a recently published report, the US Census bureau has indicated that the number of US households headed by adults age 65 and older has grown to 39 percent of all households, reflecting an increasing number of community
dwelling older adults. One in three community dwelling older adults falls each year which translates into significant direct costs to the healthcare system through the utilization of emergency services and acute, rehabilitation, and long-term care needs. \(^{1,2}\) The reasons why older adults fall is multifactorial. Fall risk has been linked to physiological deficits such as impaired balance, slowed reaction time, muscular weakness and low body mass, \(^{1}\) and has also been associated with the presence of cognitive impairments. \(^{4}\) Older adults with deficits in cognition are at a higher risk of falling with an annual incidence of 60-80%; twice that of cognitively intact older adults. \(^{4}\) As the incidence of falling increases in older adults with cognitive deficits, so does their risk for hip fracture \(^{9}\) and likelihood for institutionalization after falling. \(^{5}\)

Age-associated cognitive decline has been identified as a normal age related loss in cognitive function characterized by occasional forgetfulness which does not have a progressive quality. \(^{27}\) Mild cognitive impairment (MCI) is considered the transitional phase between normal aging and dementia. \(^{27}\) It is defined as having a global cognitive decline which impacts multiple domains of cognition greater than what is expected for an individual’s age and education level which does not notably interfere with activities of daily living. \(^{17}\) Clear diagnostic criteria for MCI has recently been established. \(^{28}\) Approximately 22% of older adults \(\geq 71\) years have diagnosed MCI with an increasing prevalence with age affecting 39% of individuals \(\geq 90\) years. \(^{29}\) Several clinical subtypes of MCI have been reported including amnestic-MCI single domain, amnestic-MCI multiple domains, nonamnestic-MCI single domain, and nonamnestic MCI multiple domains. \(^{30}\) For those with MCI, the progression to Alzheimer’s disease (AD) or other dementias continues in roughly 20-30% of individuals within three years \(^{31}\) with a greater
transition rate in those with amnestic-MCI single domain or amnestic-MCI multiple
domains subtypes. Impairments in fine and complex motor skills and coordination\textsuperscript{30} have
been found in those with MCI as well as a greater prevalence of gait variability than in
those with intact cognition when performing attention demanding tasks.\textsuperscript{18,32} The presence
of MCI has been found to be an independent risk factor for injurious or multiple falls in
community-dwelling older adults.\textsuperscript{33} The combination of deficits in cognitive function and
impairments in mobility underlie the risk for further decline in adults with MCI.

Another potential relationship between cognition and falls has been found in those
with declines in executive function.\textsuperscript{34} Executive function (EF), a higher order of
cognition, is defined as the ability to control, integrate, organize, and maintain
information when continuously presented.\textsuperscript{15} Intact EF is essential for completion of
common and complex tasks especially those requiring the coordination of multiple
subcomponents of cognition (e.g. attention, set shifting) for task completion.\textsuperscript{35} Declines
in EF with aging have been associated with changes in the prefrontal cortex of the
brain.\textsuperscript{15} Older adults with impairments in EF walk slower,\textsuperscript{36} fall more often (Odds ratio:
1.44 (1.2, 1.73),\textsuperscript{37} and perform worse on mobility tasks.\textsuperscript{18,38-40} Deficits in EF have also
been associated with poor balance, abnormal gait, and impaired performance on
instrumental activities of daily living.\textsuperscript{41} Prior researchers have demonstrated an
association between decreases in EF and fall risk and have hypothesized that this was due
to altered judgment during motor planning.\textsuperscript{34} As a result, a growing body of evidence
supports associations of cognitive processing speed and better balance, with implications
that reduced processing speed underlies much of the cognitive decline found with
impairments in EF\textsuperscript{38,39} and, by association, balance.
Recently a new area of study has emerged that has focused on the cognitive processes (i.e. cognitive domains) required for completion of functional activities such as walking and general activities of daily living. Studies examining dual task ambulation which requires a subject to walk and perform a secondary attention demanding task have reported deficits in dual task performance in those with decreased EF.\textsuperscript{42} Further, deficits found in the cognitive domains of set shifting and processing speed were associated with decreased walking speeds, changes in gait stability, and an increased fall risk in older adults.\textsuperscript{42} It has been hypothesized that changes in gait and fall risk are due to the influence of a relationship between EF and the stability and velocity of gait in older adults as declines in gait were evident when other cognitive demands of attention were utilized during walking.\textsuperscript{43-45}

Cognitive domains known to strongly influence fall risk include visual spatial ability, set shifting, and attention.\textsuperscript{12} Visual spatial ability is the ability to discriminate visual information in relation to the spatial location of an item\textsuperscript{15} This is necessary for safe functional mobility\textsuperscript{12} and has been found to decline rapidly in the preclinical period of Alzheimer’s disease.\textsuperscript{46} Set shifting refers to the ability to update and shift cognitive strategies in response to new changes in the environment which are skills necessary for processing information during gait.\textsuperscript{15} Impairments in set shifting has been associated with balance disturbances.\textsuperscript{15} EF includes controlled attention, which is one’s ability to attend to specific criteria in the environment for a period of time.\textsuperscript{15} Each of these three areas of cognition is necessary to consider in EF when processing stimuli to maintain balance and prevent falls.\textsuperscript{12}
Understanding the relationship between cognition and fall risk could help better manage risk of falling and cognitive decline in a growing number of older adults. The key to understanding this relationship begins with accurate measurement tools of both concepts. However, this is complex due to the variety of measures of cognition and of fall risk. Given the variety of presentations of both problems, the type of tools used to detect cognitive impairment and falls should be matched to the patient’s level of function and impairment.37

Assessments of Cognitive Performance

Assessments of cognitive performance are either domain specific where they address one area (i.e. memory) or they assess multiple domains of cognition as a global measure. Poor performance on global measures of cognition have been associated with serious fall related injuries37 and with increased nursing home and hospital utilization.47 In a meta-analysis performed by Muir et al., a strong relationship between a cognitive domain specific measures of EF, the Trail Making Test Part B and falling was reported in community dwelling older adults.37 In addition, the analysis revealed that impairments in EF were reported to influence the incidence of falling despite having achieved normal scores on various global measures of cognition, primarily the Mini Mental State Exam.37 The reliability, validity, and constructs addressed in cognitive measures differ which directly influences their use in clinical settings. Therefore, it is necessary to consider how cognitive measures (global or domain specific) have been associated with measures of fall risk prior to determining which tools would be best included in a fall risk assessment plan.
The Mini Mental State Examination (MMSE) is a screen for Alzheimer’s disease that is frequently used to detect dementia in the general population. Lower scores on the MMSE have been associated with an increased risk of falls and have been identified as a predictor of fall risk on the Get Up and Go test in a large group of community dwelling older adults. Studies have reported decreased sensitivity of the MMSE identifying mild deficits in cognition such as impairments in EF or the detection of MCI in older adults. To best assess mild changes in cognition that may influence fall risk other measures of cognition should be considered.

As a measure of EF, the Trail Making Test (TMT) has high validity and reliability to detect deficits in EF when both parts A and B are used and high intrarater reliability for use with experienced and non-experienced clinicians. This paper and pencil test has been described as being easy to conduct and efficient. Part A requires subjects to create a trail by connecting randomly positioned numbered circles in sequential order and is considered a measure of visual search and motor speed with a maximal completion time of 90 seconds. Part B requires subjects to create a trail by connecting randomly positioned circles with numbers (1-12) or letters (A-M) in ascending order alternating from number to letter and is considered a measure of attention, visual scanning, motor speed and coordination, set shifting, and working memory and has a maximal completion time of 300 seconds. Of the two parts of the TMT, the TMT-B is considered to be a more accurate assessment of EF than Part A.

Age and education level have been found to have a significant influence on TMT-B scores. A greater decline in performance on the TMT-B is indicative of a higher prevalence of executive dysfunction with advanced age, while longer completion
times have been reported for those with fewer years of formalized education. Norms for the TMT-B have been established based on age and education level.

Declines in performance on both parts A and B of the TMT have been found to be a strong predictor of mobility impairment, accelerated decline in lower extremity function, and death in community dwelling older adults and have been associated with impaired performance on two different measures of balance, the Berg Balance Scale and the Timed Up and Go test. However, it is unknown if those same associations exist when using just the TMT-B. Due to the fact that deficits in EF have been reported to impact fall risk despite having normal outcomes on global measures of cognition, a need exists to examine how a valid, reliable, and easy to use tool of EF, such as the TMT-B, is associated with measures of fall risk. This leads to the research question that was addressed in the first paper of this dissertation: What is the relationship between executive function and fall risk in a group of community dwelling older adults?

Mild changes in cognition may go beyond impairments in EF, but may not be enough to meet the criteria for dementia. To best screen for the mild changes in cognition present in MCI, the Montreal Cognitive Assessment tool (MoCA) can be used as a global measure of those cognitive changes. This paper and pencil test takes 10 minutes to administer and includes items to assess the cognitive domains of visual spatial ability (clock drawing and cube copying), memory (5-word list learning and delayed recall), executive function (abbreviated trails-B, phonemic fluency, and similarities tasks), attention, concentration and working memory (target detection using finger tapping, serial subtraction, and digits forward/backward) language (picture naming and sentence repetition) and orientation (time/place). The maximum possible score is 30 points.
Scoring is sensitive to the subject’s education level as an extra point is added to the total score for those with an education of less than 12 years.\textsuperscript{58} Using a cut-off score of 26, the MoCA has a sensitivity of 90% and a specificity of 78% for detecting MCI.\textsuperscript{58}

Poorer performance on the MoCA has been associated with impaired performance on measures of balance and fall risk. Lui-Ambrose et al. identified a significant relationship between decreased MoCA scores with a measure of balance on the Physiological Profile Assessment in community dwelling older adults (N=140).\textsuperscript{38} In a population based study performed in Ireland (N=4998), poorer performance on the MoCA was associated with longer completion times on the Timed Up and Go test.\textsuperscript{60} The number of published studies describing performance on measures of physical function and fall risk in older adults with MCI is limited.\textsuperscript{38} As a tool used to detect the subtle global changes in cognition in MCI, the MoCA can serve as an effective tool to detect changes in fall risk in those with MCI and is the focus of the second paper in this dissertation.

**Fall Risk Screening Tools**

Each of the following measures of fall risk has been associated with changes in cognition in either specific domains or as a global cognitive decline. However, these tools have not been associated with changes in EF (TMT-B) nor has their performance been assessed with the presence of MCI (MoCA) in community dwelling older Americans. The four fall risk screening tools include: usual gait speed, the Five Times Sit to Stand test, the Timed Up and Go test, and the Activities Specific Balance Confidence Scale.
Usual Gait Speed

Once considered an automatic function, walking is now viewed as a more complex task that requires components of cognition, motor control, muscular conditioning, sensory and perceptual functioning, as well as endurance. Slower gait speeds are a risk factor for cognitive impairment, falls, disability, institutionalization, and/or mortality. Gait speed, measured as distance traveled over time, is a highly sensitive predictor of physical decline and cognitive decline when provided a cognitive challenge. Age adjusted norms for gait speed have been established. Gait speed measurements are easily completed in a variety of settings and are highly reliable regardless of the population or the methods of measurement.

In a prospective study of healthy older adults with a mean age of 75.6 years, Atkinson et al. found that a greater decline in gait speed over 3 years was associated with a decline in global cognition by one standard deviation on the MMSE and a decline in EF as measured with the clock drawing test after adjusting for baseline gait speed. A significant association between gait deterioration and working memory has been found in those with MCI. Different measures assessing executive function, for example both parts A and B of the TMT have been associated with changes in the qualitative components of gait including impaired stepping performance, changes in stride length, and balance instability during walking. Understanding how usual gait speed is associated with measures of EF and MCI can determine how these cognitive deficits influence gait speed which may guide clinicians as to their choice of assessments and/or treatments.
Timed Up and Go

Other measures of fall risk have been associated with impaired global cognition. The Timed Up and Go test (TUG) is a valid, reliable, and efficient measure of fall risk in community dwelling older adults that includes both physical and cognitive components.\(^75,76\) During the test, subjects are asked to rise from a chair, walk 3 meters at a normal pace to a line clearly marked on the floor, turn around, walk back to the chair, and then sit down again.\(^75,77\) The test is timed with a stopwatch from the moment the subject is told to ‘go’ to the moment he sits back down in the chair.\(^75\) A score of 13.5 seconds has been established in the literature as the cutoff score indicating fall risk in cognitively intact older adults.\(^70\)

Longer TUG completion times have been associated with poorer performance on measures of global cognition,\(^60,75\) verbal fluency,\(^75\) working memory,\(^60,75\) processing speed,\(^60\) as well as with impairments in EF as measured with both parts A and B of the Trail Making Test\(^78\) and with the Colors Trails Test.\(^60\) The association between deficits in the various domains of cognition and performance on the TUG indicate that completing the TUG requires aspects of EF and that an assessment of cognition should be a part of using this fall risk screening tool. However the relationship between the TUG and EF as measured with the TMT-B or within the presence of MCI as detected with the MoCA has not been described in community dwelling older Americans.

Five Times Sit to Stand

Transitional movements, like going from sitting to standing, challenge an older adult’s ability to complete the movement without loss of balance. A commonly used and efficient screening tool to assess balance during this task, the Five Times Sit to Stand test
(FTSTS) is a valid and reliable measure of fall risk and lower extremity strength in older adults. The FTSTS also has been reported as an indicator of frailty, a predictor of fall risk, and is associated with increased disability, morbidity and falls. This test consists of measuring the amount of time it takes for a subject to go from sitting in a supportive chair to full standing five successive times without the subject using his arms to aid in the process. Time is measured with a stopwatch from the moment the subject is told to ‘go’ to the moment he sits down in the chair following the fifth repetition. Norms for scores on the FTSTS to identify fall risk have been documented in the literature, with a score of greater than 13.6 seconds being associated with increased disability and morbidity in cognitively intact older adults.

In a cross sectional study of over seven thousand community dwelling older women, longer completion times on the FTSTS were associated with lower levels of global cognitive function as screened with the Short Performance Mental Status Questionnaire. Other measures of global cognition have been associated with impaired performance on the FTSTS. In the Cardiovascular Health Study lower scores on the MMSE were associated with longer completion times on the FTSTS. Likewise, in the Health, Aging, and Body Composition Study, a significant association was found between the Modified Mini Mental State score and the FTSTS after adjusting for age, gender, education, race, weight, physical activity, and comorbid conditions. Although global measures of cognition have been associated with poorer performance on the FTSTS, it is not known if the same relationship exists with a domain specific measure of EF nor if performance is altered in those with MCI.
Activities Specific Balance Confidence Scale

Lastly, decreased balance confidence has been found to be independently associated with poor dual task gait performance. Fear of falling has been found to lead to activity restrictions and has been reported to be present in 35-55% of community dwelling older adults. Fear of falling has been associated with slower gait speeds. Assessment of balance confidence can be performed using the Activities Specific Balance Confidence Scale (ABC). The ABC assesses a person’s fear of falling and lower scores are associated with higher risk of falls. It has been shown to have good reliability to assess fall risk. In the ABC, subjects rate their confidence in maintaining their balance when performing sixteen different functional items. Confidence reported ranges from zero (not confident at all in maintaining balance during a task) to one hundred percent (completely confident in maintaining balance during a task). The reported confidence rating of the sixteen items are summed and then divided by the total number of items to generate a percentage of confidence for each subject. Norms have been established for the ABC as well as cutoff scores for functional decline.

Confidence in balance and balance performance has been shown to have a significant and strong relationship with each other. In addition, cognition has been identified as a strong predictor of balance performance. Decreased balance confidence has been associated with impaired dual task gait performance in community dwelling older women. Additionally, within that same study, impairments in set shifting which is a component of EF were found to be significantly associated with impaired dual task gait performance on the Walking While Talking test. It is not known if balance confidence
is associated with EF as measured with the TMT-B or if balance confidence changes within the presence of MCI (MoCA) and investigating this relationship is warranted.

Addressing fall risk in those with impaired EF or in the presence of MCI, before the development of Alzheimer’s disease or other dementias can provide valuable information for those working with older adults. Impaired performance on each of the fall risk screening tools mentioned above have been associated with deficits in various aspects of cognition using different cognitive performance tools, however for the practicing clinician it is challenging to extrapolate the findings of multiple studies in a clinically useful way due to the different measurements used and populations studied. This has resulted in a gap in the literature in clearly describing the relationship between a simple measure of EF and a measure of MCI with measures of fall risk in community dwelling older adults. This lack of evidence has led to the research questions addressed in the first two papers of this dissertation:

Paper one: What is the relationship between executive function and fall risk in a group of community dwelling older adults?
Paper two: How does the presence of mild cognitive impairment impact fall risk screening tool scores in a group of community dwelling older adults?

**Cognitive Interventions and Physical Function**

Due to the potential increasing number of older adults with cognitive deficits, research efforts have focused on prevention of cognitive loss and as well as maintenance of cognition through various interventions. Treatments for cognitive impairments in older adults have consisted of either a pharmacological or nonpharmacological approach, or a combination of the two. Pharmacological management includes the use of cholinesterase inhibitors for those with moderate cognitive impairment or Alzheimer’s disease.92
However, mild deficits in cognition have not been effectively addressed with pharmacologic interventions. In addition, the fall rate incidence in those taking cholinesterase inhibitors does not differ from those who have not taken the medications.

Some components of the nonpharmacologic management of cognitive decline have included physical exercise and cognitive training interventions. Exercise has been reported to decrease cognitive disease progression, improve EF in frail older adults with MCI and improve processing speed in community dwelling older adults.

Cognitive training has been shown to be effective in improving specific areas of cognition in varying populations. It is defined as a group of cognitive activities performed to address specific aspects of cognition such as memory, attention, or executive function which include guided practice on a set of standardized tasks. Cognitive training has been performed in multiple different formats and with varying content in either a rehabilitative or compensatory approach. The modes in which trainings have occurred has included one on one activities, group activities with trained personnel, or in an individualized program through the use of computerized cognitive training programs. This intervention has been performed by addressing deficits in specific cognitive domains or through a global cognitive training approach where multiple areas of cognition were addressed. Cognitive training interventions have demonstrated specificity of training to the specific domains of cognition targeted.

Cognitive training has reported to be effective for those with deficits in EF and in those with MCI. In a multisite randomized controlled double-blind study Smith et al. found a significant improvement in generalized measures of memory and attention in the group that participated in a brain plasticity-based computerized cognitive
training program. In the Advanced Cognitive Training for Independent and Vital Elderly study (ACTIVE), the first multicenter randomized controlled trial to examine the long-term effects of cognitive interventions on the daily functioning of older adults, 2832 community dwelling older adults (mean age= 73.6 years) were randomly assigned to one of four groups: memory training, reasoning training, speed-of-processing training or a no-contact control condition. Interventions were performed over 10 total sessions in groups of 3-5 participants lasting 60-75 minutes during a 5-6 week period with booster sessions of cognitive training were provided for some subjects at 11 and 25 months. Those in the speed-of-processing training group performed progressively complex speed tasks on a computer while other intervention group subjects used text materials or instructional methods of training. Assessments were administered at baseline, after the intervention, and annually at 1, 2, 3, and 5 years through performance based or self-report measures of cognition or function. The results of the ACTIVE study have been published in multiple papers and include the following findings which are directly relevant to this dissertation. Domain specific cognitive abilities addressed in each intervention group improved and the results were retained for two years after the end of the study (p<.001), however a transfer of effect between domains did not exist. Morris et al. reported that those who received computerized speed-of-processing cognitive training had less difficulty with instrumental activities of daily living in the five year follow up which was the first large study to detect this.

Following the ACTIVE study, a growing body of literature has described how improvements in cognition have translated into improvements in physical mobility including standing balance and postural control. When both exercise and computerized
cognitive training have been provided, significant improvements in physical function have been found in those with MCI after controlling for age, sex, and history of falling.\textsuperscript{106} A significant improvement in recall as well as physical function as measured with the Physical Performance Test was found in a group of older adults with MCI who received both physical activity and computerized cognitive training using a global cognitive approach.\textsuperscript{23} Verghese et al. reported a significant improvement in gait speed in sedentary older adults of greater than .04m/second and an improvement in the walking while talking test (p=.0002) after completing an eight week long computerized cognitive training program.\textsuperscript{24} In that study, a group of 10 sedentary older adults (mean age of 77.4 years, MMSE: 29) participated in 24 training sessions (3x/week) using the neuropsychological software program Mindfit.\textsuperscript{24} In addition to the changes in function that were found, subjects in the intervention group also had a significant improvement in their processing speed.\textsuperscript{24} Mindfit is a progressively challenging neuropsychological software program that provides cognitive training for users in an individualized fashion via various computerized games.\textsuperscript{24} Kueider and colleagues completed a systematic review of the influence of computerized cognitive training on areas of cognition in older adults and found effect sizes of 0.39 for EF, 0.59 for visual spatial abilities, and 0.36 for attention when training was performed using neuropsychological software program.\textsuperscript{61} At this point, the optimal mode, intensity, frequency, and duration of computerized cognitive training is unknown, however there is statistical evidence that performing a domain specific computerized cognitive training program has resulted in improvements in those domains.\textsuperscript{16,106} These results support a potential relationship between improvements in cognition with computerized cognitive training and changes in function.
Studies addressing the effect of a cognitive intervention on improvements in physical function are preliminary in nature, but they support the idea that a domain specific computerized cognitive training program focusing on visual spatial ability, set shifting, and controlled attention may reduce the risk of falls which was the focus of the third paper in this dissertation. If the results support a conclusion that a computerized cognitive training program emphasizing the areas of visual spatial ability, set shifting, and attention is associated with a reduced risk of falling, there may be practical implications for inclusion of cognitive interventions as a part of a comprehensive approach to fall risk management in the older adult.

Summary
Researchers have only recently begun to investigate the impact that changes in cognition, have on physical function and fall risk. Within this dissertation, this gap was addressed by investigating the relationship between EF, MCI, and fall risk through a comparison of performance on screening tools of those constructs. In addition, the effectiveness of participating in a neuropsychological software training program on fall risk was examined.

Approach
The collection of three papers for this dissertation proposal originated from using data gathered from a quasi-experimental study which investigated the relationship between cognition, specifically EF and MCI, and fall risk prior to and following a computerized cognitive training program in a group of community dwelling older adults.
The overall methods used for the quasi-experimental study is described in the following section followed by the individual methodology for each of the three papers.

**Methodology**

A pretest-posttest quasi experimental study investigating the relationship between cognition, fall risk, and a six week computerized cognitive training program was performed. Sixty-one adults age sixty five and older were recruited through presentations, brochures, and newsletter advertisements from senior centers in cities with similar socioeconomic statuses. Subjects who were interested in participating contacted the researchers and initial testing was scheduled to determine eligibility. Forty-nine subjects met the inclusion criteria of living independently, being 65 years of age or older, being independent with transfers and ambulation, being able to communicate in English, having good vision with or without prescriptive lenses and being able to provide consent for participation independently. Participants were excluded from the study if they had an orthopedic surgery six months prior to testing, were currently receiving physical therapy services, had a history of a cerebrovascular accident, head trauma, or other traumatic brain injury, were unable to meet the requirements of testing or the time commitment for the study, or if they were currently using or had a history of using any computerized cognition training software programs in the nine months prior to the study.

Testing of subjects was performed by a trained examiner. Demographic information was gathered through self-report and included the subject’s date of birth, race and ethnicity, and education level. Other information gathered from the subjects included medications, medical and surgical history, self-report of height and weight, and the use of prescription eyewear. Subjects were asked about their independence with activities of
daily living (ADLs) and instrumental activities of daily living (IADLS). History of falling was by self-report and recorded as the number of times the subject had fallen in the past six months. A fall was defined as an unintentional loss of balance that led to an unexpected change of position. Blood pressure was a single measurement performed in sitting using a sphygmomanometer and stethoscope. Heart rate was taken via palpation of the radial pulse and a stopwatch for sixty seconds. Vision was screened with a dichotomous assessment of whether the subject could correctly read printed material of two different sized fonts (12 point font and 18 point font) on a piece of paper. Due to the reported relationship between depression and fall risk, the thirty item paper and pencil Geriatric Depression Scale was used to screen for depression. Human Subjects Institutional Review Board approval was obtained from Western Michigan University and from the University of Michigan-Flint.

Cognition assessments were performed followed by fall risk assessments. Standardized instructions for using all assessments were provided to the subjects. All testing occurred in a single session that lasted up to 45 minutes. Examiners were not blinded to experimental conditions as a result of the location of testing but were blinded to pretest assessment scores.

Descriptive statistics of the study population will be reported for each separate study. A significance level of p=.05 was used for all comparisons. SPSS version 20 (SPSS Inc., Chicago, IL) was used for all statistical analyses.

Paper One Methods

This study investigated the relationship between executive function as measured with the Trail Making Test Part B (TMT-B) and fall risk using four clinically relevant fall
risk screening tools. The focus of the analysis was to answer the primary research question: What is the relationship between executive function and fall risk in a group of community dwelling older adults?

Sample Description: Community dwelling older adults (N=47) who were recruited for the main study were used for the analysis within this study.

Assessment tools: The TMT-B was used as a measure of executive function. Fall risk was assessed using the FTSTS, TUG, usual gait speed, and the ABC. The MoCA was used to discriminate between MCI and normal cognition in post hoc analyses.

Data Analysis: This correlational study investigated the relationship between executive function as measured with the TMT-B and four fall risk screening tools: ABC, FTSTS, TUG and usual gait speed. The main independent variable for this study was the TMT-B scores. Other independent variables that were included in the analyses include education and age. The dependent variables investigated included the four measures of fall risk. In order to meet the a priori power level of .8 with an effect size of $r^2=.35$, thirty six subjects were needed for the analyses. Descriptive statistics characterized the subjects in the study which included their age, gender, level of education, medication usage, comorbidities, fall history, and EF and fall risk assessment scores with the calculation of means, medians, and standard deviations. To answer the research question of the relationship between fall risk and EF as measured with the TMT-B, correlations between TMT-B scores and each of the four fall risk measures were performed. Pearson’s Product Moment correlations were used for the variables that met the assumptions for the use of parametric statistics while Spearman’s rho was used for non-parametric statistical
analyses. The predictive value of the TMT-B scores were explored for each measures of fall risk using multiple linear regression analysis, while controlling for the confounding variables of age\textsuperscript{57} and education,\textsuperscript{57} thus clarifying its unique contribution to predicting fall risk screening tool performance. Post-hoc analyses were completed to compare the relationship between the TMT-B and performance on fall risk measures in those with MCI using the subject’s MoCA scores. The dataset was stratified based on the presence of MCI, MoCA scores below 26 (N=26) to those whose MoCA scores were greater than or equal to 26 (N=21) which indicated that MCI was not present. This study is found in Chapter 2.

**Paper Two Methods**

This study investigated how performance on four measures of fall risk was impacted by the presence of MCI in a group of community dwelling older adults. The focus of the analysis was to answer the primary research question: How does the presence of mild cognitive impairment impact fall risk screening tool scores in a group of community dwelling older adults?

Sample Description: Community dwelling older adults who participated in the main study (N=48) were the subjects used for the analysis within this study. In this descriptive study, the subject population was stratified based on the presence of MCI during the analyses (those with a MoCA score of <26 (N=27) with a comparison to those with scores ≥ 26 (N=21)). A MoCA score of 26 has a sensitivity of 90% and a specificity of 78% for detecting MCI.\textsuperscript{58}
Assessment tools: The MoCA was used to discriminate between MCI and normal cognition. Fall risk was assessed using the FTSTS, TUG, usual gait speed, and the ABC.

Data Analysis: A comparison of the fall risk screening tool scores of two groups (subjects with MoCA scores ≥26 (Non-MCI group) and subjects with MoCA scores < 26 (MCI group)) was completed including reports of the descriptive data of the groups’ means, medians, and standard deviations. The subjects’ MoCA scores were the main independent variable for this investigation. The dependent variables that were investigated included the four fall risk screening tool scores: usual gait speed, TUG, FTSTS, and the ABC. To determine a difference in scores on the fall risk screening tools based on the presence of MCI, a comparison of mean scores (t-test for parametric analyses or Mann-Whitney U tests for non-parametric analyses) was completed to detect any significant differences between groups. Associations between each of the fall risk screening tools were performed to determine if performance on each of the tools was related with each other in those with MCI. This study is found in Chapter 3.

Paper Three Methods

This study examined if a six week computerized cognitive training program focused on the cognition domains of attention, set shifting, and visual spatial ability influenced fall risk in a group of community dwelling older adults. The focus of the analysis was to answer the primary research question: Does a six week computerized cognitive training program focused on the areas of attention, set shifting, and visual spatial ability impact fall risk in a group of community dwelling older adults?
Sample Description: Community dwelling older adults who participated in the main study were the subjects used for the analysis within this study. Subjects participated as a part of the intervention group or the non-equivalent control group based on the random assignment of the senior center. Group assignment was based on the specific senior center attended and done to decrease the threat to internal validity and cross contamination of subjects. For this study, the intervention group participated in six weeks of computerized cognitive training which consisted of four different games that focused on the areas of visual spatial ability, attention, and set shifting whereas the control group did not receive any interventions during the 6 weeks. Measurements of fall risk and cognition were taken at pre and post measurements.

Assessment tools: Cognition was assessed using the MoCA and the TMT-B, tools with good psychometric properties and established norms to discriminate between normal and impaired cognition.\textsuperscript{10,58} The MoCA was used to discriminate between MCI and normal cognition.\textsuperscript{58} The TMT-B measured EF.\textsuperscript{10} Fall risk was assessed using assessment tools that have established reliability and validity to assess risk of falling\textsuperscript{60,70,79,88,89} and to predict future falls.\textsuperscript{68,79,88} Those tools included the FTSTS,\textsuperscript{79} TUG,\textsuperscript{75} usual gait speed,\textsuperscript{70} and the ABC.\textsuperscript{88}

Description of the Intervention: Intervention group subjects participated in 6 weeks of a computerized cognitive training program using an easily accessible web based neuropsychological software program, Lumosity (Lumos Labs, CA). Under the supervision and consultation of a scientific board of neuroscientists and psychologists, Lumos Labs created a group of internet based computerized games aimed to train various domains of cognition with a progressive stimulus.\textsuperscript{112} Games that were chosen for this
study focused on specific domains of cognition that have been found to be impaired in those with an increased risk of falling.112 The four games that were used included: ‘Disconnection’ which addressed set shifting and attention; ‘Playing Koi’ which addressed visual spatial ability and attention; ‘Birdwatching’ which addressed attention and set shifting; and ‘Memory Matrix’ which addressed visual spatial ability and recall. Tasks within the games became progressively harder to challenge the user and create a training effect.113 Responses were recorded and tracked dynamically over time both within a session and across games with the level of challenge being optimized continuously for each user, increasing the challenge as performance improved and backing off when incorrect responses were made.113 Lumosity has been established for effective use in the geriatric population.112 Data gathered from Lumosity included the frequency of sessions, the subject’s progress in each of the games, and the progress in each cognitive domain. An initial introductory session to the software program occurred at the time of initial testing and was completed with the help of the researchers to assist the subjects in understanding how to use Lumosity. Subjects were provided contact information of the researchers for problems with using Lumosity during the study. Following the initial session, subjects were asked to individually complete each of the four games described once per session at a frequency of three times per week for 15-20 minutes/session for a total of six weeks on a computer of their choice. They were contacted during the 5th week of the study to remind them of their posttest session. Following completion of the sixth week of training, subjects in both groups were post tested using the same measures of cognition and fall risk.
Data Analysis: The main independent variables for this investigation were gender and age. The dependent variables included the four fall risk screening tools: usual gait speed, the TUG, the FTSTS, and the ABC as well as the measures of cognition: the TMT-B and the MoCA. Descriptive statistics including means, medians, and standard deviations were used to describe the data. Differences between groups at the pre and post measurements were analyzed by using individual \( t \)-tests or Mann Whitney \( U \) tests as appropriate. To compare the difference in mean scores on each of the fall risk and cognitive measures, paired samples \( t \)-tests were performed for variables that meet the assumptions for parametric statistics while Wilcoxon Sign Ranked tests were performed for those variables that did not meet the assumptions for parametric statistics. This study is found in Chapter 4.

This research has begun to fill gaps in the literature related to the use of clinical assessment tools of fall risk, cognition, and the impact of a computerized cognitive training program and fall risk. As changes in physical function are often present before cognitive decline, addressing fall risk before the development of Alzheimer’s disease or other dementias through the use of appropriate screening tools and interventions may assist in the medical management of fall risk in community dwelling older adults.
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CHAPTER II

THE RELATIONSHIP BETWEEN FALL RISK AND EXECUTIVE FUNCTION IN COMMUNITY DWELLING OLDER ADULTS

Abstract

Background and Purpose: Fall related injuries are the fifth leading cause of death in older adults and result in medical costs of more than $20 billion per year. Fall risk increases with declining cognition. Executive function (EF), a higher order of cognition, is known to decline with aging. Older adults with impaired EF walk slower, fall more often, and perform worse on mobility tasks. The purpose of this study was to examine the relationship between EF as measured with the Trail Making Test part B (TMT-B) and four measures of fall risk: usual gait speed, Five Times Sit to Stand test (FTSTS), the Timed Up and Go test (TUG) and the Activities Specific Balance Confidence scale (ABC) in a group of community dwelling older adults. Methods: Forty-seven older adults from three different senior centers met the inclusion/exclusion criteria. Demographic information was gathered and measures of fall risk and cognition were performed. Correlations and linear regression analyses were completed. Post hoc analyses included correlations of stratified data based on the presence of mild cognitive impairment (MCI). Results: EF was not significantly correlated with the ABC (ρ=-.085, p=.570) nor the FTSTS test (ρ=.258, p=.080). TMT-B was significantly positively correlated with the TUG (ρ=.308, p=.035) and negatively with usual gait speed (ρ=-.356, p=.014) which remained after adjusting for age and education in multivariate models. When the data was
stratified with a screen for MCI, TMT-B scores in the MCI group were significantly associated with usual gait speed ($\rho = -0.503, p=0.009$) and the TUG ($\rho = 0.577, p=0.003$).

**Discussion:** As TMT-B scores increased indicating a greater impairment in EF, gait speed decreased and it took longer to complete the TUG indicating an increased risk of falling. In those with MCI, deficits in EF had a stronger relationship with the TUG and usual gait speed. **Conclusions:** Slower walking speed and poorer TUG performance was associated with lower EF in this sample of community dwelling older adults and associations remained statistically significant after adjusting for age and education. Reduced walking speeds along with impairments in EF in older adults have implications for functional decline, injury, and institutionalization.

**Key words:** executive function, fall risk, community dwelling older adults

**Introduction**

Fall-related injuries are the fifth leading cause of death in older adults.\(^1\) They account for over 20 billion dollars per year in medical costs, with resultant implications in function, independence, and longevity.\(^1,2\) Falling can be attributed to physiological impairments such as muscular weakness, impaired balance, low body mass,\(^1\) and slowed reaction time,\(^3\) but can also be associated with the presence of cognitive impairments.\(^4\) Older adults with deficits in cognition are twice as likely to fall in comparison to those without cognitive deficits.\(^5\) Cognition is composed of multiple subcomponents or cognitive domains (e.g., attention, memory, visual spatial ability, executive function) that work together to process information during functional tasks in order to maintain balance and prevent falling in the older adult.\(^6\) Deficits in cognition as they relate to fall
risk are not typically isolated to one specific domain, but are impacted by more than one area of the larger construct of cognition.⁶

Studies demonstrate a “normal decline” in cognition with aging known as age-associated cognitive decline.⁷ This normal age related loss in cognitive function is characterized by occasional forgetfulness which does not have a progressive quality.⁷ Declines in other areas of cognition such as executive function have been associated with age related changes in the brain, primarily in the prefrontal cortex, and have been found to impact mobility and balance in older adults.⁸,⁹

Executive function (EF) is defined as the ability to control, integrate, organize, and maintain information when continuously presented and is considered a higher order of cognition.⁶,⁸ Intact EF is necessary to complete common and complex tasks with appropriate coordination of various subcomponents of cognition (e.g. attention, working memory, set shifting) in order to achieve a particular goal or complete a task.⁶

Impairments in EF have been associated with an increased risk of falling in the older adult.¹⁰⁻¹³ After controlling for age, sex, health status, education, and prior history of falls, decreased EF has been associated with an increased falls risk.¹⁴ Studies using a battery of neuropsychological tests have found that older adults with impairments in EF walk slower, fall more often, and perform worse on mobility tasks.¹¹,¹²,¹⁴,¹⁵,⁴⁸ Prior researchers have demonstrated an association between EF and fall risk and have hypothesized that this was due to altered judgment during motor planning.¹¹,¹⁶ A growing body of evidence supports associations of cognitive processing speed and better balance, with implications that reduced processing speed underlies much of the age-related declines in EF,¹²,¹⁴,¹⁵,¹⁷⁻¹⁹ and, by association, balance.
A body of literature exists exploring the relationship between falls and fall prevention in those with various forms of cognitive impairment, specifically dementia. A new area of research has emerged which focuses on identifying how deficits in EF affect physical performance. Results from various studies have indicated that impairments in physical performance are present prior to the onset of dementia, especially in those who demonstrate deficits in EF. Different measures have been utilized within the literature to examine how decreased EF has impacted measures of physical performance prior to the diagnosis of dementia, however these assessments address different components of the larger construct of EF. Tools that assess EF may include assessments of attention, set shifting, response inhibition, motor speed and coordination, mental flexibility, and working memory among others. Researchers have determined that due to the complexity of the components of the cognitive processes included in EF that no single measure of EF can adequately assess the construct in its entirety. Despite this limitation, the relationship between impairments in EF and changes in physical mobility exist and should be assessed as a part of the management of the health status of older adults. However, the validity, reliability and ease of use of the tools that measure EF differs which challenges clinicians to use a tool that meets all of their client’s needs.

The Trail Making Test, a neuropsychological test commonly used in clinical practice has high validity and reliability as an indicator of deficits in EF. It has high intrarater reliability for use with experienced and non-experienced clinicians. Comprised of parts A and B, the Trail Making Test part A (TMT-A) is a measure of visual search and motor speed, while the Trail Making Test part B (TMT- B) is a measure of visual search, attention, working memory, set shifting, and motor speed. Of the two
parts of the Trail Making Test, the TMT-B is considered a more accurate assessment of EF.\textsuperscript{24,27,28} A decline in performance on both parts A and B of the Trail Making Test has been found with increasing age, with a greater decline in performance on part B indicating a higher prevalence of executive dysfunction with advanced age.\textsuperscript{27,28} In addition, declines on both parts A and B have been associated with impaired performance on two different measures of balance, the Berg Balance Scale and the Timed Up and Go test.\textsuperscript{11} It is unknown if that same relationship exists using just the TMT-B as a measure of EF. Physical therapists commonly screen for changes in physical function and fall risk in older adults; however, their use of cognitive performance measures to quantify cognitive deficits that impact fall risk may be limited, especially ones that are easy to use and measure EF. The use of the TMT-B as an assessment of EF may be a beneficial tool to consider in practice to detect deficits and address how they influence fall risk.

Because deficits in EF impact fall risk, it is necessary to understand the relationship between a simple measure of EF and valid measures of fall risk. Published studies have not described the relationship between the TMT-B and the fall risk screening tools proposed in this paper in community dwelling older Americans. In studying this relationship between these tools, health providers may be able to understand how attention, motor speed, and set shifting, items tested in the TMT-B, relate to measures of fall risk.

**Purpose**

The purpose of this study was to determine whether performance on four measures of fall risk commonly used by physical therapists (Five Times Sit to Stand test, the Timed Up and Go test, the Activities Specific Balance Confidence scale, and usual
gait speed) was associated with a measure of EF (TMT-B) in a group of community dwelling older adults. Investigating if a relationship exists between these fall risk measures and an easy to use, valid and reliable measure of EF is important for developing physical therapy early intervention strategies for those at risk, as deficits in physical performance are often present prior to the onset of cognitive impairment. The following research question guided this study: What is the relationship between fall risk and EF in a group of community dwelling older adults?

Methods

Subject Recruitment

Sixty-one subjects were recruited through presentations, brochures, and newsletter advertisements from three senior centers in three Midwestern cities. In order to meet the a priori power level of .8 with an effect size of $r^2=.35$, thirty six subjects were needed to participate in the study. Initial testing was scheduled to determine eligibility. Subjects had to meet inclusion criteria of living independently, being 65 years of age or older, being independent with transfers and ambulation without physical assistance of another person, able to communicate in English, having good vision with or without prescriptive lenses and being able to provide consent for participation independently. Participants were excluded from this study if they had an orthopedic surgery six months prior to testing, were currently receiving physical therapy services, had a history of a cerebrovascular accident, head trauma, or other traumatic brain injury, were unable to meet the requirements of testing or the time commitment for the study, or if they were currently using or had a history of using any computerized cognitive training software programs nine months prior to the study. Human Subjects Institutional Review Board
approval was obtained from Western Michigan University and the University of Michigan-Flint.

**Testing**

All measurements were performed by the primary investigator and two graduate student examiners who were trained on the research process and administration of the outcomes assessments during a one day training session to assure consistency of data collection. Testing of subjects occurred in a quiet room in the senior centers. Demographic information gathered through self-report included the subject’s date of birth, race, ethnicity and education level. Other information gathered from the subjects included medications, medical and surgical history, self-report of height and weight, and the use of prescription eyewear. Subjects were asked about their independence with instrumental activities of daily living (IADLS) and activities of daily living (ADLs). History of falling was by self-report and recorded as the number of times the subject had fallen in the past six months. A fall was defined as an unintentional loss of balance that led to an unexpected change of position. Blood pressure was a single measurement performed in sitting using a sphygmomanometer and stethoscope. Heart rate was taken via palpation of the radial pulse and a stopwatch for sixty seconds. Vision was screened with an assessment of whether the subject could correctly read printed material of two different sized fonts (12 point and 18 point font) and was recorded as a yes or no response. Due to the potential relationship between depression and fall risk, the thirty item paper and pencil Geriatric Depression Scale (GDS) was used to screen for depression with potential scores ranging from 0 to 30. Higher scores on the GDS
indicated a greater degree of depression with scores of 0-9 considered as ‘normal’, 10-19 as ‘mildly depressed’ and 20-30 as ‘severely depressed’. 30

The TMT-B was used as a measure of EF. 24,25,27 Fall risk was examined using the Five Times Sit to Stand Test, 33 the Timed Up and Go test, 35 the Activities Specific Balance Confidence Scale 31,32 and usual gait speed. 34 The Montreal Cognitive Assessment tool (MoCA) was used in posthoc analyses to screen for mild cognitive impairment. The TMT-B and MoCA were performed first followed by the fall risk assessments. Standardized instructions for all assessments were provided to the subjects. All testing occurred in a single session that lasted, on average, 45 minutes. The assessment tools are described below.

Trail Making Test Part B

The TMT-B is considered an accurate measures of EF. 27 Five different cognitive processes found in EF are used to complete the task of drawing a continuous line (i.e., the trail) without lifting the pencil from randomly positioned numbers (1-12) and letters (A-M) in ascending order alternating from number to letter (e.g., 1 to A to 2 to B to 3 etc.) until all numbers and letters are used. 24,25,28 For this assessment the examiner observed the creation of the trail by the subject and recorded the time taken to complete the trail. A demonstration of the task was performed by the examiner followed by a practice trial on a shortened version of the TMT-B which differed in letter/number placement than the testing form. After providing instructions and performing one practice, subjects were given the opportunity to ask any questions for clarification of the task. Timing began after the test paper was turned over and the subject was told to ‘begin’ and it ended after correctly connecting all letters and numbers on the paper. If an error was made, the
researcher immediately identified the error and instructed the subject to correct the error. This was recorded as a continuous score. The maximum time allotted to complete the TMT-B was 300 seconds and if a subject reached this time, the test stopped and the maximum score of 300 seconds was recorded. Longer completion times on the TMT-B indicate worse EF.

**Montreal Cognitive Assessment Tool**

The MoCA was used as a screening tool for mild cognitive impairment (MCI). This paper and pencil test took less than 10 minutes to administer and included items to assess the cognitive domains of visual spatial ability, memory, executive function, attention, concentration and working memory, language and orientation. The maximum possible score on the MoCA is 30 points and is sensitive to the subject’s education level as an extra point is added to the total score for those with an education of less than 12 years. Using a cut-off score of 26, the MoCA has a sensitivity of 90% and a specificity of 78% for detecting MCI.

**Usual Gait Speed**

Slower gait speeds have been identified as a risk factor for disability, cognitive impairment, institutionalization, falls, and/or mortality. Gait speed, measured as distance traveled over time, has been found to be a highly sensitive predictor of physical decline and cognitive decline when provided a cognitive challenge. Gait speed measurements have been noted to be highly reliable regardless of the population or the method of measurement, easily utilized in various environments, with age-adjusted norms in the literature. Usual gait speed was measured as the amount of time required to walk ten feet at the subject’s normal walking speed (speed: distance/time) and was
recorded in feet/second and later converted to meters/second for the analyses.\textsuperscript{41,43} Five feet of space was provided on each side of the marked distance to allow for acceleration and deceleration.\textsuperscript{41}

\textit{Five Times Sit to Stand}

The Five Times Sit to Stand (FTSTS) test is a valid and reliable tool to assess fall risk in the older adult that is easily performed in a variety of settings\textsuperscript{33} with established norms to identify fall risk.\textsuperscript{33,44} For this timed test, the subject moved from a full sitting position to a full standing position as quickly as possible five times without using his arms. Time was measured in seconds from the moment the subject was told to ‘go’ to the moment he sat down in the chair following the fifth repetition.

\textit{Timed Up and Go}

The Timed Up and Go (TUG) test required individuals to go from sitting to standing, walk 3 meters at a fast pace, turn around and return back to the original chair.\textsuperscript{40} Norms to identify risk of falling have been established.\textsuperscript{35} This timed test began when the subject was told to ‘go’ and ended when the subject sat down in the chair after walking the set distance. Longer TUG completion times have been associated with poorer performance on measures of global cognition,\textsuperscript{45,46} verbal fluency,\textsuperscript{46} working memory,\textsuperscript{45,46} processing speed,\textsuperscript{45} as well as with impairments in EF as measured with the TMT-B in those with amnestic MCI,\textsuperscript{21} both parts A and B of the Trail Making Test\textsuperscript{16} and with the Colors Trails Test.\textsuperscript{45}

\textit{Activities Specific Balance Confidence Scale}

The Activities Specific Balance Confidence Scale (ABC) is a measure of self-efficacy of balance confidence and has been shown to have good reliability to assess fall
risk and to predict future falls.\textsuperscript{31,32} Using the protocol established by Powell and Myers,\textsuperscript{32} the subjects read each question on their own and then rated how confident they were in their balance on sixteen different items. Each item was rated on a scale of 0\% (not confident) to 100\% (completely confident that they would not lose their balance or become unsteady while performing the activity) and balance confidence was scored as a percentage of the mean of the sixteen responses.

**Data Analysis**

Descriptive statistics were used to characterize the subjects in the study including their age, gender, level of education, medication usage, comorbidities, fall history, and EF and fall risk assessment scores. Means, standard deviations, medians, and ranges were calculated as appropriate. To answer the research question of the relationship between fall risk and EF as measured with the TMT-B, first correlations between TMT-B scores and each of the four fall risk measures were performed. Pearson’s Product Moment correlations were used for the variables that met the assumptions for the use of parametric statistics while Spearman’s rho was used for non-parametric statistical analyses. The predictive value of the TMT-B scores was then explored using multiple linear regression analysis, while controlling for the confounding variables of age\textsuperscript{27,51} and education\textsuperscript{51} thus clarifying its unique contribution to predicting fall risk assessment tool performance. Post-hoc analyses were completed to compare the relationship between TMT-B scores in those with MCI as determined by the subject’s MoCA scores. The data was stratified into two group based on MoCA scores to indicate the presence of MCI: those with scores below 26 indicating the presence of MCI (MCI group, N=26) and those with scores greater than or equal to 26 (Non MCI group, N=21).\textsuperscript{36} Due to the small
sample size and the influence that any one point may have had on the overall results of the study, any of the assessment tools scores that resulted in a measurement that was greater than 3 SD from the mean was considered an outlier and that data point was not included in the analyses. A significance level of p=.05 was set for all comparisons and SPSS version 20 (SPSS Inc., Chicago, IL) was used for all statistical analyses.

Results

Sixty-one older adults were recruited for the study. Forty-eight met the inclusion criteria and went through the informed consent process and initial testing. One subject’s TMT-B scores were greater than 3 SD from the mean resulting in the exclusion of this measurement in the final analyses for a total of 47 subjects used in the analyses. Demographics of the group can be found in Table 2a. Seventy-two percent of subjects were female with 97.8% of all subjects reporting being white. Forty-six percent of the participants reporting having either a bachelor’s degree or education beyond the bachelor’s degree. Ten percent reported having only a high school diploma. All subjects were independent with ADLs and IADLs and passed the vision screening.

Thirty percent reported a history of falling at least once in the past 6 months, while 15% reported a greater fall frequency. On average, subjects were taking 6.5 medications and had a body mass index of 27.7%. GDS scores ranged from 0-11 with a mean score of 2.89 (SD=2.75). The prevalence of conditions reported in their past medical history can be found in Table 2a, while the average scores for the assessment tools can be found in Table 2b.
Table 2a. Demographics, Past Medical History, and Medical Conditions of Community Dwelling Older Adult Participants (N=47)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean or percentage (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (years)</td>
<td>74.89 (5.93)</td>
<td>66-91</td>
</tr>
<tr>
<td>Medications</td>
<td>6.49 (4.59)</td>
<td>0-24</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>27.68 (4.93)</td>
<td>15.6-39.4</td>
</tr>
<tr>
<td>GDS scores</td>
<td>2.89 (2.75)</td>
<td>0-11</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>female</td>
<td>34 (72)</td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>13 (28)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>white</td>
<td>46 (97.8)</td>
<td></td>
</tr>
<tr>
<td>Unknown/not reported</td>
<td>1 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high school</td>
<td>5 (10.6)</td>
<td></td>
</tr>
<tr>
<td>some college</td>
<td>15 (31.9)</td>
<td></td>
</tr>
<tr>
<td>associate degree</td>
<td>5 (10.6)</td>
<td></td>
</tr>
<tr>
<td>bachelor’s degree</td>
<td>9 (19.1)</td>
<td></td>
</tr>
<tr>
<td>education beyond bachelor’s degree</td>
<td>13 (27.7)</td>
<td></td>
</tr>
<tr>
<td>Number of Falls in Past 6 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>26 (55.3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>14 (29.8)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6 (12.8)</td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td>1 (2.1)</td>
<td></td>
</tr>
<tr>
<td>PMH Condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>28 (59.6)</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>21 (44.7)</td>
<td></td>
</tr>
<tr>
<td>HEENT</td>
<td>22 (46.7)</td>
<td></td>
</tr>
<tr>
<td>Allergies</td>
<td>16 (34.0)</td>
<td></td>
</tr>
<tr>
<td>Endocrine</td>
<td>13 (27.7)</td>
<td></td>
</tr>
<tr>
<td>Other (Cancers)</td>
<td>13 (27.7)</td>
<td></td>
</tr>
<tr>
<td>Dermatologic</td>
<td>11 (23.4)</td>
<td></td>
</tr>
<tr>
<td>GI</td>
<td>10 (21.3)</td>
<td></td>
</tr>
<tr>
<td>Psychiatric</td>
<td>7 (14.9)</td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>8 (17.0)</td>
<td></td>
</tr>
<tr>
<td>Blood</td>
<td>6 (12.8)</td>
<td></td>
</tr>
<tr>
<td>GU</td>
<td>5 (10.6)</td>
<td></td>
</tr>
<tr>
<td>Neurological</td>
<td>5 (10.6)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: GDS: Geriatric Depression Scale; PMH: Past Medical History; HEENT: Head, Eyes, Ears, Nose Throat; GI: Gastrointestinal; GU: Genitourinary
Table 2b. Assessment Tool Scores and Correlations with TMT-B Scores of Community Dwelling Older Adults (N=47)

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>Mean (SD)</th>
<th>Range</th>
<th>Correlation to TMT-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMT-B (sec)</td>
<td>89.69 (37.5)</td>
<td>35.9-175.5</td>
<td>ρ=.258 †</td>
</tr>
<tr>
<td>FTSTS (sec)</td>
<td>14.35 (3.7)</td>
<td>8.0- 30.3</td>
<td>ρ=.308* †</td>
</tr>
<tr>
<td>TUG (sec)</td>
<td>10.5 (3.8)</td>
<td>5.2-27.6</td>
<td>ρ=-.085 †</td>
</tr>
<tr>
<td>ABC (%)</td>
<td>83.6 (15.2)</td>
<td>21.25 – 99.37</td>
<td>ρ=- .085 †</td>
</tr>
<tr>
<td>Usual Gait Speed (m/sec)</td>
<td>.99 (.28)</td>
<td>.45-1.62</td>
<td>r = -.356* ‡</td>
</tr>
</tbody>
</table>

Abbreviations: TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale, SD: standard deviation, sec: seconds

*: p<.05
†: correlations performed with Spearman’s rho
‡: correlations performed with Pearson’s Product Moment Correlation

Gait speed was the only outcome variable that met the assumptions for the use of parametric statistics and correlations were performed using Pearson’s Product Moment correlation. Non-parametric statistical analyses were performed for the other fall risk measures using Spearman’s rho. EF as measured with the TMT-B was not significantly correlated with the ABC (ρ=-.085, p=.570) nor the FTSTS test (ρ=.258, p=.080). TMT-B scores were positively correlated with scores on the TUG test (ρ=.308, p=.035) and negatively correlated with the measurement of usual gait speed (r=-.356, p=.014), both correlations had a moderate effect size. Multiple linear regression analyses including all subjects were completed to determine if EF as measured with the TMT-B was predictive of fall risk assessment scores when controlling for education and age (Table 2c). Of the four models, scores on the TMT-B were only able to statistically significantly predict usual gait speed (β= -.002, 95% CI (-.004, .000) p=.031) when controlling for age and education. Post hoc power analyses for the usual gait speed multiple regression model revealed a power of 99% with the sample size (N=47) and a probability level of p=.05.

Due to the wide range of TMT-B scores in the full sample, the data was stratified into two groups using a screen for MCI based on a MoCA score of less than 26. EF in the
Table 2c: Four Different Linear Regression Models to Predict Fall Risk Assessment Tools Scores with TMT-B Scores, Controlling for Age and Education (N=47)

<table>
<thead>
<tr>
<th>Model 1: FTSTS</th>
<th>Predictor: Executive Function</th>
<th>β</th>
<th>B</th>
<th>95% CI</th>
<th>P-value</th>
<th>R²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 2: ABC</td>
<td>TMT-B</td>
<td>-.039</td>
<td>-.097</td>
<td>(-.148, .070)</td>
<td>.471</td>
<td>.297</td>
</tr>
<tr>
<td>Model 3: TUG</td>
<td>TMT-B</td>
<td>.025</td>
<td>.246</td>
<td>(.001, .051)</td>
<td>.063</td>
<td>.350</td>
</tr>
<tr>
<td>Model 4: Usual Gait Speed</td>
<td>TMT-B</td>
<td>-.002</td>
<td>-.295</td>
<td>(-.004, .000)</td>
<td>.031*</td>
<td>.316</td>
</tr>
</tbody>
</table>

Abbreviations: TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale
β: Unstandardized Beta, B: Standardized Beta, CI=confidence interval
*: p<.05

Non MCI group was not significantly correlated with any of the fall risk measures; usual gait speed (ρ = -.172, p=.457), TUG (ρ = .061, p=.792), FTSTS (ρ =.192, p=.405), ABC (ρ=.057, p=.806). However, in the MCI group TMT-B scores were statistically significantly correlated with usual gait speed (ρ = -.503, p=.009) and TUG (ρ =.577, p=.003) but not statistically significantly correlated with the ABC (ρ = -.124, p=.545) nor the FTSTS (ρ =.337, p=.092) (Table 2d).

Table 2d: Correlations between TMT-B and Four Fall Risk Measures in the Non-MCI Group (N=21) and the MCI Group (N=26)

<table>
<thead>
<tr>
<th>Fall Risk Measure</th>
<th>Correlation with TMT-B</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non MCI Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FTSTS</td>
<td>.192</td>
<td>.405</td>
</tr>
<tr>
<td>ABC</td>
<td>.057</td>
<td>.806</td>
</tr>
<tr>
<td>TUG</td>
<td>.061</td>
<td>.792</td>
</tr>
<tr>
<td>Usual Gait Speed</td>
<td>-.172</td>
<td>.457</td>
</tr>
<tr>
<td><strong>MCI Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FTSTS</td>
<td>.337</td>
<td>.092</td>
</tr>
<tr>
<td>ABC</td>
<td>-.124</td>
<td>.545</td>
</tr>
<tr>
<td>TUG</td>
<td>.577</td>
<td>.003*</td>
</tr>
<tr>
<td>Usual Gait Speed</td>
<td>-.503</td>
<td>.009*</td>
</tr>
</tbody>
</table>

Abbreviations: TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale, SD: standard deviation, sec: seconds
*: p<.05
†: correlations performed with Spearman’s rho
‡: correlations performed with Pearson’s Product Moment Correlation

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Discussion

In a group of community dwelling older adults, deficits in EF as measured with the TMT-B were inversely correlated with usual gait speed measurements and directly correlated with TUG scores, however the relationship between the TMT-B and the TUG was no longer statistically significant when age and education were controlled for in regression modeling. In those with MCI, a strong relationship was found between EF and the TUG and with usual gait speed. The inverse relationship between gait speed and TMT-B scores indicated that as it took a longer period of time to complete the TMT-B, indicating a greater impairment in EF, gait speed, on average, slowed. Similarly, as EF became more impaired (increased TMT-B time) it took longer to complete the TUG indicating an increased risk of falling. This finding may be clinically relevant for community dwelling older adults as deficits in EF increase the risk for functional decline and disability, therefore utilizing clinically relevant measures that are easy to use will assist in detecting those risks.

The use of the TMT-B as a measure of EF incorporates the cognitive areas of visual scanning, speed, attention, and set shifting for completion. The results of this study are consistent with previous studies that have demonstrated that older adults with impairments in EF walk slower and perform worse on mobility tasks. However, the lack of an association between the FTSTS and the ABC, two tools that measure fall risk, may indicate that EF does not strongly influence performance on those tools.

TMT-B scores of all subjects in the study had a wide range of time required for completion (35.9 – 175.5 seconds) which served as the basis for post hoc analyses to discriminate how mild deficits in cognition may have influenced the relationship between
EF and fall risk. Results indicated that in those with MCI, EF had a stronger relationship with usual gait speed and TUG measurements than the full group of subjects. The strong relationship between these measures in older adults with cognitive deficits supports previous findings that gait requires cognitive resources and is not entirely an automatic activity.\(^{37}\) Despite the difference in assessment tools used in previous studies, this result is consistent with other studies that have reported changes in gait speed in those with executive dysfunction.\(^{47}\)

Age has been reported to influence performance on the TMT-B as well as gait speed in older adults.\(^{27,41}\) In this study, mean scores on the TMT-B as well as mean gait speeds were consistent with age associated norms.\(^{27,42}\) The significant relationship between EF and usual gait speed after controlling for age suggests that the relationship between EF and gait may be present well before the influence of age on these constructs and serves as an indicator to examine EF in a fall risk assessment for older adults.

Many of the published studies that have examined EF and fall risk in older adults have utilized other measures of EF, both parts A and B of the Trail Making Test or other assessments of fall risk.\(^{22-24}\) In a study similar to this one, Hirota et al. found an association between usual walking speed, the TUG, and EF using the difference in performance times of both parts of the Trail Making Test, known as \(\Delta\text{TMT}\) in a group of 493 Japanese subjects aged 65 years or older.\(^{22}\) The strength of the relationship between TMT-B and gait speed in this study (\(r=.356\)) was stronger than the relationship between gait speed and the \(\Delta\text{TMT}\) (\(\rho = .190\))\(^{22}\) indicating a stronger association between usual gait speed and the TMT-B as a measure of EF. This is worthy of consideration in that the amount of time to administer and score the TMT-B is less than the \(\Delta\text{TMT}\) which may
influence its use in clinical settings. Hirota and colleagues also reported a significant association between the ΔTMT and the TUG (ρ = .309) after adjusting for age and gender in community dwelling older adults,\textsuperscript{22} whereas a significant association between the TMT-B and the TUG (ρ = .308) was found only in those with MCI in this study. This difference may be due to the variability between sample sizes; however it would be worth further study to determine if ΔTMT scores have an association with TUG scores in community dwelling older Americans.

The relationship between the TMT-B and measures of physical performance has been studied in different populations of older adults. Similar to the findings in the post-hoc analyses, McGough et al. found a significant relationship between EF as measured with the TMT-B and gait speed (B = -0.215, p = .003) as well as the TUG (B = -0.256, p < .001) in a cross sectional study of 201 sedentary older adults with amnestic-MCI.\textsuperscript{21} In this study, EF had a stronger association with usual gait speed as represented by the beta (B = -0.513, p = .009), however because the MoCA does not discriminate between the subtypes of MCI, the difference in the relationship between EF and usual gait speed in those with various subtypes of MCI should be investigated further.

When the data was stratified based on the presence of MCI, the strength of the relationship between the TMT-B and two measures of physical performance, gait speed and the TUG, was stronger in those with MCI. These results suggest that deficits in EF have a stronger association on performance of measures of fall risk in those with MCI versus community dwelling older adults.

Despite their ability to predict fall risk, the FTSTS and ABC were not statistically significantly associated with TMT-B scores. The mean score of the FTSTS (14.35) in this
study was greater than the cutoff score in the literature (13.6 seconds) indicating an increased fall risk,\textsuperscript{33} yet this assessment was not statistically significantly correlated with a measure of EF. In contrast, impaired performance on the FTSTS has been associated with poorer performance on global measures of cognition such as a screen for Alzheimer’s disease.\textsuperscript{52,53} The difference in the focus of the cognitive measures may assist in explaining the contrast in findings as it could be postulated that perhaps the task of going from sitting to standing multiple times does not require higher order processing of EF into performance of this task. Likewise, the FTSTS has been identified as an indicator of frailty\textsuperscript{49} of which frailty may be more consistent with global cognitive decline rather than a decrease in EF. The lack of an assessment of lower extremity strength of the subjects in this study may have been a confounder when investigating a relationship between the FTSTS and the TMT-B and should be included in future studies to examine the relationship between these tools.

Confidence in balance as measured with the ABC was not statistically significantly associated with EF in this study. Confidence in balance has been reported to have a significant and strong relationship with balance performance.\textsuperscript{40} In addition, cognition has been identified as a strong predictor of balance performance.\textsuperscript{40} A relationship between impaired balance confidence and decreased EF may be expected among seniors with a high risk of falling, such as those with significant physical impairments or with a history of falls. However, in this study, less than half of the subjects reported a history of falling in the previous six months and mean scores on the measures of fall risk did not reflect a significantly impaired population which may account for the lack of an association. The results in this study are not consistent with
those of Lui-Ambrose and colleagues who reported an association between balance confidence (ABC) and a component of EF, impaired set shifting, when performing a dual ambulation task.\textsuperscript{26} Set shifting is described as the ability to update and shift cognitive strategies in response to new changes in the environment and has been reported to be required for processing information during gait.\textsuperscript{6} Deficits in set shifting have been associated with decreased walking speeds, changes in gait stability, and an increased fall risk in older adults.\textsuperscript{10} The contrasting results are most likely due to the differences in measurements as set shifting is one specific component of EF, whereas, the TMT-B utilizes multiple subcomponents of cognition. In addition, the lack of an association in this study is likely a result of completing a self-assessment of balance confidence, which may not require higher order cognitive processing such as EF.\textsuperscript{26} This finding should be taken into consideration for the selection of measures of fall risk as a self-assessment of balance confidence did not have a significant relationship with EF in community dwelling older adults or in those with MCI. This suggests that ABC scores are not associated with an older adult’s level of EF, regardless of having normal or impaired EF, and therefore caution should be employed with the use of the ABC as an assessment of fall risk in those with EF deficits. Further studies should examine how balance confidence is associated with other measures of fall risk in those with cognitive impairment.

Deficits in EF have been correlated to changes in measures of functional mobility, however previously published studies have not included the measures used in this study. As there are many variables that impact fall risk, taking into consideration the risk of cognitive deficits in older adults is of utmost concern.
Limitations

Subjects involved in this study were taken from a convenience sample of mostly white, educated older adults from one geographic location, limiting the generalizability of this study. Subjects were highly functional, independent with ADLs and IADLs, and had a limited history of falling and thus performance on the fall risk assessments reflected the characteristics of this group which may not be congruent with the general population of community dwelling older adults. In addition, the mean scores for some of the fall risk assessments did not indicate that the subjects, on average, were at a risk of falling. Dependence in ADLs and a history of falling are both risk factors for falling and the fact that this study population did not portray those risk factors, may assist in explaining how scores on some measures of fall risk were not associated with the TMT-B. The lack of an assessment of lower extremity strength of the subjects in this study may have been a confounder when investigating a relationship between the FTSTS and the TMT-B and should be included in future studies to examine the relationship between these tools. This study may have been limited in using the TMT-B as the measure of EF as some authors have noted that the use of the ΔTMT is a better measure of EF as it reduces measurer error and increases the reliability of the test, and therefore the use of the ΔTMT should be considered in future studies to determine if the same relationships exist. Most of the subjects had a higher than average education level which may have influenced the results as deficits in cognition are associated with education level. As a result, the relationship between EF and the physical measures of fall risk may have been influenced. The small sample size limited the ability to examine regression modeling when the subjects were stratified into smaller groups and further studies should consider recruiting a greater
number of subjects in order to perform this analysis. Finally, the cross-sectional design used in this study does not allow the inference that deficits in EF caused deficits in performance on the four fall risk measures. However, due to the fact that statistically significant associations were found, this would suggest that the combination of measures of physical function and EF may assist in detecting early functional decline in older adults.

Areas for Further Study

As the relationship between EF and measures of physical function and fall risk continues to be investigated, in addition to the areas previously mentioned, future studies should emphasize recruiting a more diverse population of older adults with more deficits cognition as well as a greater history of falling or balance impairments in order to identify and stratify fall risk based on those variables and examine relationships over a wider spectrum of performance.

Conclusion

In a general sample of community dwelling older adults, deficits in EF were associated with slowed walking speeds. Longer completion times on the TUG and slower walking speeds were associated with impairments in EF in those with MCI. Impairments in EF along with reduced walking speeds have implications for functional decline, injury, and institutionalization in older adults. Clinicians who examine fall risk in community dwelling older adults should consider the assessment of EF using the TMT-B when measures of usual gait speed are performed in the general population of older adults and the TUG or usual gait speed measurements in those with MCI. Further research is needed
to determine the mechanism for this relationship and to examine if early intervention strategies for those with deficits in EF are effective in slowing functional decline in community dwelling older adults.
References


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CHAPTER III

THE INFLUENCE OF MILD COGNITIVE IMPAIRMENT ON FALL RISK IN COMMUNITY DWELLING OLDER ADULTS

Abstract

Background and Purpose: Fall related injuries are the fifth leading cause of death in older adults and result in medical costs of more than $20 billion per year. Cognitive impairment is a risk for falls and those with mild cognitive impairment (MCI) have changes in gait and are at a greater risk for falling. The purpose of this study was to determine how the presence of MCI as measured with the Montreal Cognitive Assessment tool (MoCA) influences performance on fall risk screening tools: the Five Times Sit to Stand test (FTSTS), usual gait speed, the Timed Up and Go test (TUG) and the Activities Specific Balance Confidence scale (ABC) measures. Methods: Forty-eight community dwelling older adults participated. The MoCA was used to stratify the subjects into those with MCI and those without MCI based on a cutoff score of 26. Descriptive statistics and mean scores on each of the fall risk screening tools were reported. Correlations and comparisons of mean scores between groups were completed. Results: Mean scores on the fall risk tools did not differ between groups. Significant associations between each of the fall risk screening tools were found in those with MCI with the exception of the ABC and usual gait speed measurements. Discussion: The influence of deficits in cognitive processes reported in those with MCI may impact performance on fall risk measures, however further investigation is warranted.
Conclusion: Although there were no significant differences detected in overall mean scores, these finding may provide evidence to the subtle influence that early cognitive loss as found in MCI has over overall performance on measures of fall risk. Further studies are needed to examine this influence.

Key words: mild cognitive impairment, fall risk, community dwelling older adults

Introduction

Impairments in cognition in older adults, those 65 years of age and older, range from mild deficits to the severe impairments found in those with dementia. Mild cognitive impairment (MCI) is defined as having a global cognitive decline impacting multiple domains of cognition greater than what is expected for an individual’s age and education level which does not notably interfere with activities of daily living.\textsuperscript{1,2} It is considered an intermediate state between normal cognitive aging and dementia\textsuperscript{1} and has an estimated prevalence between 22\% and 39\% in those 71 to 90 years of age.\textsuperscript{3,4} In many cases MCI precedes the diagnoses of dementia\textsuperscript{5} with an annual transition rate to Alzheimer’s disease or other dementias of 10 to 15\% which increases to 20-30\% over three years.\textsuperscript{6} Older adults with MCI may exhibit deficits in memory (amnestic) or non-memory (non-amnestic) domains of cognition as well as impairments in fine and complex motor skills and coordination.\textsuperscript{7}

Despite the growing prevalence of MCI in older adults, the detection of MCI by general practitioners has been reported to be low.\textsuperscript{8} This may present as an increasing number of older adults going through the healthcare system with cognitive and physical deficits associated with MCI that could have otherwise been addressed with appropriate interventions. Therefore, the use of a screening tool for MCI, such as the Montreal
Cognitive Assessment tool (MoCA), may be beneficial for utilization in clinical settings in order to distinguish between those with MCI from those with normal age associated declines in cognition. The MoCA is a valid and reliable global measure of cognition created to identify cognitive deficits present in MCI\(^9\) and is described further in the methods section.

Using an effective screening tool for the presence of MCI in community dwelling older adults may be necessary to consider as a part of a fall risk assessment as older adults with deficits in cognition are twice as likely to fall.\(^{10}\) In those with MCI, a greater prevalence of impairments in balance and gait\(^{11}\) including changes in both the qualitative and quantitative components of gait\(^{12}\) have been reported. Mild deficits in cognition may account for this increased falls risk as intact cognitive function is necessary for coordinating and processing multiple inputs in order to maintain stability and balance during functional activities.\(^{10}\) Poorer performance on the MoCA has been associated with impaired performance on measures of fall risk and balance.\(^{9,13,14}\) Due to the potential for impaired recall in those with MCI, researchers have proposed the use of objective mobility tests as a valuable way to assess fall risk in cognitively impaired older adults. However, it is unknown if performance, in general, differs on measures of fall risk in those with MCI.

As cognitive declines are often present before physical declines,\(^5\) understanding how fall risk may differ within those with MCI can allow health care practitioners to effectively identify and address the impairments in physical mobility and cognition that may influence risk of falling. It can also assist in the selection of appropriate measures of fall risk in this population.
Purpose

This study had two purposes. The first purpose was to determine if there was a difference in performance on four commonly used measures of fall risk in those with MCI while the second purpose was to explore associations between performances on each of the fall risk screening tools in a group of community dwelling older adults with MCI. Understanding how performance on these measures of fall risk may differ in those with MCI can assist clinicians in choosing, administering, and interpreting the findings of fall risk screening tools for this population. The following overall research question guided this study: How does the presence of mild cognitive impairment impact fall risk screening tool performance in a group of community dwelling older adults?

Two hypotheses were formed. The first was that fall risk screening tool performance will differ between those with MCI and those without MCI. The second hypothesis was that performance on each of the fall risk screening tools will be associated with each other in those with MCI.

Methods

Sixty-one subjects were recruited through presentations, brochures, and newsletter advertisements from senior centers in three Midwestern cities. Subjects who met inclusion and exclusion criteria went through initial testing. Inclusion criteria consisted of subjects living independently, having good vision with or without prescriptive lenses, being age 65 or older, independent with transfers and ambulation (use of assistive devices was acceptable), and being able to communicate in English and provide consent for participation independently. Subjects were excluded from this study if they had an orthopedic surgery six months prior to testing, were currently receiving physical therapy
services, had a history of a cerebrovascular accident, head trauma, or other traumatic brain injury, were unable to meet the requirements of testing or the time commitment for the study, or if they were currently using or had a history of using a computerized cognition training software programs nine months prior to the study. This resulted in a total of 48 subjects. Human Subjects Institutional Review Board approval was obtained from Western Michigan University and the University of Michigan-Flint.

**Testing**

All measurements were performed by the primary investigator and two graduate student examiners. To assure consistency between examiners, all examiners completed a one day training session which covered the testing protocol and administration of the assessments. Subjects provided informed consent and underwent a medical interview for comorbidities, medications (total number and names of medications), number of falls in the past six months,\textsuperscript{15} and a report of their dependence or independence with activities of daily living and instrumental activities of daily living. History of falling was by self-report and a fall was defined as an unintentional loss of balance that led to an unexpected change of position. Demographic information gathered included the subject’s date of birth, education level and race and ethnicity. Other information gathered included a self-report of height and weight, and the use of prescription eyewear. Blood pressure was a single measurement performed in sitting using a sphygmomanometer and stethoscope. Heart rate was taken via palpation of the radial pulse and a stopwatch for sixty seconds. Vision was screened with an assessment of whether the subject could correctly read printed material of two different sized fonts (12 point and 18 point font) on a written paper and was recorded as a yes or no response. The thirty item paper and pencil
Geriatric Depression Scale (GDS) was used to screen for depression with potential scores ranging from 0 to 30.\textsuperscript{16} Higher scores on the GDS indicated a greater degree of depression with scores of 0-9 considered as ‘normal’, 10-19 as ‘mildly depressed’ and 20-30 as ‘severely depressed’.\textsuperscript{16}

The MoCA tool was used to discriminate between MCI and normal cognition.\textsuperscript{9} Fall risk was assessed using the Five Times Sit to Stand Test,\textsuperscript{17} usual gait speed,\textsuperscript{18} the Timed Up and Go test,\textsuperscript{19,20} and the Activities Specific Balance Confidence Scale.\textsuperscript{21} Standardized instructions were given to all subjects and the MoCA was performed first followed by the fall risk measures. All testing occurred in a single session in a quiet room of the senior center that lasted up to 45 minutes. The assessment tools are described below.

**Cognitive and Fall Risk Assessments**

*Montreal Cognitive Assessment Tool (MoCA)*

All subjects were screened for the presence of MCI with a valid and reliable neuropsychological assessment, the MoCA, which assesses several different cognitive domains impacted by MCI.\textsuperscript{9} Within the MoCA, visual spatial ability was assessed using a clock-drawing task and a three-dimensional cube copy. Short term memory recall involved learning two trials of five nouns and then recalling them after approximately five minutes. Executive function was assessed using an abbreviated task from the TMT-B, a phonemic fluency task and a two item verbal abstraction task. Attention, concentration and working memory were assessed using a sustained attention task, a serial subtraction task, and digits forward and backward task. Language was assessed using a three-item naming task, repetition of two syntactically complex sentences and a
fluency task. Lastly, orientation to place and time was evaluated.\textsuperscript{9,22} Scoring of each of the items constitute the total score on the MoCA (ranging from 0-30) and scoring on the MoCA has been reported to be sensitive to the subject’s education level with an extra being added to the total score for those who had an education of less than 12 years.\textsuperscript{9}

Using a cut-off score of 26, the MoCA has a sensitivity of 90% and a specificity of 78% for detecting MCI.\textsuperscript{22} A cut-off score of 26 on the MoCA was used as the basis of subject group assignment into one of two groups, the MCI group (those who scored <26) or the Non MCI group (those who scored >26).

\textit{Usual Gait Speed}

A significant association between gait deterioration and working memory has been found in those with MCI.\textsuperscript{23} Slower gait speeds have been identified as a risk factor for cognitive impairment, falls, disability, institutionalization, and mortality.\textsuperscript{24} Age-adjusted norms for gait speed have been established in the literature but have not been identified for those with MCI.\textsuperscript{25} Gait speed assessment is easily utilized in both clinical and research environments.\textsuperscript{26} Subjects were instructed to walk at their normal pace over a distance of ten feet and the amount of time required to walk that distance was recorded. Gait speed (speed: distance/time) was converted to meters/second. Five feet of space was provided on each side of the marked distance to allow for acceleration and deceleration.

\textit{Timed Up and Go}

The Timed Up and Go test (TUG) is a valid, reliable, and efficient measure of fall risk for community dwelling older adults that includes both physical and cognitive components.\textsuperscript{19,20,27} Using the TUG version originally proposed by Podsiadlo et al., subjects were asked to rise from a chair, walk 3 meters at a normal pace to a line clearly
marked on the floor, turn around, walk back to the chair, and then sit down again. A demonstration of the task was performed by the examiner. Subjects were timed with a stopwatch from the moment the subject was told to ‘go’ to the moment the subject sat back down in the chair. Longer TUG completion times have been associated with poorer performance on measures of global cognition, verbal fluency, working memory, processing speed, and executive function.

Five Times Sit to Stand

The Five Times Sit to Stand test (FTSTS) is a valid and reliable measure of fall risk and lower extremity strength in older adults which assesses balance during transitional movements. The FTSTS has been reported as an indicator of frailty, a predictor of fall risk, and is associated with increased disability, morbidity and falls. This test consisted of measuring the amount of time it took a subject to go from sitting in a supportive chair to full standing five successive times without using their arms. A demonstration of the task was performed by the examiner. Subjects were instructed to perform this task as quickly as possible. Time was measured with a stopwatch from the moment the subject was told to ‘go’ to the moment he sat down in the chair following the fifth repetition. Norms for scores on the FTSTS to identify fall risk have been documented in the literature. Longer completion times on the FTSTS have been associated with lower levels of global cognitive function, but have not been observed in the presence of MCI.

Activities Specific Balance Confidence Scale

The Activities Specific Balance Confidence Scale (ABC) is a self-assessment of balance confidence with lower scores being associated with higher fall risk. It has good
reliability to assess fall risk.\textsuperscript{21,34} Using the protocol established by Powell and Myers, the subjects read each question on their own and then provided a numerical value of how confident they were in their balance on sixteen different items. Each item was rated on a scale of 0\% (not confident) to 100\% (completely confident that they would not lose their balance or become unsteady while performing the activity) and balance confidence was scored as the mean of the sixteen responses as a percentage.

Data Analysis

Two groups of subjects were created based on their MoCA scores: MCI (those with a MoCA score of <26) and a Non-MCI group (those with a MoCA score of $\geq 26$) which served as a control for comparisons. For each group, descriptive statistics were used to characterize the subjects including their age, gender, education level, number of medications, comorbidities, fall history, and fall risk measure scores. All continuous data was examined for normality using the Shapiro-Wilk statistic. Differences between groups were analyzed by using individual $t$-tests or Mann Whitney $U$ (`exact’ method) tests as appropriate. Each of the screening tools has been reported to be correlated with performance on the others in older adults without cognitive impairment.\textsuperscript{20,29,35-39} To determine if these same associations existed in those with MCI, the relationship between each fall risk screening tool to the other fall risk screening tools was examined within each group using Pearson’s Product Moment correlations for normally distributed continuous variables or Spearman’s rho for non-normally distributed continuous variables. Statistical significance was set at 0.05 and analyses were conducted using SPSS version 20 (SPSS, Inc., Chicago, IL).
Results

Sixty-one older adults were recruited for the study. Forty-eight met the inclusion criteria, provided informed consent, and completed testing. The control group consisted of 21 subjects while the MCI group had 27 subjects. Demographics of the two groups can be found in Table 3a. Individual t-tests revealed no statistically significant differences between groups in their age $t(46) = -1.48, p = 0.145$; education level $t(46) = 1.06, p = 0.292$; medications $t(46) = -1.19, p = 0.239$; BMI $t(46) = .791, p = 0.433$; or fall history $t(46) = -.250, p = 0.804$. Mean MoCA scores were significantly different between the two groups $t(46) = 8.20, p = .000$. Subjects in the MCI group, on average, walked slower, took more time to complete the FTSTS and TUG and were less confident in their balance, however no statistically significant differences existed in their performance on the

Table 3a. Demographics, Past Medical History, and Medical Conditions of Community Dwelling Older Adult Participants (N=48)

<table>
<thead>
<tr>
<th>Variable</th>
<th>MCI (MoCA score &lt;26) N=27</th>
<th>Non MCI (MoCA score &gt; 26) N=21</th>
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<tr>
<td>Average age (years)</td>
<td>75.81 (6.32)</td>
<td>73.24 (5.48)</td>
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<tr>
<td>Medications</td>
<td>7.12 (5.19)</td>
<td>5.5 (3.51)</td>
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<tr>
<td>Body Mass Index (kg/m²)</td>
<td>27.21 (4.27)</td>
<td>28.34 (5.62)</td>
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<tr>
<td>GDS scores</td>
<td>3.48 (2.99)</td>
<td>2.0 (2.21)</td>
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<tr>
<td>ABC (%)</td>
<td>82.02 (17.03)</td>
<td>86.33 (12.40)</td>
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<tr>
<td>FTSTS (sec)</td>
<td>14.42 (3.74)</td>
<td>14.10 (3.76)</td>
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<tr>
<td>Usual Gait Speed (sec)</td>
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<td>1.04 (.30)</td>
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<tr>
<td>TUG (sec)</td>
<td>10.76 (4.44)</td>
<td>10.01 (2.79)</td>
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<td>Total Number</td>
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<td>28.6</td>
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<td>3</td>
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</table>

Abbreviations:  GDS: Geriatric Depression Scale; PMH: Past Medical History; HEENT: Head, Eyes, Ears, Nose Throat; GI: Gastrointestinal; GU: Genitourinary  *: p<.05

fall risk measures: usual gait speed $t(46) = 0.830, p =0.411$;  FTSTS $t(46) = -0.290, p =0.773$;  ABC $t(46) = 0.976, p =0.334$; and TUG $t(46) = -0.669, p =0.507$.

To examine associations between performance on each of the measures of fall risk, correlations between each of the measures was completed. In those with MCI (Table 3b), usual gait speed was strongly inversely associated with performance on the TUG ($\rho = -0.680, p = .000$) and moderately inversely associated with the FTSTS ($\rho = -0.463, p = .015$) while a significant moderate relationship between the FTSTS and the TUG ($\rho = .586, p = .001$) existed. Balance confidence as measured with the ABC, had a statistically
significant moderate relationship with the TUG ($\rho = -0.476, p = 0.012$), but non-statistically significant relationships with FTSTS scores ($\rho = -0.265, p = 0.181$) and usual gait speed ($\rho = -0.223, p = 0.264$) in those with MCI. In the Non-MCI group, associations between each of the fall risk screening tools were statistically significant, with the exception of the FTSTS and the ABC ($r = -0.344, p = 0.127$) (Table 3c).

**Table 3b. Correlations between Fall Risk Screening Tool Scores in those with MCI (N=27)**

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>FTSTS</th>
<th>TUG</th>
<th>ABC</th>
<th>Usual Gait Speed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTSTS</td>
<td>$\rho = 0.586^*$</td>
<td>$\rho = -0.265$</td>
<td>$\rho = -0.463^*$</td>
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<tr>
<td>TUG</td>
<td>$\rho = 0.586^*$</td>
<td>$\rho = -0.476^*$</td>
<td>$\rho = -0.476^*$</td>
<td>$\rho = -0.680^*$</td>
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<tr>
<td>ABC</td>
<td>$\rho = -0.265$</td>
<td>$\rho = -0.476^*$</td>
<td>$\rho = -0.680^*$</td>
<td>$\rho = 0.223$</td>
</tr>
</tbody>
</table>

Abbreviations: TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale

*: $p < 0.05$ All correlations performed with Spearman’s rho

**Table 3c. Correlations between Fall Risk Screening Tool Scores in those without MCI (Non-MCI group) (N=21)**

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>FTSTS</th>
<th>TUG</th>
<th>ABC</th>
<th>Usual Gait Speed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTSTS</td>
<td>$r = 0.653^*$</td>
<td>$r = -0.411$</td>
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<tr>
<td>TUG</td>
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<tr>
<td>ABC</td>
<td>$r = -0.411$</td>
<td>$r = -0.718^*$</td>
<td>$r = -0.588^*$</td>
<td>$r = 0.599^*$</td>
</tr>
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</table>

Abbreviations: TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale

*: $p < 0.05$ All correlations performed with Pearson’s Product Moment Correlation

**Discussion**

In general, those with MCI had a greater history of falling and performed worse on the four different measures of fall risk, however, they were not statistically significantly different than the control group. These findings may be a reflection of a small sample size and varying methodology as previous researchers have reported differences in gait speed, impaired performance on measures of balance, and poorer performance on the TUG in those with MCI.
Average gait speed measurements in the MCI group were below 1.0 m/sec indicating that they were at a higher risk of physical decline and falls. Although changes in gait have been reported in those with MCI, a statistically significant difference was not found in gait speed between the two groups in this study. This difference may possibly be a result of the methods used in measuring gait speed. First, changes in gait speed in those with MCI have been detected using measurements performed over six meters whereas this study used a three meter measurement which, despite having established reliability, it may not be an equal comparison. Second, differences in gait speed have been reported when older adults with MCI were required to perform a secondary attention demanding task while walking. It was hypothesized that gait speed changes in older adults with MCI were directly influenced by the additional cognitive challenge required during dual task ambulation. This may indicate that perhaps a pure gait speed measure, without any required cognitive component, may not be able to detect changes in gait speed influenced by the decreased cognitive processes found in MCI. This may present in daily activities in older adults through increased variability in gait speed in challenging environments (such as walking in a crowded area) where the task requires processing of multiple cognitive inputs and thus increasing their risk of falling as compared to quiet hallway walking.

A wide range of TUG scores were present in those with MCI, however mean scores were below the cutoff for fall risk and not significantly different than those in the control group. Other studies have reported a significant relationship between the cognitive deficits in MCI and the TUG despite having mean scores on the TUG below the cutoff for risk for falling. In Donoghue and colleagues population based study, a
statistically significant association between poorer performance on the TUG and the MoCA was found despite having median scores on the TUG (8.5 seconds) which were better than mean TUG score of subjects with MCI in this study (10.76 seconds). In addition, a significant relationship between decreased executive function and poorer performance on the TUG (mean score: 11.96 seconds) has been reported in those in those with amnestic MCI. In this study, scores on the TUG did not significantly differ in those with MCI, however significant associations have been reported between the TUG and cognitive deficits found in MCI, which may suggest that the TUG should be used in conjunction with a measure of MCI, such as the MoCA. The MoCA could then be used as an early indicator for cognitive decline in order to help choose appropriate measures of fall risk and create interventions which can still challenge the individual, however further investigation is warranted.

Associations between performances on each of the four fall risk screening tools used in this study have been reported in the literature, however these same relationships were not present in the MCI group. When correlations between the measures of fall risk were performed, the ABC was not significantly associated with the FTST or usual gait speed in those with MCI despite having mean scores on those fall risk measures that would indicate impaired performance on those tools. This finding may be explained through the use of a self-report measure of balance confidence in those with cognitive impairments, of which confidence may be over or under reported.

Decreased balance confidence has been previously associated with decreased gait speeds in cognitively intact older adults, yet the lack of a relationship between the ABC and usual gait speed in those with MCI provides more evidence to the questionable
efficacy in using the ABC in older adults with MCI. In addition, it has been reported that changes in gait speed have been found in older adults with MCI. The lack of a significant relationship between gait speed and the ABC in those with MCI indicates that a measure of balance confidence may not be the strongest choice of instruments to assess fall risk in this population. This finding has practical use in that other measures of fall risk should be employed for older adults with MCI as impairments in physical performance previously described in those with MCI were not associated with a self-assessment of balance confidence.

Performance on the FTSTS and ABC were not associated with each other in those with MCI. A significant relationship between these tools has been previously reported in cognitively intact older adults with balance disorders. The difference in finding may be a result of the different study populations as roughly half of the subjects in the previous study had a diagnosed balance disorder with a higher history of falling, of which, the same could not be said of the subjects in this study.

Finally, impaired performance on the FTSTS has been reported in frail older adults. The lack of a statistically significant difference in performance on this tool in those with MCI could be accounted for in the population as subjects in the MCI group were high functioning. This indicates that the FTSTS should be considered for those older adults with deficits beyond those found in MCI, however further studies should be performed to examine the relationship between FTSTS performance and measures of MCI.
Limitations

This study used an age matched control group along with a sample of community dwelling older adults with MCI to compare performance on valid and reliable measures of MCI and fall risk. There were however, several limitations. Overall, the small sample size limits the ability to determine predictors of fall risk in this study and, therefore, it is unknown if the same risk factors for falling in cognitively intact older adults can predict fall risk in those with MCI. Subjects were taken from a convenience sample of mostly white, highly educated older adults in one geographic location and this relatively homogenous population limits the generalizability of this study. Subjects were highly functional, independent with ADLs and IADLs, and had a limited history of falling (less than 50%) and thus performance on the fall risk assessments reflected the characteristics of this group which may not be consistent with community dwelling older adults with an established diagnosis of MCI. The criteria to categorize MCI has been controversial and has only recently been agreed upon, therefore a limitation exists in that only one neuropsychological assessment tool was used to determine the presence of MCI. Future studies should include other cognitive measures to determine how MCI would influence measures of fall risk. Finally, over half of the subjects had MCI which may have limited their ability to recall their history of falling.

Areas for Further Study

A wider range of scores was present for each of the measures of fall risk in those with MCI which may indicate the presence of a low functioning group within the twenty-seven subjects and therefore this should be investigated further through the use of a larger more diverse population of older adults representing the different subtypes of MCI would
be beneficial to utilize in future studies to examine the influence of MCI on measures of fall risk. Deficits in other cognitive processes found in MCI, like executive function, have been shown to influence risk of falling\textsuperscript{44} and although this was not a part of the analyses in this study, controlling for EF in those with MCI should be considered in future studies to determine if EF influences performance on various fall risk tools. Further studies should include variables that could be used to predict fall risk measure performance in those with MCI. Finally, it may be beneficial to consider adding physical and cognitive tasks of graded complexity to identify the point at which MCI significantly influences physical performance.

**Conclusion**

In summary, statistically significant differences were not found between overall mean scores on the ABC, FTSTS, TUG and usual gait speed measures in those with MCI as determined with a MoCA score of less than 26. Due to the limitations of the sample population including size, further studies should be performed to examine how other screening or diagnostic measures of MCI may influence performance on measures of fall risk.
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CHAPTER IV

THE EFFECT OF A COMPUTERIZED COGNITIVE TRAINING PROGRAM ON FALL RISK IN A GROUP OF COMMUNITY DWELLING OLDER ADULTS

Abstract

Background and Purpose: With the growing population of older adults in the United States, the increasing incidence of cognitive disorders is a concern as those with impaired cognition are at a higher risk of falling. Results of cognitive training studies have demonstrated improvements in various domains of cognition with some reported transfer effects of improvements in function, however it is unknown if changes on measures of fall risk are present following cognitive training. The purpose of this study was to examine if a six week computerized cognitive training program focused on the areas of attention, set shifting, and visual spatial ability impacts fall risk in a group of community dwelling older adults. Methods: Thirty nine community dwelling older adults participated in either the control group (N=25) or the intervention group (N=14). Intervention group subjects participated in 6 weeks of computerized cognitive training using an online neuropsychological software program, Lumosity. Comparisons of mean scores on six measures; four measures of fall risk (usual gait speed, FTSTS, TUG and ABC) and two measures of cognition (TMT-B, MoCA) were completed between groups at pretest and within groups at posttest. Results: Individual t-tests and Mann Whitney U tests indicated that the groups did not differ in their age $t(37) = .740, p = .464$; education level $t(37) =$
1.50, p = .140; nor in the performance on measures of fall risk and cognition at pre-test measurements. Following completion of an average of 19.2 sessions of computerized cognitive training, there were no statistically significant improvements on outcomes measures in the intervention group. Discussion: Participating in a six week computerized cognitive training program did not result in a statistically significant improvement in measures of fall risk or cognition which may have been subject to recall bias.

Conclusions: It is inconclusive as to whether improvements on outcomes measures were a result of cognitive training due to improvements found in both the control and intervention group and further investigation is warranted.

Key words: computerized cognitive training, fall risk, community dwelling older adults

Introduction

As the largest growing segment of the population, it is estimated that there will be 72 million older adults over the age of 65 by the year 2030 which is twice the number found in 2009.\textsuperscript{1} Along with this growth comes an increasing prevalence of age-associated cognitive diseases and disorders\textsuperscript{2} which will place a strain on available health care resources as declines in cognition have been associated with functional decline and nursing home placement.\textsuperscript{3,4} As one ages, the likelihood of cognitive loss increases. The terminal stage of cognitive loss known as dementia increases in prevalence with age affecting close to forty percent of those >90 years.\textsuperscript{5} Alzheimer’s disease (AD), the most common form of dementia, accounts for seventy percent of all dementias in the United States\textsuperscript{5,6} and is characterized by a decrease in cognition with resulting implications in safety and decision making.\textsuperscript{7} Interventions that address early cognitive loss have an
opportunity to improve the health and quality of life in older adults and as a result, research has recently begun to focus on early cognitive decline.

One type of early cognitive loss includes mild cognitive impairment (MCI) which is considered an intermediate state between normal cognitive aging and dementia and in many cases precedes the diagnoses of dementia. \(^6,^8\) It is characterized by having a global decline in cognition impacting multiple domains greater than what is expected for an individual’s age and education level but which does not interfere with activities of daily living. \(^9\) Several clinical subtypes of MCI exist and are characterized by the number and type of domains affected. \(^10\) MCI impacts between 22-39% \(^5\) of adults over the age of 65, with the progression to AD or other dementias continuing in roughly 20-30% of older adults. \(^11\) Another form of early cognitive loss occurs due to deficits in executive function (EF). Older adults with impaired EF have difficulty coordinating, integrating, organizing, and maintaining multiple inputs when continuously presented \(^12\) in order to complete common and complex tasks. \(^13\)

With a growing number of older adults at risk for cognitive decline, research efforts have concentrated on treatment and prevention efforts for various cognitive impairments with the overall goal of reducing the risk of cognitive decline while maximizing cognitive function. The available treatments for cognitive impairments have consisted of either a pharmacologic or nonpharmacologic approach, or a combination of the two. Pharmacologic interventions have not been effective in addressing mild deficits in cognition. \(^14\) Successful treatments for cognitive decline using a nonpharmacologic approach has included physical exercise \(^15\)-\(^17\) and cognitive training interventions \(^18,^19\). Cognitive training has been shown to be effective in those with MCI with improvements
in specific areas of cognition including EF.\textsuperscript{20-26} A domain specific approach to cognitive training has resulted in statistically significant improvements in the domains trained.\textsuperscript{14-16,19-29} Previous studies have used multiple different methods of training including differences in the frequency and duration of training sessions and programs used.

Improvements in function have been reported in older adults who have participated in computerized cognitive training interventions. This finding was first reported in a group of subjects assigned to the speed-of-processing training group in the Advanced Cognitive Training for Independent and Vital Elderly study (ACTIVE) which required them to complete progressively complex tasks on a computer.\textsuperscript{30,31} This intervention resulted in those subjects having less difficulty with instrumental activities of daily living in the five year follow up.\textsuperscript{30,31} When both computerized cognitive training and physical activities or exercises and have been provided, significant improvements in physical function have been found\textsuperscript{22} including in those with MCI.\textsuperscript{31} Statistically significant improvements in processing speed and in gait speed (.04 m/second) have been reported in a group of sedentary older adults after completing an eight week long computerized cognitive training program using a progressively challenging neuropsychological software program.\textsuperscript{32} Because cognitive training has been shown to be effective in maintaining the cognitive vitality of healthy older adults, it has been suggested that it may serve to ‘optimize’ the cognitive functioning of persons with MCI and perhaps contribute to a slowing of cognitive decline and onset of disability.\textsuperscript{29}

Recently a new area of study has emerged that has focused on the cognitive processes (i.e. cognitive domains) which influence maintaining balance and stability for completion of activities in older adults with cognitive impairments. A twofold increased
risk of falling exists in older adults with deficits in cognition\textsuperscript{33} and along with that, an increased likelihood for institutionalization\textsuperscript{34} after falling. For those with early cognitive loss, a greater prevalence of impairments in balance and gait have been reported,\textsuperscript{35} as well as poor performance on functional mobility tasks.\textsuperscript{17,35,36} Deficits in the specific cognitive domains of set shifting and processing speed have been associated with decreased walking speeds, changes in gait stability, and an increased risk of falling in older adults.\textsuperscript{37} Other cognitive processes that are a part of EF that impact fall risk include visual spatial ability which is necessary for safe functional mobility\textsuperscript{38-39} and attention.\textsuperscript{38}

The influence of cognitive impairments on physical function and fall risk has resulted in an increased amount of research being performed that addresses interventions to prevent, maintain, and improve cognition. Studies addressing the effect of a cognitive intervention on improvements in physical function are preliminary in nature, but they support the idea that a domain specific computerized cognitive training program focusing on visual spatial ability, set shifting, and attention may improve cognitive components that influence gait, and perhaps reduce the risk of falls.\textsuperscript{38-40}

**Purpose**

This purpose of this study was to examine if a six week computerized cognitive training program which trained three cognitive domains reported to influence risk impacted performance on measures of fall risk in a group of community dwelling older adults. The following research question guided this study: Does a six week computerized cognitive training program focused on the areas of attention, set shifting, and visual spatial ability impact fall risk in a group of community dwelling older adults?
Methods

A pretest-posttest quasi experimental study comparing two groups of community dwelling older adults was completed. Recruitment occurred via presentations, brochures, and senior center newsletters which resulted in sixty-one potential subjects. Subjects who participated in the study met the inclusion criteria of living independently, being 65 years of age or older, being independent with transfers and ambulation without physical assistance of another person, able to communicate in English, having good vision with or without prescriptive lenses and being able to independently provide consent for participation. Subjects were excluded from this study if they had an orthopedic surgery six months prior to testing, were currently receiving physical therapy services, had a history of a cerebrovascular accident, head trauma, other traumatic brain injury, were unable to meet the requirements of testing or the time commitment for the study, or if they were currently using or had a history of using any computerized cognition training software programs nine months prior to the study. Human Subjects Institutional Review Board approval was obtained from Western Michigan University and the University of Michigan-Flint.

Testing

Examiners consisted of the primary investigator and two graduate students who were trained on the research process and administration of the outcomes assessments during a one day training session to assure consistency of testing. Testing of subjects occurred in a quiet room at the senior centers between September 2011 and January 2012. Demographic information gathered through self-report included the subject’s date of birth, race and ethnicity, and education level. Other information gathered from the
subjects included medications, medical and surgical history, report of height and weight, and the use of prescription eyewear. Subjects were asked about their independence with instrumental activities of daily living (IADLS) and activities of daily living (ADLs). Subjects were asked to recall the number of times that he or she had fallen in the past six months. A fall was defined as an unintentional loss of balance that led to an unexpected change of position. Blood pressure was a single measurement performed in sitting using a sphygmomanometer and stethoscope. Heart rate was taken via palpation of the radial pulse and a stopwatch for sixty seconds. Vision was screened by their ability to correctly read printed material of two different sized fonts (12 point and 18 point font) and was graded as a yes or no response. Due to the influence of depression on fall risk, the thirty item paper and pencil Geriatric Depression Scale (GDS) was used to screen for depression with potential scores ranging from 0 to 30. Higher scores on the GDS indicate a greater degree of depression with scores of 0-9 considered ‘normal’, 10-19 as ‘mildly depressed’ and 20-30 as ‘severely depressed’.

Executive function was assessed using the Trail Making Test Part B (TMT-B) while the Montreal Cognitive Assessment tool (MoCA) was used as a measure of MCI. Fall risk was assessed using four assessment tools (Five Times Sit to Stand Test, Timed Up and Go, usual gait speed, and the Activities Specific Balance Confidence Scale) which have established reliability and validity to assess risk of falling. Cognition assessments were performed followed by fall risk assessments with standardized instructions provided. Initial testing occurred in a single session that lasted up to 45 minutes. All subjects were contacted by phone during the 5th week of the study as a reminder of their posttest session which occurred in the seventh week of the study. The
same measures of cognition and fall risk were completed in the post test measurement. Examiners were not blinded to experimental conditions as a result of the location of testing but were blinded to pretest assessment scores.

Cognitive and Fall Risk Measures

Montreal Cognitive Assessment Tool

The MoCA is a 30 point global measure of cognition used to screen for MCI. The MoCA assesses several different cognitive domains including short term memory recall, visuospatial ability, executive function, attention, concentration, working memory, orientation, and language. High sensitivity and specificity scores in detecting MCI have been reported.

Trail Making Test Part B (TMT-B)

The TMT-B is one component of the larger Trail Making Test which is comprised of parts A and B. TMT-B assesses attention, visual scanning, motor speed and coordination, mental flexibility, and working memory and is considered an accurate measure of EF. TMT-B is a paper and pencil test which consisted of the subject’s ability to draw a continuous line (i.e., the trail) without lifting the pencil from randomly positioned numbers (1-12) and letters (A-M) in ascending order alternating from number to letter (e.g., 1 to A to 2 to B to 3 etc.) until all numbers and letters are used. For this assessment the researcher observed the creation of the trail by the subject and recorded the time taken to complete the trail. If an error was made, the researcher immediately identified the error and instructed the subject to correct it. The maximum time allotted to complete the TMT-B was 300 seconds and the test was stopped if the subject reached this time.
Usual Gait Speed

Slower gait speeds have been identified as a risk factor for disability, cognitive impairment, institutionalization, falls, and/or mortality. Gait speed, measured as distance traveled over time, has been found to be highly reliable, and is easily performed in various environments. It has been identified as a predictor of physical decline and cognitive decline when provided a cognitive challenge. Age-adjusted norms for gait speed have been established. Usual gait speed was measured as the amount of time required to walk ten feet at the subject’s normal walking speed (speed: distance/time) which was later translated into meters/second for the analysis. Five feet of space was provided on each side of the marked distance to allow for acceleration and deceleration. Subjects performed this task twice and the mean time of the two trials was recorded.

Five Times Sit to Stand

The Five Times Sit to Stand (FTSTS) test is a valid and reliable tool to assess fall risk in the older adult which is easily performed in a variety of settings. It functions as an indicator of frailty and is associated with increased disability, morbidity and falls. This test consisted of measuring the amount of time it took for a subject to go from sitting in a supportive chair to full standing five successive times without the subject using his arms to aid in the process. Time was measured with a stopwatch from the moment the subject was told to ‘go’ to the moment he sat down in the chair following the fifth repetition. Norms for scores on the FTSTS to identify fall risk have been reported in the literature.
Timed Up and Go

The Timed Up and Go (TUG) test is a valid, reliable, and efficient measure of fall risk of community dwelling older adults that includes both physical and cognitive components.\textsuperscript{61-62} It requires individuals to go from sitting to standing, walk three meters, turn around and return back to the original chair and sit down again.\textsuperscript{63} Norms to identify risk of falling have been reported.\textsuperscript{44} A stopwatch was used to time the subject from the moment the subject was told to ‘go’ to the moment he sat back down in the chair.\textsuperscript{61}

Activities Specific Balance Confidence Scale

Assessment of balance confidence was performed using the Activities Specific Balance Confidence Scale (ABC).\textsuperscript{47} The ABC assesses a person’s fear of falling and lower scores are associated with higher risk of falls.\textsuperscript{47} It has been shown to have good reliability to assess fall risk.\textsuperscript{47,64} Using the protocol established by Powell and Myers,\textsuperscript{47} the subjects read each question on their own and then provided a numerical rating of how confident they were in their balance on sixteen different items. Each item was rated on a scale of 0\% (not confident) to 100\% (completely confident that they would not lose their balance or become unsteady while performing the activity) and balance confidence was scored as the mean of the sixteen responses as a percentage. Norms have been established for the ABC as well as cutoff scores for functional decline.\textsuperscript{47,64}

Intervention

Subjects in the intervention group participated in 6 weeks of computerized cognitive training using an easily accessible web based neuropsychological software program, Lumosity (Lumos Labs, CA). Lumosity was created under the supervision and consultation of a scientific board of neuroscientists and psychologists and includes
multiple computerized games aimed to train various domains of cognition with a progressive stimulus. It has been established for effective use in the geriatric population. Games chosen for this study focused on addressing specific cognitive domains that impact fall risk. The four games included: ‘Disconnection’ which addressed set shifting and attention; ‘Playing Koi’ which addressed visual spatial ability and attention; ‘Birdwatching’ which addressed attention and set shifting; and ‘Memory Matrix’ which addressed visual spatial ability and recall. Responses were recorded and tracked dynamically over time both within a session and across games. An individualized training effect was created through adjustments made to increase the challenge as performance improved or decrease the challenge when incorrect responses were made.

Data gathered from Lumosity included the frequency of sessions, the subject’s progress in each of the games, and the progress in each cognitive domain. Subjects were guided on how to complete each game in an introductory session to the software program where specific instructions were provided in both written and verbal forms. Subjects were provided an opportunity for further clarification of the instructions following the session. After the initial session, subjects were asked to independently complete each of the four games once per session at a frequency of three times per week for 15-20 minutes/session over a total of six weeks using a computer of their choice. Subjects were requested to refrain from playing other Lumosity games during the study and to track this, they were asked in the posttest session whether they had used any other forms of computerized or noncomputerized cognitive training programs during the duration of the study.
Data Analysis

The main independent variables for this investigation were gender and age. The dependent variables included the measures of fall risk and cognition. Descriptive statistics including means, medians, and standard deviations were used to describe the data. Between groups differences at the pre and post measurements were analyzed by using individual \( t \)-tests or Mann Whitney nonparametric (‘exact’ method) tests as appropriate. To compare the difference in measures of cognition and fall risk following computerized cognitive training, paired samples \( t \)-tests were performed for variables that met the assumptions for the use of parametric statistics while Wilcoxon Sign Ranked tests were performed for nonparametric comparisons. A significance level of .05 was used for all comparisons and statistical analyses were completed with SPSS version 20 (SPSS Inc., Chicago, IL).

Results

Sixty-one older adults were recruited for the study. Forty-eight met the inclusion criteria and went through the informed consent process and testing. Twenty-five subjects were in the control group, while twenty four were in the intervention group. In the intervention group two subjects dropped out; one due to computer issues while the other was not able to comply with the training protocol and two additional subjects did not complete post testing despite being contacted by the researchers. Another six subjects were excluded due to poor compliance (less than 50%) with the training protocol. This resulted in a total of fourteen subjects in the intervention group used in the analyses. Demographics for each of the groups can be found in Table 4a. All subjects were independent with ADLs and IADLs and passed the vision screening as they were able to
Table 4a. Demographics, Past Medical History, and Medical Conditions of Community Dwelling Older Adult Participants by Group Assignment (N=39)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group N=25</th>
<th>Intervention Group N=14</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean or percentage (SD)</td>
<td>Range</td>
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<tr>
<td>Average age (years)</td>
<td>75.68 (6.88)</td>
<td>66-91</td>
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<tr>
<td>Medications</td>
<td>6.38 (5.21)</td>
<td>0-24</td>
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<tr>
<td>Body Mass Index (kg/m²)</td>
<td>26.93 (5.75)</td>
<td>15.6-39.4</td>
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<tr>
<td>GDS scores</td>
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</table>

Abbreviations: GDS: Geriatric Depression Scale; PMH: Past Medical History; HEENT: Head, Eyes, Ears, Nose Throat; GI: Gastrointestinal; GU: Genitourinary
read the printed material of both font sizes. Individual $t$-tests and Mann Whitney $U$ tests indicated that the groups did not differ at pretest in their age $t(37) = .740, p = .464$; education level $t(37) = 1.50, p = .140$; nor in the performance on the fall risk and cognition assessments TMT-B $t(37) = 1.17, p = 0.246$; MoCA $t(37) = -0.252, p = 0.803$; usual gait speed $t(37) = -1.581, p = 0.122$; FTSTS $U= 121.5, z=-1.57, p=0.12$; ABC $U=145.0, z=-0.879, p=0.38$; and TUG $U= 153.00, z= -0.644, p=0.529$. No significant differences were found between groups on cognition and fall risk measures in post testing.

Following completion of six weeks of computerized cognitive training with an average of 19.2 sessions, results indicated that subjects in the intervention group demonstrated an improvement in usual gait speed ($M_{change} = 0.04, SD= 0.29, t(13) = -0.577, p = 0.57, d=0.13$); MoCA scores ($M_{change} = 1.78, SD= 3.26, t(13) = 1.08, p = 0.29, d= 0.72$); and TMT-B scores ($M_{change} = -8.54, SD= 29.4, t(13) = -2.04, p = 0.06, d=0.25$); however they were not statistically significant. Scores on the FTSTS, ABC, and TUG did not improve following the computerized cognitive training and were not statistically significant: FTSTS ($M_{change}=0.09, z= -.03, p=1.0, r= -0.01$); ABC ($M_{change} =-0.91, z= -0.734, p=0.497, r= -0.40$); TUG ($M_{change} = 0.36, z= -0.879, p=0.97, r=-.017$). Changes in the fall risk and cognitive measures in both groups can be found in Table 4b.
Table 4b. Measurement Tool Scores by Group Assignment (N=39)

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>Intervention Group (N=13)</th>
<th>Control Group (N=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pretest (T₁) Mean (SD) Range</td>
<td>Posttest (T₂) Mean (SD) Range</td>
</tr>
<tr>
<td>ABC</td>
<td>84.53 (7.05) 73.0- 95.63</td>
<td>83.03 (11.81) 58.75- 95.31</td>
</tr>
<tr>
<td>FTSTS</td>
<td>12.91 (2.63) 8.0-15.70</td>
<td>13.01 (2.81) 7.30-16.20</td>
</tr>
<tr>
<td>Usual Gait Speed</td>
<td>1.08 (.36) .49- 1.62</td>
<td>1.12 (.29) .53- 1.74</td>
</tr>
<tr>
<td>TUG</td>
<td>9.60 (2.17) 6.80-14.12</td>
<td>9.96 (2.51) 6.10-15.70</td>
</tr>
<tr>
<td>MoCA</td>
<td>24.64 (2.17) 21-28</td>
<td>26.43 (2.79) 20-30</td>
</tr>
<tr>
<td>TMT-B</td>
<td>83.43 (36.65) 35.88-175.5</td>
<td>74.90 (32.10) 40.93-141.0</td>
</tr>
<tr>
<td></td>
<td>81.84 (19.14) 21.25-99.37</td>
<td>84.60 (15.83) 39.27-100.00</td>
</tr>
<tr>
<td>FTSTS</td>
<td>15.17 (4.49) 8.5-30.30</td>
<td>14.21 (3.43) 7.70-21.80</td>
</tr>
<tr>
<td>Usual Gait Speed</td>
<td>.93 (.26) .45- 1.45</td>
<td>1.03 (.22) .60- 1.39</td>
</tr>
<tr>
<td>TUG</td>
<td>11.17 (4.59) 6.6-27.60</td>
<td>10.38 (2.83) 7.30-17.90</td>
</tr>
<tr>
<td>MoCA</td>
<td>24.40 (3.21) 17- 29</td>
<td>26.32 (2.76) 20-30</td>
</tr>
<tr>
<td>TMT-B</td>
<td>97.93 (36.97) 49.10-164.00</td>
<td>84.49 (27.11) 37.60-140.00</td>
</tr>
</tbody>
</table>

Abbreviations: MoCA: Montreal Cognitive Assessment Tool, TMT-B: Trail Making Test part B, FTSTS: Five Times Sit to Stand test, TUG: Timed Up and Go test, ABC: Activities Specific Balance Confidence Scale
*: p<.05

Discussion

This study examined whether participating in a six week computerized cognitive training program focused on the areas of attention, set shifting, and visual spatial ability impact fall risk in a group of community dwelling older adults and found no statistically significant differences on measures of fall risk, MCI, or EF in the intervention group after completing cognitive training. Differences in mean scores on the ABC, usual gait speed, MoCA, and TMT-B were found in the control group which may be likely due to an influence of recall bias or test-retest error.
Of the four fall risk screening tools used in this study, the only measure that demonstrated a trend towards improvement following cognitive training was usual gait speed, however it was not statistically significant. In a comparable study, Verghese et al. found a statistically significant improvement in gait speed following the completion of a similar computerized cognitive program.\textsuperscript{32} The difference in findings may be likely due to the dissimilarity in methodology, specifically, the methods of measuring gait speed as well as the use of specific inclusion criteria relative to baseline gait speed.\textsuperscript{32} As a part of the inclusion criteria, Verghese and colleagues controlled for primary gait speed measurements and sought to include only those with walking speeds of less than 1.0m/sec.\textsuperscript{32} Gait speeds of less than 1.0m/sec have been reported to be statistically significant predictors of fall risk and physical decline.\textsuperscript{11} In addition, although gait speed measurements of three meters (10 feet) have established reliability,\textsuperscript{72} other researchers have reported greater reliability in gait speed measurements of six meters (20 feet).

Although there were no statistically significant improvements on a measure of MCI, the MoCA, improvements on other measures of cognition have been reported following computerized cognitive training interventions in those with MCI.\textsuperscript{67,68} In a randomized controlled trial of a small group of older adults with amnestic MCI, Finn and McDonald reported a statistically significant improvement on a measure of attention following computerized cognitive training with the same software in this study.\textsuperscript{68} Cipriani et al. found a statistically significant improvement on a global measure of cognition, the MMSE, and an assessment of memory, the digit symbol test, in a group of 10 subjects with MCI following completion of a computerized neuropsychological software training program.\textsuperscript{67} Each of these studies had small sample sizes, however the difference in results
may be attributed to the study populations as both of the other studies had MCI. Comparatively, subject group assignment in this study was based on location and not on level of cognitive impairment which is a limitation that can be addressed in future studies.

The minimally clinical important difference of the MoCA has not been established, although some have suggested that a two point increase is a significant finding.\textsuperscript{10} The mean difference in scores on the MoCA in the intervention group (1.78 points), although not statistically significant, generated a large effect size. The magnitude of the effect size of the TMT-B in the intervention group is also noteworthy as high effect sizes have been reported following the completion of non-computerized cognitive training interventions.\textsuperscript{69} Guidelines from the APA have defined the threshold for clinical significance for cognitive interventions as having an effect size of 0.20 along with a statistically significant result.\textsuperscript{70} Because sample size may have limited statistical significance, further investigation with a larger sample population should be performed to determine if these large effect sizes persist along with a statistically significant result.

Subjects in the intervention group did not demonstrate a statistically significant improvement after completing an average of 19.2 sessions over six weeks. Currently, the most effective treatment dosage of a computerized cognitive training program has not been established. Studies which have reported statistically significant improvements on cognitive measures after cognitive training have used training frequencies that ranged from once per week to 5x/wk with the length of time per session ranging from 15 to 45 minutes over a period of 3-14 weeks.\textsuperscript{32,55,67,68} In addition, the differences in neuropsychological instruments used to measure outcomes creates an additional
challenge of performing an accurate comparison. Due to the variability in dosage and modes of training used in other cognitive training studies which have reported statistically significant changes following computerized cognitive training, it may be likely that the intervention dosage and frequency was not sufficient in this study.

The effectiveness of this specific form of computerized cognitive training varies. Similar to this study, Fortman used cognitive games from Lumosity and reported no statistically significant differences on sixteen different cognitive measures, including the TMT-B, in a group of 16 older adults (mean age= 70.3 years) following a training program of 10-15 minutes per session, 4x/wk over 8 weeks. In contrast, others have reported an improvement on a measure of attention following a training program with the same software in this study. The difference in results may be attributed to the different cognitive training games used. Due to the high degree of variability between methods employed in computerized cognitive training intervention studies which have resulted in significant findings, further investigation into the appropriate frequency and duration of interventions should be performed.

TMT-B scores in the intervention group were lower at the pretest measurement indicating that EF was less impaired in the intervention group; however a wide range of scores existed at both the pretest and posttest measurements. This indicates that a potential bimodal distribution of TMT-B scores may have been present at both measurements which would have limited the ability to detect a difference in overall mean scores after completion of a cognitive training program targeted to address components of EF. Future studies should consider including controlling for the subjects’ level of EF in the methodology in order to detect a difference in scores following cognitive training.
Measures of fall risk that have not been reported to be associated with deficits in EF, the FTSTS and ABC, did not change following the completion of a computerized cognitive training program. This result might be expected as completion of a cognitive training program targeted to address cognitive domains required for higher order processing should not result in a difference in performance on tasks that do not utilize those cognitive processes.

**Limitations**

Some limitations of the study should be acknowledged. The study was small and underpowered with a high (41%) attrition rate (combined drop out and poor compliance) in the intervention group limiting the ability to detect real effects. The study was a single, not double blind study. Subjects involved in this study were taken from a convenience sample of mostly white, highly educated older adults in one geographic location, limiting the generalizability of this study. Over half of the subjects in both groups did not report a history of falling, which may bias both the results of the fall risk screening tool performance as well as limit any improvement they might have had as a result of the intervention. Post testing occurred during the winter months in Michigan which may have influenced the subject’s self-report of confidence in balance. In addition, administration of the cognitive assessment tools six weeks after the initial assessment may have been subject to a learning effect which could have influenced the results in post testing.

Although a gait speed measurement over ten feet has reported reliability, a limitation exists in the comparison of gait speed measurements of 10 feet (3 meters) in comparison to other studies which have used measures of 20 feet or more. Further studies
should include a measure of 20 feet with 10 feet on each side for acceleration and deceleration.

The recommended dose of cognitive training does not currently exist in the literature, therefore it is unknown if the training program used in this study was strong enough to facilitate a training effect. Further studies should examine how different dosages of cognitive training may impact measures of fall risk.

Subjects completed the trainings at home using their own computers and using a more structured clinical environment may have improved training compliance. The lack of compliance impacted the overall number of subjects included in the final analyses which influenced the ability to detect a difference in fall risk and cognitive measures in post testing.

The presence of cognitive impairments within subjects may have influenced the outcomes in both groups and was not controlled for in the analyses. Addressing the presence of impairments in cognition would have been beneficial to examine in this study, yet with the small number of subjects in the intervention group a significant finding in this group may still have limited generalizability.

**Areas for Further Study**

This study was considerably limited by sample size as well as the lack of random assignment. Future studies should include a larger number of subjects with random assignment to intervention/control groups in order to determine if cognitive training interventions impact performance on measures of fall risk. In addition, as previous research has reported a beneficial result of computerized cognitive training in those with MCI, and as the transition rate to Alzheimer’s disease differs for the different forms of
MCI, future studies should examine how older adults with various types of MCI benefit from participation in a computerized cognitive training program.

**Conclusion**

In this study, participation in a six week computerized cognitive training program did not result in a statistically significant difference on four measures of fall risk nor on measures of MCI or EF. However, limitations in the study impacted overall findings and further studies should be conducted.
References


CHAPTER V

CONCLUSION AND DISCUSSION

Overview

The aim of this three-paper dissertation was to examine the relationship between fall risk, EF, and MCI in community dwelling older adults. An additional aim was to examine if participation in a computerized cognitive training program targeting cognitive domains reported to influence fall risk impacted performance on measures of fall risk in community dwelling older adults.

All three papers used data obtained from a cross sectional intervention study completed in a group of community dwelling older adults. Valid and reliable measures of fall risk used included the FTSTS, the ABC, usual gait speed, and the TUG. Papers one and two examined associations between an older adult’s performance on four fall risk measures and two different cognitive measures; a measure of EF and a measure of MCI. Paper one examined the relationship between the TMT-B, a measure of EF, and the four measures of fall risk including the completion of regression models to determine if EF could serve as a predictor of performance on fall risk measures. In paper two, the MoCA was used to detect the presence of MCI and was used as the basis for subject group assignment where comparisons of performance on each of the four fall risk measures was completed.
In paper three, results of an intervention study were examined to determine if participation in a six week domain specific computerized cognitive training program influenced performance on measures of cognition and fall risk in a group of community dwelling older adults.

This final chapter summarizes the major findings and their implications for future research. It also discusses the limitations of the research and how those limitations may have affected the results.

**Summary of Study Findings**

**Paper One**

This paper investigated associations between EF as measured with the TMT-B and performance on four different measures of fall risk in a group of forty seven community dwelling older adults from three different senior centers. The following research question was addressed in this study: What is the relationship between EF and fall risk in a group of community dwelling older adults? Correlations between each of the four measures of fall risk and a measure of EF, the TMT-B, was completed. The predictive value of the TMT-B scores were then explored for each fall risk measure using multiple linear regression analyses, while controlling for the confounding variables of age\(^1\) and education,\(^1\) in order to clarify its unique contribution to predicting fall risk screening tool performance. Due to the presence of a wide range of TMT-B scores, the data was split into two groups in posthoc analyses using a cutoff score of 26 on the MoCA which indicates the presence of MCI.\(^2\) Correlations were completed for each group to further examine the relationship between EF and measures of fall risk in those with MCI and those without MCI.
Descriptive statistics revealed a relatively homogeneous group with the majority of adults being educated white females with a limited history of falling and above average performance on fall risk measures. EF as measured with the TMT-B was found to be statistically significantly associated with usual gait speed in this group of community dwelling older adults which remained in regression analyses after adjusting for age and education. Post hoc analyses revealed statistically significant moderate associations between EF and the TUG as well as a stronger relationship between EF and usual gait speed in those with MCI. Statistically significant associations were not found between EF and the FTSTS or with balance confidence (ABC) measures in the general population of subjects or in those with MCI.

**Paper Two**

This study sought to describe how performance differed on measures of fall risk in those with MCI in a group of community dwelling older adults. Using the MoCA as a screening tool for MCI, mean scores between two groups of community dwelling older adults, those with MCI (MoCA scores <26 (N=27)) and those without MCI (MoCA scores ≥ 26 (N=21)) were compared to determine if performance on four fall risk screening tools, the TUG, ABC, FTSTS, and usual gait speed, differed in the presence of MCI. The focus of the analysis was to answer the primary research question: How does the presence of mild cognitive impairment impact fall risk screening tool scores in a group of community dwelling older adults? Comparisons of mean scores on the four measures of fall risk were completed to detect any statistically significant differences between groups. Because performance on each of the four fall risk screening tools has been found to be significantly associated with one another in cognitively intact
correlations between each of the fall risk screening tools were performed in both groups to determine if the same relationships existed. The results of the analyses indicated that statistically significant differences between groups were not found on the four fall risk measures. A significant relationship between the TUG, FTSTS, and usual gait speed was present within both groups which is consistent with previous literature. In the MCI group, the ABC, was not associated with usual gait speed which differs from the Non-MCI group as well as previous studies. In both groups, the ABC and the FTSTS were not significantly associated.

**Paper Three**

Using an intervention and non-equivalent control group, this study examined if a six week computerized neuropsychological software training program focused on training the cognitive domains of attention, set shifting, and visual spatial ability influenced fall risk in a group of community dwelling older adults. Group assignment was completed based on the specific senior center of attendance and done to decrease the threat to internal validity and cross contamination of subjects. Measures of fall risk, EF, and MCI were assessed at pre and post measurements.

The primary research question was: Does a six week computerized cognitive training program focused on the areas of attention, set shifting, and visual spatial ability impact fall risk in a group of community dwelling older adults?

Differences between groups at the pre and post measurements were analyzed using individual *t*-tests or Mann Whitney *U* tests. To compare the difference in mean scores on each of the fall risk measures and cognitive assessments within the intervention group, paired samples *t*-tests were performed for variables that met the assumptions for
parametric statistics while Wilcoxon Sign Ranked tests were performed for variables that did not meet the assumptions for parametric statistics.

The completion of a six week computerized cognitive training program using an internet based neuropsychological software program with games targeting the cognitive domains of set shifting, attention, and visual spatial ability did not change scores in a statistically significant manner on measures of fall risk, EF, and MCI in a group of fourteen community dwelling older adults. Improvements on the measures of usual gait speed, the MoCA, and the TMT-B were found in both the intervention and control groups which may have been a result of test-retest error or recall bias.

**Discussion of Results**

This dissertation sought to investigate the relationship between EF, MCI, and fall risk in a group of community dwelling older adults. Results of the three studies add to the existing body of knowledge in this area.

Decreased gait speeds have been reported in those with cognitive impairment.\(^3,4\) Paper one found a significant association between usual gait speed measurements and EF as measured with the TMT-B which was present after controlling for age and education and found to be even more strongly associated in those with MCI. This finding adds to what Montero et al. reported when examining the qualitative and quantitative components of gait in adults with MCI,\(^5\) but also expands this area in that an association was found using simple measures of EF and MCI which could be easily employed in practice. Because oftentimes the presence of cognitive impairment goes undetected,\(^6\) these results provide evidence for the necessary utilization of screening tools to determine baseline EF levels and screen for MCI as a component of a fall risk assessment.
Impaired performance on the TUG has been found in those with MCI in a population of older adults using the MoCA as a screening tool and similarly, the TUG was statistically significantly associated with EF deficits in those with MCI. McGough et al. reported a statistically significant association between the TMT-B and the TUG in those with amnestic MCI. Paper one provides more evidence to the relationship between EF and TUG performance as it was stronger in those with MCI as determined by MoCA scores as opposed to just the amnestic subtype of MCI. Older adults with MCI have been reported to perform worse on activities with a high cognitive load and therefore the relationship between EF and the cognitive demand required to complete the TUG may underlie this association.

Associations between the ABC and the FTSTS were not found to be significantly associated with EF in the general population or in those with MCI as described in paper one. Performance on those same tools did not significantly differ in those with MCI as compared to cognitively intact older adults in paper two and showed no appreciable or statistically significant changes after computerized cognitive training as reported in paper three. It may be likely that those fall risk measures may not use the higher order cognitive functions found in EF or those known to be impaired in MCI, which may account for the findings. The lack of a relationship between EF and those tools should be considered when selecting measures of fall risk in community dwelling older adults with decreased EF. Although an association between a component of EF, set shifting, and the ABC has been reported, it is possible that the TMT-B which utilizes several different areas of cognition may not be able to detect a relationship with balance confidence. Further research is needed to examine this relationship.
Global measures of cognition that have been used primarily to detect Alzheimer’s disease have reported to be associated with impaired FTSTS performance, however a statistically significant correlation between a measure of EF and the FTSTS was not found in paper one. This suggests that the FTSTS may not require the high level cognitive processes associated with EF. The FTSTS has also been reported to function as an indicator of frailty of which the subjects in these papers would not be considered frail. Therefore, the results of paper one expand our understanding that perhaps the FTSTS would be best used as a measure of fall risk in those with cognitive impairments greater than having deficits in EF.

Mean scores on four fall risk screening tools were not statistically significantly different in paper two in a group of community dwelling older adults with MCI which contrasts previous researchers who found differences in gait speed, and impaired performance on a balance assessment in this population. This difference may be explained through the methods used in measuring gait speed. First, a measure of gait speed over ten feet (3 meters), despite having established reliability, may serve as a limitation to comparing gait speed measures performed over twenty feet (6 meters). Second, differences in gait speed, variability, step time and double support time were reported in older adults with MCI and were hypothesized to be influenced by an additional cognitive challenge which was performed during ambulation. This may perhaps indicate that a pure gait speed measure, without any required cognitive component, may not detect changes in gait speed in those with MCI as gait variability has been reported to be much more evident when older adults were required to complete a cognitive task.
The lack of a relationship between the ABC and usual gait speed in paper two in the MCI group contrasts with previous studies which have found an association between decreased balance confidence and decreased gait speeds in cognitively intact older adults.9,18 This finding has practical use in that the utilization of the ABC in older adults with MCI should be performed with caution as a self-rating of balance confidence was not associated with physical performance measures.

A statistically significant difference on measures of fall risk and cognition were not found after completion of a six week computerized neuropsychological training program, however limitations within the study’s design and sample size may have influenced the overall outcomes found. Improvements in gait speed by .04m/sec, the same improvement found in the intervention group, were reported in a group of sedentary older adults whose baseline gait speed was less than 1.0m/sec.19 Gait speeds of less than 1.0 m/sec have been reported to predict fall risk and physical decline20 and have also been associated with decreased EF.3 Therefore it is possible that older adults who are at a higher risk of falling or who have a greater degree of cognitive impairment than those used in this study may benefit from cognitive training interventions, however further studies should be performed.

Conclusion and Clinical Implications

The results of these three papers provide evidence of the relationship between EF, MCI and fall risk that may be used in clinical settings.

Paper one provides several key recommendations for the examination of fall risk in clinical practice for those with deficits in EF. First, as deficits in EF were statistically significantly associated with usual gait speed in both the general population and in those
with MCI, the inclusion of a measure of EF, such as the TMT-B should be considered when examining gait speed as a component of a fall risk assessment in older adults. Second, in those with MCI as detected with the MoCA, the TMT-B had a moderate relationship with performance on the TUG and with usual gait speed and as a result, impairments on these fall risk screening tools may be highly influenced by impairments in EF. Therefore, screening for EF in older adults with MCI may provide more information as to the role that impaired processing has with functional mobility. Finally, higher order cognitive processes of EF were not associated with balance confidence or FTSTS performance and should be taken into consideration when choosing fall risk measures in those with EF impairments. Specifically, one would not expect that deficits in EF would be associated with FTSTS performance or with balance confidence.

Paper two provides evidence that may assist clinicians in the selection and interpretation of measure of fall risk in those with MCI. First, impairments on the TUG, usual gait speed, and the FTSTS were significantly associated with performance on one another. For example, if gait speed is impaired, then the FTSTS should be as well. This finding is worth consideration as in paper one the FTSTS was not associated with deficits in EF. Because deficits in cognition in MCI go beyond just EF, it should be noteworthy to consider that the FTSTS was associated with mild impairments in cognition. This may direct clinicians to consider using the FTSTS in those with deficits in cognition greater than just those deficits in EF which would be consistent with other studies where performance on the FTSTS was associated with global measures of cognitive decline. Second, the use of self-reported measures of balance confidence, the ABC, as a component of a fall risk assessment may provide contrasting findings to measures of
physical performance in those with MCI as it was not statistically significantly associated with usual gait speed or the FTSTS. Although this makes practical sense as cognitive deficits may influence confidence in performing activities that put a person at risk of falling, the use of a measure like the ABC may inadvertently be considered as a staple fall risk measure, and using this in those with MCI may contrast results of other fall risk measures.

A key finding of paper three was that following the completion of the computerized cognitive training program, fall risk screening tools that were not associated with EF, the FTSTS and the ABC did not change. The clinical usefulness of this finding rests in that these measures should not be expected to improve with cognitive interventions that target higher order processes found in EF.

Improvements in gait speed have been reported following computerized cognitive training interventions in those with decreased cognition,\textsuperscript{19} however a statistically significant improvement in usual gait speed was not found in the third study. There may be clinical implications for the use of a computerized cognitive training program in a falls and balance rehabilitation program in those with decreased cognition, however further studies are needed to examine this.

**Limitations**

Overall the sample size of the study population used in all three papers was a significant limitation. The small sample size may have limited the ability to detect a difference in performance on the fall risk measures. In addition, most of the subjects in the sample were of one race, most were well educated, and had a limited fall history, which limited the generalizability of the study.
Paper one was limited by the study population recruited as there was a wide range of TMT-B scores present. However this was addressed in post hoc comparisons when EF scores were stratified in analyses of those with MCI. In addition, as EF can be assessed with multiple neuropsychological tools, the use of one tool to measure the complex cognitive processes of EF may have been a limitation of the study.

Two limitations characterized the second paper. The first is the categorization of MCI through the use of one neuropsychological tool. The diagnostic criteria for MCI were, until recently, debatable, and it may have been beneficial to use other assessment tools or an experienced diagnostician. This study was limited due to the lack of blinding of examiners to the presence of MCI which may have influenced the administration and interpretation of measures of fall risk.

In paper three, attrition and noncompliance significantly limited the sample size used in the analyses which directly impacted the ability to detect a robust change in outcomes scores. In addition, the best practice for intervention studies that use computerized cognitive training programs has not been established and the frequency and duration of the intervention used in this study may have limited the overall findings.

**Recommendations for Future Research**

Two subtypes of MCI have been reported to have a greater transition rate to Alzheimer’s disease and as the presence of cognitive impairment increases fall risk, future studies should investigate how performance on measures of fall risk differ in those different MCI subtypes. In addition, in order to determine if fall risk screening tool performance in those MCI subtypes could predict future falls, a prospective tracking of the incidence of falling in the year following testing should be included. These results
may assist in guiding falls and balance assessment and early intervention options for those with different subtypes of MCI.

Although the TMT-B is a valid and reliable tool that can be easily administered, it does however require the use of either a printed copy or electronic version for completion. This may limit its use in clinical settings. Whereas another measure of EF, like the clock drawing test, can be performed without those resources and may be easily incorporated into a comprehensive assessment of fall risk. Future studies should consider how performance on the clock drawing test is associated with measures of fall risk in community dwelling older adults.

Moderate to large effect sizes have been reported in EF, visual spatial ability, and attention after completing a neuropsychological training program. In addition, improvements in gait speed have been reported following the completion of computerized cognitive training. Future studies should examine how dual task ambulation and gait speed may be influenced by completion of a neuropsychological software program in a large randomized controlled trial. Additionally, as exercise has been reported to decreased cognitive disease progression, improve EF, and improve processing speed, it may be worthy to examine how a combination of both an exercise based fall prevention program and participation in a computerized cognitive training program influences performance on measures of fall risk. However, this should be performed when more evidence is published regarding the appropriate dosage and frequency of an effective computerized cognitive training program.
References


Appendix A

Glossary of Terms
Glossary of Terms

**Attention:** a subcomponent of cognition which is characterized by one’s ability to attend to specific criteria in the environment for a period of time.

**Cognition:** a group of mental processes that includes attention, memory, producing and understanding language, learning, reasoning, problem solving, and decision making.

**Cognitive Training:** cognitive activities that include guided practice on a set of standardized tasks that aim to address specific aspects of cognition such as memory, attention, or executive function.

**Community Dwelling Older Adults:** adults age 65 years and older who live independently or with others and are not residing in an institution such as a skilled nursing facility, assisted living facility, sub-acute care facility, or senior living community where assistance with activities of daily living are provided as a component of the living environment.

**Computerized Cognitive Training:** cognitive training performed through the use of neuropsychological software that aims to address cognitive deficits with computerized games, tasks, or activities of the software program with varying levels of difficulty based on the severity of cognitive impairment in order to produce a training effect.

**Executive Function:** the set of cognitive skills that are required to plan, monitor and execute a sequence of goal-directed complex actions including the ability to control, integrate, organize, and maintain information when continuously presented.
Mild Cognitive Impairment: the condition of having a cognitive decline greater than what is expected for an individual’s age and education level but that does not notably interfere with activities of daily living

Set Shifting: a subcomponent of cognition which is characterized by the ability to update and shift cognitive strategies in response to new changes in the environment and processing information

Visual spatial ability: a subcomponent of cognition which is characterized the ability to discriminate visual information in relation to the spatial location of an item
Appendix B

Approval Letter from the Human Subjects Institutional Review Board, Western Michigan University
Date: September 1, 2011

To: Kieran Fogarty, Principal Investigator
    Jennifer Blackwood, Student Investigator

From: Christopher Cheatham, Ph.D., Vice Chair

Re: HSIRB Project Number 11-07-13

This letter will serve as confirmation that your research project titled "Assessment of Balance and Cognition as Risk Factors for Falls in Community Dwelling Older Adults" has been approved under the full category of review by the Human Subjects Institutional Review Board. 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 that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. 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 HSIRB for consultation.

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

Approval Termination: August 17, 2012
Appendix C

Approval Letter from the Institutional Review Board,
University of Michigan-Flint
To: Jennifer Blackwood

From: Marianne McGrath

Cc: Heather Hess
     Megan Chupka
     Jennifer Blackwood
     Kieran Fogarty

Subject: Initial Study Approval for [HUM00052852]

SUBMISSION INFORMATION:
Study Title: Assessment of Balance and Cognition as Risk Factors for Falls in Community Dwelling Older Adults
Full Study Title (if applicable): Assessment of Balance and Cognition as Risk Factors for Falls in Community Dwelling Older Adults
Study eResearch ID: HUM00052852
Date of this Notification from IRB: 9/21/2011
Review: Full Committee
Initial IRB Approval Date: 9/8/2011
Expiration Date: Approval for this expires at 11:59 p.m. on 9/7/2012
UM Federalwide Assurance (FWA): FWA00004969 expiring on 11/17/2011
OHRP IRB Registration Number(s): IRB00000248

Approved Risk Level(s):

Name       Risk Level
HUM00052852 No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRB Flint has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS).
You must conduct this study in accordance with the description and information provided in the approved application and associated documents.
APPROVAL PERIOD AND EXPIRATION:
The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the “Currently Approved Documents” section on the “Documents” tab.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.med.umich.edu/irbmed/ae_orio/index.htm), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION:
You can find additional information about UM’s Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: www.research.umich.edu/hrpp.
Marianne McGrath
Chair, IRB Flint