Spring 2-20-2018

Exploring the Use of the Timed Up and Go Test to Identify Patient Fall Risk in an Inpatient Geriatric Psychiatry Unit

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BY

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Submitted in partial fulfillment of the
requirements for the degree of Doctor of Philosophy in Health Sciences
Seton Hall University
2018

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ACKNOWLEDGEMENTS

Personal and scholarly growth are not easy. I am blessed to have spent my doctoral years under the care of amazing faculty. I am immensely grateful to my dissertation committee for their dedication to my development. Dr. Pinto Zipp has been a steadfast support, encouraging me to accept that "life happens," and to see the true value of the journey itself. She has been both a role model and a mentor. Dr. DeLuca taught me the importance of being "uncomfortable" in scholarly pursuit, and I will sincerely miss her unbelievably thought-provoking edits of my work. Dr. Zhang provided needed advice, with clear and focused guidance of my study. In addition to my committee, I would also like to thank Dr. Terrence Cahill, Dr. Lee Cabell, Dr. Wendiann Sethi, and Ms. Joann DeBerto for their instruction and assistance over the years.

This research was inspired by my work on Unit 4S(2N) at NewYork-Presbyterian/Westchester Division. I never intended to pursue a physical therapy career in a psychiatric hospital- I was a new grad and a new mom looking for a part- time job! But this unit immediately felt like home. Here I have colleagues who give the best of themselves every day, work together, and provide skilled and compassionate care. I am incredibly proud to be a member of this treatment team. May this research enhance the safe care of all inpatient geriatric psychiatry patients, on Unit 4 South and beyond.

DEDICATION

This dissertation is dedicated to my loving family, who always believed in me.

For late nights, homework at the table, and weekends studying,

with deepest gratitude to Mom, Chris, Emily & Alexis.

Thank you for sharing in my journey.

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ABSTRACT

Background: Patient falls during hospitalization influence healthcare costs and quality, and hospitals are mandated to complete fall risk assessments on all patients. Inpatient geriatric psychiatry units have the highest fall rates in the acute care setting, and most falls in this population occur during the mobility tasks of transfers and ambulation. The Timed Up and Go (TUG) test includes these two specific functional tasks, and has been used to predict falls in other geriatric populations, but has never been tested in an inpatient geriatric psychiatry unit. The purpose of this study was to determine if the TUG is a predictive tool to identify high fall risk patients in the inpatient geriatric psychiatry setting. **Methods:** The study was a retrospective chart review using a between groups design. The sample was obtained from patients admitted to one inpatient geriatric psychiatry unit during the four month study period. **Results:** The total sample size was $N = 62$ and included 33 non-fallers and 29 fallers. The mean age of fallers ($M = 75.79$, $SD = 9.60$) was not significantly different from the age of non-fallers ($M = 74.03$, $SD = 7.62$), $p = .424$. Both groups had higher proportions of female subjects; non-faller 75.8% ($n = 25$) female and faller 69.0% ($n = 20$) female. Most non-fallers (84.8%) completed the TUG testing without an assistive device, while most fallers (48.3%) used a walker. A significant difference was found between the TUG times of non-fallers and fallers, $U = 737.00$, $z = 3.65$, $p = <.001$, $r = .46$. Fallers took longer to complete the TUG test ($Mdn = 26.48$) than non-fallers ($Mdn = 13.56$). The TUG time predictor variable was statistically significant, $p = .002$. Increasing TUG times were associated with an increased likelihood of patient falls (OR = 1.10). The optimal TUG cut-off score was 16.46 seconds, with 79.3% sensitivity and 72.7% specificity.
Conclusions: The TUG was found to be a predictive tool to identify high fall risk patients in the

inpatient geriatric psychiatry setting. A cut-off time of 16.46 seconds is recommended to identify non-fallers from fallers in this patient population.

Key words: falls, hospital, geriatric psychiatry, patient mobility, fall risk assessment, Timed Up and Go Test

Chapter I

INTRODUCTION

Background of the Problem

Psychiatric illness in the elderly. In the United States, psychiatric illness is prevalent in older adults (Reynolds et al., 2015) and Karel et al. (2012) reported that 20.4% of adults aged 65 and older met criteria for mental illnesses including dementia. According to the National Institute of Mental Health (2016), more than 2 million older adults suffer from depression. While most adults with serious mental illness receive outpatient treatment (The National Institute of Mental Health, 2016), inpatient psychiatry hospitalization rates for the geriatric population have been reported to be 807.55 per 100,000 individuals (Blader, 2011).

The geriatric psychiatry environment. Geriatric psychiatry units are specialty care units within an acute care hospital or a freestanding psychiatric hospital. Designed for patients aged 60 (de Carle & Kohn, 2001; Blair & Gruman, 2006) to 65 years (Draper et al., 2004) and older, they provide psychiatric stabilization for patients with diagnoses including major depressive disorder, bipolar disorder, schizophrenia, schizoaffective disorder, and dementia (Blair & Gruman, 2006). The units can range in size from 10 (Draper, 2004) to 28 (Blair & Gruman, 2006) beds, and patients receive interdisciplinary care from treatment teams that often include physicians, nurses, occupational therapists, physical therapists (Wynaden et al., 2016), recreational therapists and social workers. Unlike an acute medical unit, patients in geriatric psychiatry spend long periods of time out of their rooms. These units have an active milieu (Blair & Gruman, 2006) where patients attend therapeutic activities such as discussion, exercise and recreation groups. This environment promotes high levels of physical mobility, requiring patients to walk and change positions frequently throughout their day, thus the potential for falls is present.

Falls. A patient fall must be defined in order to be measured adequately. The use of clear and consistent definitions forms a strong foundation for hospitals, who produce internal and external reports of falls, and researchers, who measure falls as outcome variables. A fall can be defined as an "unplanned descent to the floor" (Edmonson et al., 2011, p. 33) or as "the patient came to rest on the floor" (Morse et al., 1989, p. 367). The most commonly used definition, however, is much more comprehensive. Developed by the American Nurses Association (ANA), a fall is defined as a "sudden, unintentional descent with or without injury to the patient, that results in the patient coming to rest on the floor or against some other surface" (Press Ganey Associates, Inc., 2016, p. 2).

Hospitals that report external fall data to the National Database of Nursing Quality Indicators (NDNQI) use the comprehensive ANA fall definition, since the NDNQI was developed by the ANA. NDNQI compiles and analyzes data from more than 1500 member hospitals and is the primary external database for collection of hospital-based patient fall data. NDNQI measures fall event frequencies by unit type, injury levels (no injury, minor, moderate, major, death), fall type (anticipated physiological, unanticipated physiological, accidental, intentional and developmental), and assistance levels (staff assisted or unassisted). Fall rate quantitative values are calculated for each inpatient unit from a ratio of patient falls (numerator) to patient days (denominator). This ratio is multiplied by 1000 to obtain the fall rate, which is expressed as a value per 1000 patient days. The NDNQI publishes inpatient hospital fall rate benchmarks for total falls, injury falls, and unassisted falls that are unit specific (i.e., geriatric psychiatry or general adult psychiatry) on a quarterly basis (Press Ganey Associates, Inc., 2016).

While hospital-based patient falls are prevalent and their impact on the healthcare system is evident, there appears to be no gold standard patient fall related outcome measure present in the scientific literature. The outcomes most commonly reported are fall rates and fall event frequencies. For example, studies include overall frequency counts (Chan et al., 2013), injury-based frequencies (Blair & Gruman, 2006), or fall rates (He et al, 2012). Although many researchers report fall rates based on the NDNQI formula (Press Ganey Associates, Inc., 2016), some studies report frequencies as fall rates (de Carle & Kohn, 2001). Given these discrepancies, outcomes must be carefully reviewed.

Overall fall rates. Using the NDNQI fall rate formula (Press Ganey Associates, Inc., 2016), three large studies have shown that inpatient acute care hospitals have similar fall rates of 3.1/1000 (Fischer et al., 2005), 3.16/1000 (Williams et al., 2014), and 3.53/1000 (Bouldin et al., 2013). Fischer et al. (2005) reported the fall rate of 3.1/1000 in a large academic hospital with a sample size of 1,082 patients and 1,235 total falls. Williams et al. (2014) reported an average fall rate of 3.16/1000 patient days in a retrospective review of 25,510 falls in inpatient units from 40 hospitals. Bouldin et al. (2013) found an average fall rate of 3.53/1000 patient days in a large sample of 6,100 inpatient acute care units.

Hospital fall rates have been found to vary based on unit specialization (He et al., 2012). Low fall rates have been found in critical care (1.27/1000) (He et al., 2012) and surgical units (2.76/1000) (Bouldin et al., 2013) while high fall rates have been reported in medical (4.03/1000) (Bouldin et al., 2013) and rehabilitation units (8.12/1000) (He et al., 2012).

Surprisingly, inpatient adult psychiatry units have high rates of patient falls. In a large sample of falls (*N* = 25,510) in inpatient and emergency department units, Williams et al (2014), found that psychiatric units were the second most common location for inpatient falls, accounting for 11% of the total sample. The fall rates for psychiatric fall rates in this study were 5.6/1000 patient bed days. Yates and Creech Tart (2012) found fall rates between 5.09/1000-7.97/1000 in their study of three inpatient psychiatry units in a 258 bed community hospital.

Not surprising, inpatient geriatric psychiatry units have the highest fall rates across the acute care setting. Fischer et al. (2005) reported a fall rate of 13.66/1000 in a geriatric psychiatry unit; the highest of any unit in the large academic hospital. Draper et al (2004) reported that 29% of admissions to an acute geriatric psychiatry unit fell (*n* = 95). DeCarle & Kohn (2001) reported that 9.5% of the patients on a specialty geriatric psychiatry unit had at least one fall during their admission. In addition, 11.3% of the patients in the ≥80 year old age group had at least one fall (de Carle & Kohn, 2001).

Falls with injury rates. Often secondary injuries are a direct result of a fall and further impact the patient plan of care. Inpatient acute care hospitals have average injury rates between .53/1000 (Williams et al., 2014) and .91/1000 (Bouldin et al., 2013), and Williams et al. (2014) reported that 23% of falls in an academic medical center resulted in patient injury. At the unit level, non-psychiatric fall with injury rates have been reported between .96-1.41 (Reich et al., 2016). Injury rates in general adult psychiatry units are higher, 4.11/1000-5.09/1000 (Yates & Creech Tart, 2012), with 39.9% of falls resulting in patient injury (Fischer et al., 2005). In geriatric psychiatry units, injury frequencies range between 50% (Blair & Gruman, 2006) and 56% (Draper et al., 2004). In addition, Williams et al. (2014) reported that 2% of falls in a geriatric psychiatry unit resulted in major injury or death and thus can impact the healthcare system in various ways.

Impact of falls on the healthcare system. Patient falls during hospitalization can influence healthcare costs and quality.

Financial impact. Injurious patient falls can increase medical costs through additional medical interventions and/or admission days. Wong et al. (2011) reported the most common injuries sustained from a fall during hospitalization were hip/pelvis fractures (28.1%) and upper extremity or lower extremity fractures (21.1% each). 12.3% of the falls in their sample of three mid-western hospitals resulted in patient death, and 35.1% of the injuries required surgery. Fallers with serious injury were found to have had a mean cost increase of $14, 454 (Wong et al., 2011). A study by Finkelstein et al. (2007) reported that elderly male fallers had increased costs of $4,100, and elderly females had increased costs of $5,700. For both genders, a mental health diagnosis further increased fall related costs by an additional $4,100 (female) to $6,000 (male).

Post-fall management can also require a longer length of stay, leading to additional medical costs. Wong et al. (2011) reported a mean 7.2 day increase in length of stay for fallers in a sample of three academic and community Missouri hospitals. In inpatient geriatric psychiatry, de Carle & Kohn (2001) reported that fallers had significantly longer length of stay values: (19.6 ± 11.5 days) vs non-fallers (12.6 ± 7.7 days). Draper et al. (2004) also reported longer length of stay values for inpatient geriatric psychiatry fallers (35.2 days) compared to non-fallers (27.9 days), although the difference was not significant ($p = 0.102$). Williams et al. (2014) reported that repeat falls were most common on psychiatric units, and recurrent falls in geriatric psychiatry have been shown to be significantly related to longer hospital admissions. In a study of geriatric psychiatry inpatients, Green et al. (2001) concluded that having "recurrent falls (>2) whilst an inpatient showed a statistically significant association with length of stay, $p = 0.0006$" (p. 967). In addition, recurrent falls were found to be the only independent variable associated with increased length of stay (Green et al., 2001). In another inpatient geriatric psychiatry unit, repeat fallers (two or more) did have significantly longer lengths of stay (47.9 days, SD = 31.3) than non-fallers (27.2 days, SD = 15.9; $p = 0.037$) (Draper et al., 2004).

Falls create unreimbursed costs for a hospital, since the Center for Medicare and Medicaid Services (CMS) no longer pays for inpatient fall-related medical expenses. The United States Deficit Reduction Act of 2005 required the identification of hospital events that could "reasonably" (Civic Impulse, 2018) be prevented with the use of evidence-based practices. In 2008, CMS developed a list of ten "Hospital Acquired Conditions" (HACs) that included trauma from inpatient patient falls. In an attempt to address the rate of falls, CMS, as of October 1, 2008, instituted a reimbursement plan that no longer pays hospitals for medical services related to injurious inpatient falls (i.e., fracture, dislocation, intracranial injury) in attempt to manage and reduce the incidence of falls (CMS, 2015).

Quality of care impact. The Joint Commission (TJC) is an independent accrediting agency that focuses on quality and patient safety. Many states recognize this accreditation for healthcare facility licensure and Medicaid payments (The Joint Commission, 2017). In 2005, The Joint Commission published National Patient Safety Goal 9, "Reduce the risk of patient harm resulting from falls" (The Joint Commission, 2005). In 2010, The Joint Commission upgraded the National Patient Safety Goal 9 to a standard, with two "Elements of Performance." First, hospitals must assess and manage patient fall risk. Second, they must develop and utilize risk-specific fall prevention interventions (fall reduction program) (The Joint Commission, 2015). Fall risk assessments are expected to occur upon a patient's admission and transfer, as well as after a change in medical status, and after a fall (Nadzam, 2013). Initial fall risk assessments must be completed within the first 24 hours of inpatient admission (The Joint Commission, 2013). Patients who are characterized as at risk for falling are to have ongoing fall risk assessments during their hospital admission (Nadzam, 2013). As a standard, National Patient Safety Goal 9 is expected to be fully met during a hospital's Joint Commission accreditation survey. If this goal is not met, it is considered "an immediate risk to patient safety or quality of care" (The Joint Commission, 2018), and deficient hospitals must take corrective action within 45 days to maintain accreditation (The Joint Commission, 2018).

Although concerned by the increasing numbers of falls and potential for fall risk in hospitals nationwide, the Joint Commission currently does not require the utilization of a particular fall risk assessment or fall prevention protocol. Hospitals are given authority to make their own selections, although evidence-based assessments and programs are suggested (The Joint Commission, 2015). To date, this author was unable to identify a specific gold standard assessment tool noted in our review of the literature. The literature, however, describes several fall risk assessments and suggests that when choosing a tool it should correspond to identified risk factors within a particular population (Simpson et al., 2013), have good predictive validity (Oliver & Healey, 2009), and be feasible in a clinical environment (Degelau et al, 2012).

Purpose of the Study

The purpose of this study is to determine if the Timed Up and Go Test is a predictive tool to identify high fall risk patients in the inpatient geriatric psychiatry setting by using a retrospective chart review process of inquiry. There are two identified research questions and corresponding research hypotheses:

• Research question 1: Is there a difference in Timed Up and Go Test measurements between faller and non-faller inpatient geriatric psychiatry patients?

• Research hypothesis 1: There is a difference between Timed Up and Go Test measurements between faller and non-faller inpatient geriatric psychiatry patients.

• Research question 2: Does the Timed Up and Go Test predict falls in inpatient geriatric psychiatry patients?

• Research hypothesis 2: Inpatient geriatric psychiatry patients who take longer on the Timed Up and Go Test are predicted to fall.

This study has the potential to improve the clinical care of inpatient geriatric psychiatry patients by identifying a more predictive fall risk assessment than is currently in use. It is possible that the use of the Timed Up and Go Test, when used as a fall risk assessment tool, might help to better triage patients at risk of falling to target appropriate interventions and prevent further injuries and their associated healthcare costs.

Theoretical Framework

The key concepts of this research are falls, mobility, and the hospital environment (Figure 1). The relationship among these three variables can be best explained by the model of “functional balance” described by Huxham, Goldie, & Patla in 2001. This framework described balance as “a product of the task undertaken and the environment in which it is performed” (p. 89). In clinical application, the model recommends the consideration of both the task constraints and environmental context during the selection of clinical balance tests, particularly those aimed at fall risk identification. Thus, fall risk assessments need to test balance as it relates to a particular task within a certain environment.

When applied to this proposed research, the model of functional balance (Huxham et al., 2001) can be modified to represent what is known about the three key concepts. That is, falls in inpatient geriatric units occur most during the mobility tasks of transfers and ambulation (Blair & Gruman, 2006). In this study, the balance assessment, the Timed Up and Go Test, is being tested to determine its ability to predict a patient's fall risk. The study design relates specifically to Huxham's model by addressing both the task constraints and environmental context. The task constraints are the specific patient mobility tasks of transfers and ambulation. The environmental context is the hospital environment of interest, an inpatient geriatric psychiatry unit.

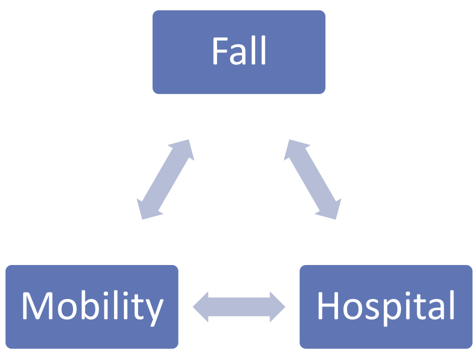

Figure 1. Theoretical frame, adapted from Huxham et al.'s (2001) model of functional balance.

Chapter II

REVIEW OF THE LITERATURE

Fall Risk Factors in Inpatient Adult General Psychiatry

Patient characteristics. In adult general psychiatry units, the average age of a faller varies. Chan et al. (2013) reported the lowest average age, 47.4 years, in a large study of 145 fall events. Tsai et al. (1998) reported an average age of 50.9 years, and Yates and Creech Tart (2012) reported slightly higher average ages of 58.2-59.3 in their two-phase study. Three large studies have reported that patients aged 60 and older were more likely to fall. In a study of 74 fallers by Estrin et al. (2009), 89% of patients aged 60 and older fell. Edmonson et al. (2011) reported an average faller age of 64.6 years in a study of 50 inpatient psychiatry falls. In a large study of 774 inpatient adult psychiatry falls, Lavsa et al. (2010) reported that fallers had a median age of 60 years, but patients aged 75-79 had the highest frequencies of falls (p. 1276).

The literature supports that females are more likely to fall than males in acute general psychiatry. Six studies have reported that more than half of all fallers were female including: Chan et al. (2013) (57.2% female), Lavsa et al. (2010) (57.6%), Edmonson et al. (2011) (60%), Estrin et al (2009) (63.5%),Tsai et al. (1998) (68%), and Yates & Creech Tart (2012) (69.4%-73.8%).

Physiological characteristics. In a study of falls in inpatient adult psychiatry units, Scanlan et al. (2012) found that physiological factors contributed to 50% of falls. Physiological risk factors include blood pressure changes (Chan et al., 2013; Edmonson et al., 2011), extrapyramidal symptoms (Chan et al., 2013), high temperature (Tsai et al., 1998), malnutrition

(Edmonson et al., 2011), sleep disturbance (Edmonson et al., 2011) and altered elimination (Tsai et al., 1998; Williams et al., 2014). Additional risk factors identified in this patient population included: recent medication changes (prior 24-72 hours) (Chan et al., 2013; Edmonson et al., 2011), mania (Chan et al., 2013), and altered mental status/cognitive impairments (Tsai et al., 1998; Williams et al., 2014; Edmonson et al., 2011). Estrin et al. (2009) reported that patients who fell had more physical symptoms on the day that they fell (p.1247).

Scanlan et al. (2012) also reported that 19% of falls were related to balance or mobility issues. This finding is supported by other studies of adult psychiatric inpatients who fell. Chan et al. (2013) reported fallers were more likely to have had unsteady gait, impaired mobility, and lower extremity impairments. In a small sample (n=12) Tsai et al. (1998) found that general weakness and impaired mobility/walking were statistically significant characteristics of fallers in an adult psychiatry unit. Williams et al. (2014) reported that 19% of falls in their large sample (N = 25,510 falls) were related to a patient's inability to rise from a surface without assistance.

Location and time. Two studies reported that patient falls commonly occurred in the hallways of inpatient psychiatric units (Chan et al, 2013; Scanlan et al., 2012). Other falls occurred in bedrooms, outdoor areas, and bathrooms (Scanlan et al, 2012). High incidence of falls have been reported at various times throughout a day including: 7 am to 9 pm (Chan et al.,2013) and between midnight and noon (Tsai et al., 1998). Williams et al (2014) reported that psychiatric fall incidence peaked at 10 pm. Two studies (Tsai et al., 1998; Lavsa et al., 2010) found that falls were likely to occur within the first week of admission, and Lavsa et al. (2010) also reported that fall frequency was highest on the patient's first full day of hospitalization.

Mobility. The most common patient mobility tasks associated with falls in adult inpatient psychiatry have been identified as transfers, ambulation and toileting. Scanlan et al. (2012)

reported that 17% of falls occurred during transfers. Tsai et al. (1998) reported that 21% of falls occurred during bed transfers, and another 21% of falls were associated with sit to stand transfers. Lee et al. (2012) reported a similar finding; 21.1% of falls in VA psychiatric inpatient falls were related to transfers from a bed or chair.

Studies have shown that between 19.7% (Lee et al., 2012) to 41% (Williams et al., 2014) of inpatient adult psychiatry falls occurred when a patient was walking. Lee et al. (2012) reported that 19.7% of patients were walking/running at the time of their falls. Tsai et al. (1998) reported that 21% of falls occurred when patients were walking to the bathroom. Williams et al. (2014) reported that 22% of falls occurred during ambulation. Scanlan et al. (2012) reported the highest percentage of falls, 41%, that occurred when patients were walking.

Toileting is also another activity associated with inpatient psychiatry falls. In the Lee et al. (2012) study, 18.3% of patients fell while using the bathroom. Williams et al (2014) reported that 23% of falls occurred during toileting.

Fall Risk Factors in Inpatient Geriatric Psychiatry

Patient characteristics. In a 2006 study of inpatient geriatric psychiatry falls, Blair and Gruman reported that falls were more likely (but not statistically significant) in patients with older age or who were African-American. de Carle & Kohn (2001) reported that female gender was a risk factor for falling in a geriatric psychiatry unit.

Physiological characteristics. In a geriatric psychiatry unit, de Carle & Kohn (2001) found multiple independent characteristics of fallers in their sample of 175 patients. Medical comorbidities included cardiac arrhythmias, Parkinson’s disease, and dementia. Medications and interventions included mood stabilizers and electroconvulsive therapy (ECT). Blair and Gruman (2006) reported medications to be the “strongest predictor of a falls episode…with high dose antipsychotic medication…having the highest correlation to falls" (p.352). In a 10 bed acute geriatric psychiatry unit in Australia, 86% of falls occurred when the patient was behaviorally disturbed or emotionally distressed, and nearly all patients had received psychotropic medication in the previous 48 hours. The authors concluded that "behavioral over-activity in combination with a history of recent falls and ECT were the only significant predictors of falling."(Draper et al., 2004).

Location and time. In a sample of 55 acute geriatric psychiatry falls, Draper et al. (2004) reported the most common locations of the falls were the patient room (17;34%), followed by the ward (11; 22%), the bathroom (8; 16%) and the corridor (5; 10%). The peak times of the day for falls in this study were 6:30–07:00 am (5; 10%) and 2:30–5:00 pm (9; 18%). In another geriatric psychiatry unit, falls were most likely to occur during the day shift (de Carle & Kohn, 2001). The mean day of a fall event has been reported to be 10.1±8.3 (de Carle & Kohn, 2001) to 21 days (Draper et al., 2004) since admission.

Mobility. Blair and Gruman (2006) found that most inpatient geriatric psychiatry falls occurred during ambulation and transfers. In this study, the activity most associated with falls was ambulation (12 falls), followed by transfers to/from a chair (8 falls), transfers to/from a bed (6 falls), and getting to the bathroom (5 falls).

Fall Risk Assessments

Fall risk assessments have the most value if they can correctly identify patients at risk of falling without misidentifying low-risk patients (Hendrich, 2003, p. 18). Although the literature supports the use of fall risk assessments that correspond to the risk factors of a particular population (Oliver et al., 1997), it is common for hospitals to use the same fall risk assessment across all patient units (Edmonson, 2011; Wynaden et al., 2016). This may be a factor that leads to the misidentification of a patient's fall risk.

Fall risk assessments in acute care. In 2016, Callis reported that the most common fall risk assessment tools used in acute care are the Morse Fall Scale (MFS) (Morse et al., 1989), Hendrich II Fall Risk Model (HRMII) (Hendrich et al., 2003), and St. Thomas Risk Assessment Tool (STRATIFY) (Oliver et al., 1997). All three tools converted the statistically significant variables from their samples into the fall risk factors of the assessment. That is, the final version of each tool includes the risk factors that were found to have been the most significant contributors to patient falls in their respective samples.

Morse fall scale. The Morse Fall Scale (Morse et al., 1989) includes six risk factors: fall history, secondary diagnosis, ambulatory aid, intravenous therapy, gait and mental status. This scale was initially developed and tested in an urban hospital in Canada that included 1200 acute care beds, 50 long-term geriatric beds, and 140 beds in a Veteran's home. The significant variables were identified from a sample of 100 fallers and 100 controls from all three sites. Each variable is weighted based on the Fisher's linear exact score as follows: a value of 10 for gait, 15 for secondary diagnosis, ambulatory aid and mental status, 20 for intravenous therapy, and 25 for a history of falls. The final Morse Fall Scale, with three possible values for ambulatory aid (0, 15, 30) and gait (0, 10, 20) has a maximum score of 125. Morse et al. (1989) reported sensitivity as 78% and specificity as 83%. The positive predictive value was 10.3% and the negative predictive value was 99.2%.

Hendrich II fall risk model. The Hendrich II Fall Risk Model (Hendrich et al., 2003) includes fall risk factors found to be statistically significant in a large sample in a 750 bed acute care hospital in the United States. The final sample included 1135 total patients, 355 fall cases and 780 controls. Stepwise logistic regression identified eight statistically significant variables for inclusion in the model: confusion/impulsivity, depression, altered elimination, dizziness/vertigo, male gender, antiepileptic use, benzodiazepine use, and mobility (measured by "rise from a chair"). Regression coefficients were converted to a points system, with each risk factor assigned a score ranging from 0-4. A single risk point value was assigned to altered elimination, dizziness/vertigo, male gender, and benzodiazepine use. Two risk points were assigned to symptomatic depression and antiepileptic use, and confusion/impulsivity was valued at four points. The "rise from a chair" score ranges from 0 (no difficulty) to 4 (unable without assistance). The final model has a maximum total of 16 points. Henrich et al. (2003) identified a score cutoff of 5, meaning that patients who scored 5 or higher should be categorized as a high risk for falling. Using this cutoff score on the original sample, the model was reported to have sensitivity of 74.9% and specificity of 73.9%.

St. Thomas's risk assessment tool in falling elderly inpatients (STRATIFY).

The STATIFY (Oliver et al., 1997) was developed in England, and utilized a through three phase process that involved different hospitals and inpatient unit types. The five statistically significant fall risk factors were identified from a sample of geriatric patients (minimum age of 65) from an Elderly Care Unit (a 96 bed unit within a 700 bed urban teaching hospital). The Elderly Care Unit included one unit specializing in stroke rehabilitation and three units in general medicine. The STRATIFY tool includes five dichotomous (yes = 1, no = 2) risk factors: fall history, agitation, visual impairment, frequent toileting and transfer/mobility. STRATIFY has a maximum score of five. The study was validated on the Elderly Care Unit, and using a score of 2 or greater as the cutoff for fall risk, resulted in sensitivity of 93% and specificity of 88%. In the third phase of this study, the scale was validated in another hospital's

(500 bed district general) geriatric units (2 acute medical and 4 rehabilitation; minimum age of 75 years), with resulting sensitivity of 92% and specificity of 68%.

Summary of acute care tools. The Morse, Hendrich II, and STRATIFY all had acceptable levels of sensitivity and specificity in their initial validations. As such, these tools are clinically used in United States hospitals, and are reported on in the literature. However, these tools share few similarities. To begin, the tools were developed in three different countries: the United States, Canada and England. They were developed with different patient populations. They identify a total of fifteen separate fall risk factors, but not one risk factor is present in all three scales. The Morse and Hendrich II share only 1 risk factor (mental status); the Hendrich II and STRATIFY share two common risk factors (altered elimination and ability to transfer), and the Morse and STRATIFY share three (fall history, use of ambulatory aid and gait).

In a systematic review and meta-analysis from 2013, Aranda-Gallardo et al. compared all three of these fall scales, and concluded, “the behavior of these risk assessment instruments varies considerably depending on the population and the environment in which they are administered (p. 12).” They could not recommend “the general adoption of any single method without its prior testing in the healthcare setting of the intended implementation” (p.12).

Acute care tools applied to inpatient adult psychiatry. In a 2014 study, Williams et al. reported that 26% of psychiatric inpatients were incorrectly assessed for fall risk when using common acute care risk assessments, including Morse and Henrich II. In this large sample, 553 patients who fell were originally assessed to be at low risk for falling. Another study found that the Morse had lower predictive validity when used in inpatient adult psychiatry units. In a sample of 43 falls on two inpatient adult psychiatry units, the Morse was reported to have sensitivity of .49 and specificity of .85 (Edmonson et al., 2011, p.35). Although the Hendrich II was reported to have sensitivity of 100% and specificity of 67.8% in a 12 bed rural inpatient adult psychiatry unit, the small sample size (2 falls) limits the strength and interpretation of the finding.

Fall risk assessments in inpatient adult psychiatry. Until 2011, there were no published fall risk assessments specific to the inpatient adult psychiatric population. The first of its kind, the Edmonson Psychiatric Fall Risk Assessment Tool was developed in Illinois (Edmonson et al., 2011). Two years later, the Wilson-Sims Fall Risk Assessment was developed in Michigan (Billeen et al., 2013). At this time, these are the only two published fall risk assessment tools developed for, and tested in, inpatient adult psychiatry units.

Edmonson psychiatric fall risk assessment tool. The Edmonson Psychiatric Fall Risk Assessment Tool (EPFRAT) (Edmonson et al., 2011) was developed on two 34 bed inpatient acute psychiatry units in a 350+ bed Magnet hospital. The nine fall risk factors, identified through a literature review and expert panel, include: age, mental status, elimination, medications, psychiatric medication, ambulation/balance, nutrition, sleep disturbance, and fall history. Multidimensional scaling and expert review were used to weight each of the nine variables, and each risk factor has its own score range based on specific criteria. For example, the ambulation/balance risk factor has possible values of 7 (independent/steady/immobile), 8 (proper use of assistive device or unsteady and aware of abilities), 10 (vertigo/orthostatic hypotension/weakness), or 15 (unsteady but forgets limitations). The full assessment has a total maximal score of 129. The EPFRST was validated through retrospective analysis of 43 patient falls on the same two inpatient adult psychiatry units. Using a score cutoff of 90 or more as high risk of falls, the tool was reported to have sensitivity of .63, specificity of .86, and a positive predictive value of .68.

Wilson-Sims fall risk assessment tool. The Wilson-Sims Fall Risk Assessment Tool (WSFRAT) (Billeen et al., 2013)) was developed in a Magnet community hospital specifically for the inpatient psychiatry population. Established from internal fall analyses and literature review, the 14 fall risk factors include: age, gender, mental status, physical status, elimination, impairments, gait/balance, fall history, medications (6 classes) and detoxification protocol. Theses 14 risk factors are scored individually with possible values ranging from 0-3. The total maximum score of the assessment is 39 and the researchers reported that a score of 7 or more identified patients at high risk of falling (Billeen et al, 2013). It is important to note that this scale also allows testers to make clinical judgments that can be used to overrule the summed numerical score. The Wilson-Sims was first validated by Van Dyke et al. (2014), using a convenience sample of 50 inpatients from an adult psychiatry unit. With a high risk cutoff score of 7 or greater, the WSFRAT had reported sensitivity of 100% and specificity of 63.1%. These results should be viewed cautiously, however, as these values were calculated from only 2 fall episodes.

Summary of inpatient adult psychiatry tools. Although they were developed for the same patient population, the Edmonson and Wilson-Sims tools do not utilize the same fall risk factors. Combined, these tools include 27 separate variables, but only share nine (33%). The shared risk factors include fall history, ambulatory aid, gait, mental status, altered elimination, dizziness/vertigo, age, benzodiazepine use, and muscle weakness. The Edmonson had higher specificity (.86) than sensitivity (.63). The Wilson-Sims sensitivity of 1.0 was misleading, since the sample size (*n*=2 falls) was very small.

Fall risk assessments in inpatient geriatric psychiatry. After an extensive literature search, only one published fall risk assessment tool specifically designed for inpatient geriatric psychiatry could be identified.

Fall risk assessment in geriatric-psychiatric inpatients to lower events (FRAGILE). The Fall Risk Assessment in Geriatric-Psychiatry Inpatients to Lower Events (FRAGILE) (Nanda et al., 2011) is the only published assessment tool developed for inpatient geriatric psychiatry. It was developed in a community hospital's geriatric psychiatry unit; the original sample included 136 fallers and 89 non-falling controls. The regression analysis produced 12 statistically significant fall risk factors that were included in the scale. Of note, two of the items (depression and acute sedative/antipsychotic use) had negative regression coefficients, meaning that they were protective factors against falls. To calculate fall risk, all constants are combined (added and subtracted) to produce a FRAGILE score. The final score is converted to a probability curve, and the authors reported using a probability of $p \geq 0.5$ as the cutoff. Using this cutoff point, the FRAGILE scale was found to have a sensitivity of 92% and specificity of 83%. It is important to note that there have been no other published studies using the FRAGILE scale since its initial publication in 2011.

Limitations of the Published Fall Risk Assessments

A main theme from the literature is that fall risk assessments must match the unique risk factors and environment of a particular target population. Generalizability is limited and in 2016(a), Abraham concluded, "no hospital should have a single scale to assess patients in all specialties. The assessment tool should depend on the type of patient population served" (p.3). This supports Oliver's (1997) earlier finding that "the predictive power of risk factors is likely to be specific to one unit or patient group" (p. 1052). At this time, there is little evidence to support that the widely used acute care tools are valid predictors of falls when used outside of their designated population, although this is common practice. Mental health professionals have expressed frustration with this, and in qualitative analysis have been critical of the use of generic (medically based) fall risk assessments in the inpatient geriatric psychiatry environment (Wynaden, 2016). Although the Edmonson and Wilson-Sims are adult psychiatry specific, they have not been extensively tested. In addition, the validation of the Wilson-Sims had little value, since it was based on only two patient fall events. The FRAGILE, designed specifically for the inpatient geriatric psychiatry environment, has a complicated scoring system and has not been reported on since the initial development publication in 2011.

In addition, it appears that standardized mobility assessments are an underutilized component in inpatient fall risk assessments although impaired patient mobility is a clear risk factor for falls (Morse et al., 1989; Hendrich et al., 2003; Oliver et al., 1997; Edmonson et al., 2011; Billeen et al., 2013; Nanda et al., 2011). In fact, although transfers and ambulation are frequently associated with inpatient falls (Scanlan et al., 2012; Tsai et al., 1998; Lee et al., 2012; Blair & Gruman, 2006), none of the discussed published fall risk assessments includes a full assessment of both of these tasks. Clinically, mobility tests fall under the physical therapist domain (APTA, 2014), but interdisciplinary management of inpatient fall prevention is well supported (Wynaden et al., 2016; Degelau et al., 2012). In 2011, Stubbs reported that in inpatient geriatric psychiatry, "physiotherapists play a central role in such (multidisciplinary) approaches and may complete a range of risk assessments to assess balance and advise the clinical team accordingly" (p. 460). Additionally, in qualitative and descriptive studies, mental health professionals have reported that they recognize the importance of physical therapy mobility tests to prevent falls in inpatient geriatric psychiatry (Wynaden et al., 2016; Abraham, 2016(b)). In this unique highly mobile geriatric environment, a new research question emerges: can standardized mobility tests identify high fall risk patients in the inpatient geriatric psychiatry environment?

The Timed Up and Go Test

Patient chair transfers and ambulation are the two patient activities most commonly associated with falls on inpatient geriatric psychiatry units (Blair & Gruman, 2006). The Get-up and Go (GUG) (Mathias et al., 1986) and Timed Up and Go (TUG) Tests (Podsiadlo & Richardson, 1991) are standardized mobility tests that include both of these specific functional activities. The GUG and TUG are performance-based tests that require a patient to stand up from a standard arm chair, walk 3 meters, turn, walk back to the arm chair, and sit down (Mathias et al., 1986; Podsiadlo & Richardson, 1991).

The Get-up and Go Test was published in 1986 as a test of functional balance and fall risk. An observer scores patient performance based on a five point scale where 1 indicates normal performance and 5 represents severely abnormal performance. In the initial mixed sample (inpatient, outpatient, day hospital) of 40 patients with balance impairments (mean age= 73.8) in England, Mathias et al. (1986) concluded that patients with a score of 3 or more were at high risk for falling.

Citing “imprecise” (p. 142) scoring of the Get-up and Go Test, Podsiadlo & Richardson developed the Timed Up and Go Test (TUG) in Canada in 1991. The TUG uses the identical patient task, but measures performance by time instead of observation. Unlike the Get Up and Go test, the TUG was developed only as a measure of functional mobility, not fall risk. In the original sample of 60 elderly day hospital patients (mean age = 79.5 years) and 10 healthy elderly controls (mean age = 75.0), Podsiadlo and Richardson (1991) identified cutoff score times that were associated with a patient’s level of physical mobility. Patients who performed the test in <10 seconds were functionally independent, and those who took longer than 30 seconds were functionally dependent. In addition, the test was found to have good inter-rater (ICC 0.99) and intra-rater reliability (ICC 0.99), and had good correlation to tests of balance (Berg Balance Scale, r = -0.81), gait speed (r = -0.61), and activities of daily living (Barthel Index Score, r =-0.78).

Although the GUG test was originally designed for fall risk identification, the TUG was not applied to fall risk until the work of Shumway-Cook, Brauer, and Woollacott in 2000. In their sample of 30 community dwelling elders, Shumway-Cook et al. (2000) recommended a fall risk cut-off score of 14 seconds (p. 901), meaning that patients who took longer than 14 seconds to complete the test were at a high risk for falls. Since this seminal work, the TUG has been widely used for fall risk assessment in physical therapist clinical practice (APTA, 2014), and is recommended for geriatric fall risk assessment by the American Geriatrics Society (2011) and the Centers for Disease Control and Prevention (2017).

In the literature, the TUG has been tested as a measure of geriatric fall risk in a variety of settings, including community dwellings (Chiu et al., 2003), day hospital (Thomas et al., 2005), residential care facilities (Nordin et al., 2008), and acute care (Lindsay et al., 2004). In geriatric populations, the TUG has been reported to be useful in discriminating fallers from non-fallers in "less-healthy, lower-functioning groups" (Schoene et al., 2013, p. 207), but there is no current consensus regarding fall risk cut-off times. In fact, a systematic review by Beuchet et al. (2011) reported a time range of 10-32.6 seconds, and another systematic review and meta-analysis concluded that "cut-points were so different between studies that it is not possible to make a recommendation regarding threshold values between fallers and non-fallers…" (Shoene et al.,2013, p.207). Shoene et al. (2013) discouraged health professionals from "taking a cut point from one study and applying it in a clinical setting (as this) may lead to incorrect clinical decision-making" (p. 207).

At this time, no studies have tested the TUG's ability to predict falls in the inpatient geriatric psychiatry environment. There is also limited evidence in acute care; only two Australian studies have used the TUG to identify fall risk in inpatient acute care geriatric samples (Lindsay et al, 2004; Large et al., 2006).

Lindsay et al. (2004) used a retrospective audit of 160 patient medical records to determine if the TUG was able to effectively predict falls on a medical unit. The sample included patients aged 65 and older (mean =81 years; range = 65-99) who had been referred for physical therapy, and had documented TUG scores completed within 24 hours of the physical therapy referral. Patients unable to complete the TUG due to confusion or dementia were excluded from the study. In this sample, the mean TUG score on initial assessment was 45.7 seconds (SD = 36.4, n=100), and TUG scores for patients using a walker were statistically slower than those who used a cane or no device, TUG= 59.9 seconds (SD = 42.4, n = 37). During the study, 11% (n = 17) of patients fell, and the authors found no statistically significant relationship between the admission TUG score and fall risk (p = 0.61, n = 141) (p.250). They concluded, the "TUG used in isolation was not able to identify those patients who fell whilst admitted to hospital" (p.250).

In 2006, Large et al. used a prospective design to determine if the TUG could stratify the fall risks of geriatric inpatients. The authors also hypothesized that patients unable to complete the TUG were the highest fall risk (p. 422). Completed in an aged care unit, the total sample included 2388 patients (mean 82.1 ± 7.7 years), of which 180 patients fell. All patients completed the TUG within 24 hours of admission, and the median TUG score was 28 seconds. Patients unable to complete the TUG were designated into 2 groups: physical disability (unable to sit, walk, etc.) or non-physical (refusal, unable to follow directions). The most common non-physical disability reasons were refusal (43%), medical contraindication (40%), and unable to follow instructions (17%). Large et al. (2006) reported that patients unable to complete the TUG due to non-physical disabilities had the highest fall frequency (11%, 38 falls), followed by those with physical disability (9%, 83 falls). Patients who were able to do the TUG had the lowest number of falls (6%, 54 falls). When the analysis included patients unable to complete the TUG, the authors reported that the TUG did significantly predict falls in multivariate analyses. They reported, "excluding patients unable to complete the TUG fails to detect those with the highest fall rates" (p.425) and "suggest that the value of the TUG lies in the inability to complete the test, rather than the time recorded" (p.426).

Summary

Many patients fall in inpatient geriatric psychiatry units (Fischer et al., 2005; Draper et al., 2004; de Carle & Kohn, 2001), and hospitals, obligated to assess fall risk (The Joint Commission, 2010), should use fall risk assessment tools that match the unique risk factors of a population (Oliver et al., 1997). However, at this time, there are no identified fall risk assessments that adequately capture the unique risk factors of these particular patients (Bunn et al., 2014). Referring to the lack of valid fall risk assessment tools in acute mental health settings, Narayanan et al. (2016) concluded that there is an "urgent need to improve the care of older people at risk of falls" (p.178) in the inpatient setting.

Patients on inpatient geriatric psychiatry units have high levels of physical mobility (Wynaden et al., 2016) driven by the active therapeutic milieu (Blair & Gruman, 2006), and most geriatric psychiatry inpatient falls occur during transfers and ambulation (Blair & Gruman, 2006). Patient mobility is a clear risk factor for falls, and the evidence suggests that patient mobility tests should be a component of inpatient geriatric psychiatry fall risk assessment. To account for changes in a patient's status, mobility tests must be able to be feasibly completed on admission, and at the very least, on a daily basis (Abraham, 2016 (b)). However, there has been "minimal scholarly work conducted in relation to (fall prevention) in older adults with serious mental illness"(Stubbs, 2011,p. 457), and thus no solid evidence base to support a particular standardized mobility tool in this patient population. However, the TUG meets several pieces of important criteria: 1) it has been able to identify fall risk in other geriatric populations (Schoene et al., 2013), 2) it is quick and easy to administer, requiring no special equipment or time burden (Podsiadlo & Richardson, 1991), 3) it allows for multiple disciplines to complete testing (i.e., physical therapy or nursing), and 4) it aligns with and tests the specific patient mobility tasks most associated with falls in the inpatient geriatric psychiatry environment (Blair & Gruman, 2006) .

Chapter III

METHODS

Subjects

The study was a retrospective chart review using a between groups design. The sample was obtained from patients admitted to one inpatient geriatric psychiatry unit at New York-Presbyterian Hospital/Westchester Division who were referred to Physical Therapy during the four-month study period, 4/1/17-7/31/17. Subjects were divided into two groups (non-fallers, fallers) with the following inclusion and exclusion criteria:

<u>Non-faller inclusion criteria</u>: age 60 years or older, admitted with a primary psychiatric diagnosis, ability to walk 6 meters independently with or without an assistive device, no past history of a fall in past 6 months

<u>Faller inclusion criteria</u>: age 60 years or older, admitted with a primary psychiatric diagnosis, ability to walk 6 meters independently with or without an assistive device, at least one fall in the past 6 months

<u>Exclusion criteria</u>: legally blind, severe cognitive impairment as evident by their inability to follow therapist's commands for TUG testing.

The a-priori power analysis required the analysis of 52 charts. For a non-directional alpha = .05 independent *t*-test, using power =.80 and *d* =0.8, a value of *n* = 26 was required for each group. Thus, the total sample size needed (2*n*) was 52.

Sampling Unit & Known TUG Test Procedures

The inpatient geriatric psychiatry unit used for sampling is a 22 bed unit located within the suburban New York inpatient psychiatry campus of a major academic medical center.

Although this study is a chart review, the description of the sample hospital's clinical procedures provide important background and context. The Timed Up and Go Test is a standard component of the physical therapy evaluation for all patients on this inpatient geriatric psychiatry unit, regardless of admitting diagnosis or reason for physical therapy referral. The physical therapy department at the hospital uses a standardized TUG procedure that is based on the seminal study of Podsiadlo & Richardson (1991). On the inpatient geriatric psychiatry unit, all TUG testing is completed in the same location on the unit at the end of a short corridor. The chair used for testing is a high-backed arm-chair with a seat height of 44 cm. As part of the hospital's environmental safety procedures, this chair is anchored to the floor, and therefore is always located in the same position. A white line of one-inch adhesive medical tape is secured to the floor exactly 3 meters from the TUG test chair. During TUG testing, external distractions are minimized (i.e., the nearby hallway television is turned off). Physical therapists give verbal instructions for patients to walk at a "comfortable and safe pace" (Podsiadlo & Richardson, 1991, p. 143) during the TUG test, and if needed, patients use their typical assistive device, which is defined as the type of device that was being used prior to admission on the inpatient geriatric psychiatry unit. TUG times are measured with a stopwatch and recorded in the physical therapy evaluation in the electronic medical record.

Data Collection Procedures

IRB approval for this study was received from both Weill Cornell Medical College/New York-Presbyterian Hospital (Protocol # 1708018435) (Appendix A) and Seton Hall University

(Appendix B). After both IRB approvals were received, data were collected using a three-step process. First, the patient list was obtained from the hospital's Physical Therapy Department records and screened by the principal investigator (PI). Second, the electronic medical records were reviewed and Chart Review forms (Appendix C) were completed by the PI. The medical records were reviewed for five specific variables: (1) patient age, (2) patient gender, (3) patient fall history, (4) patient Timed Up and Go Test score, and (5) assistive device use during Timed Up and Go Test. Patient age and gender variables were found in the demographic section of the electronic medical record. The patient fall history was found in the Nursing and Physical Therapy records. The Timed Up and Go scores and assistive device descriptions were found in Physical Therapy records. Finally, the de-identified variables (random ID, age, gender, fall category, TUG time, assistive device use) were entered into the SPSS (IBM Corp., 2017) database by the PI.

Chapter IV

RESULTS AND DISCUSSION

Results

The data analysis included three types of statistics: descriptive, comparative and associational. All data were analyzed with SPSS version 25 (IBM Corp., 2017).

Descriptive analysis. The total sample size was *N* = 62, with an average age of 74.85(*SD* = 8.57), and range of 60-97 years old. 72.6% (*n* = 45) of the sample was female and 27.4% (*n* = 17) was male. The total sample was 53.2% (*n* = 33) non-faller and 46.8% (*n* = 29) faller (Table 1).

Table 1

Sample Characteristics of Non-Fallers and Fallers

	Non-Faller	**Faller**
Sample Size	*n*=33	*n*=29
Age		
Mean	74.03 (*SD*=7.62)	75.79 (*SD*=9.60)
Range	62-89	60-97
Gender		
Male	24.2% (*n*=8)	31.0% (*n*=9)
Female	75.8% (*n*=25)	69.0% (*n*=20)
Device Used		
No device	84.8% (*n*=28)	41.4% (*n*=12)
Cane	9.1% (*n*=3)	10.3% (*n*=3)
Walker	6.1% (*n*=2)	48.3% (*n*=14)

The average age of a non-faller was 74.03 (*SD* = 7.62), with a minimum age of 62 and a maximum age of 89 years old. The average age of a faller was 75.79 (*SD* = 9.60), with a minimum age of 60 and a maximum age of 97 years old. Fallers were slightly older than non-fallers (Figure 2). However, an independent samples *t*-test comparing the mean ages of the faller group and non-faller group found a non-significant difference between the mean ages of the two groups, $t(60) = -.81$, $p = .424$. The mean age of fallers ($M = 75.79$, $SD = 9.60$) was not significantly different from the age of non-fallers ($M = 74.03$, $SD = 7.62$).

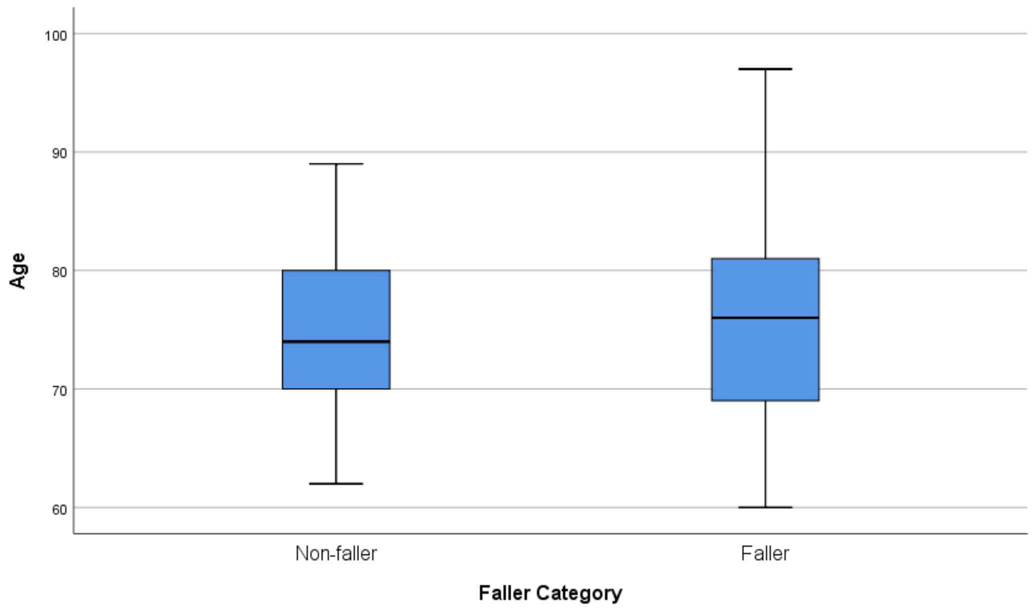

Figure 2. Fallers ($M = 75.79$, $SD = 9.60$) were slightly older than non-fallers ($M = 74.03$, $SD = 7.62$), but the difference was not significant, $p = .424$.

The non-faller group was 75.8% ($n = 25$) female and 24.2% ($n = 8$) male. The faller group was 69.0% ($n = 20$) female and 31.0% ($n = 9$) male (Figure 3). The test of two proportions used was the chi-square test of homogeneity. There was not a statistically significant difference in proportions of gender .07, $p = .550$.

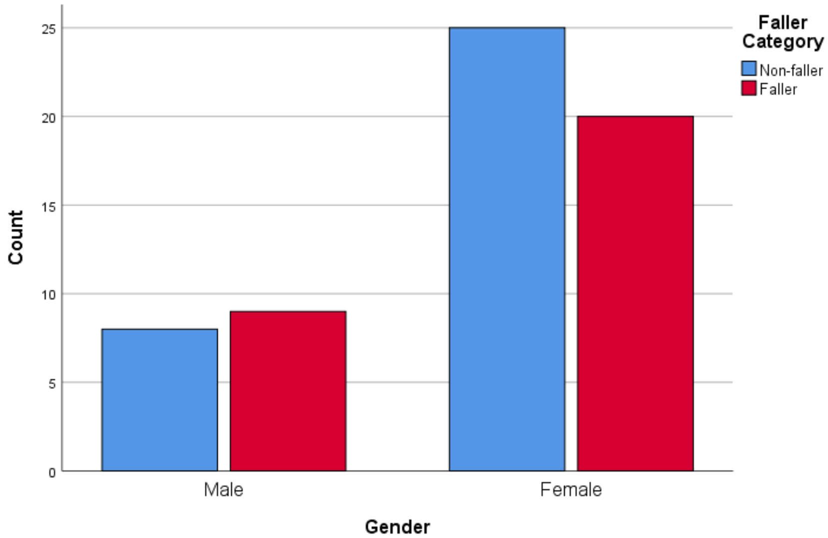

Figure 3. There were more females than males in both the faller and non-faller groups.

For the non-faller group, 84.8% (*n* = 28) used no device, 9.1% (*n* = 3) used a cane, and 6.1% (*n* = 2) used a walker to complete Timed Up and Go testing. For the faller group, 48.3% (*n* = 14) used a walker, 41.4% (*n* = 12) used no device, and 10.3% (*n* = 3) used a cane to complete the Timed Up and Go testing. Most non-fallers completed the TUG testing without an assistive device. Most fallers completed the TUG testing with a walker.

Fisher's exact test was conducted due to an inadequate sample size for the chi-square test of homogeneity, as established according to Cochran (1954). The two multinomial probability distributions were not equal in the population, $p < .001$. Observed frequencies and percentages of assistive device use for each fall type category are presented in Table 2.

Post hoc analysis involved pairwise comparisons using multiple Fisher's exact tests (2 x 2) with a Bonferroni correction. Statistical significance was accepted at $p < .016667$. There were statistically significant differences in the proportion of non-fallers who used no assistive device than fallers (*n* = 28, 84.8% versus *n* = 12, 41.4%), as well as the proportion of non-fallers who used a walker than fallers (*n* = 2, 6.1% versus *n* = 14, 48.3%), $p < .001$. There was no statistically significant difference in the proportion of non-fallers who used a cane than fallers (*n* = 3, 9.1% versus n = 3, 10.3%), *p* = 1.000.

Table 2

Crosstabulation of Faller Type and Assistive Device Type

ASSISTIVE DEVICE TYPE	FALLER CATEGORY	
	NON-FALLER	FALLER
NONE	28 (84.8)	12 (41.4)
CANE	3 (9.1)	3 (10.3)
WALKER	2 (6.1)	14 (48.3)

Research Question #1: Is there a difference in Timed Up and Go measurements between faller and non-faller inpatient geriatric psychiatry patients?

The planned analysis was an independent-samples *t* test. However, the data failed two of the five assumptions required for an independent-samples *t* test (Cronk, 2014): normality and homogeneity of variance. The TUG times of fallers were moderately skewed, skew = .69, and the TUG times of non-fallers were highly positively skewed, skew = 2.58. Log, square root, and reciprocal data transformations were completed, but none were able to produce normal distributions of the non-faller TUG times. In addition, the sample violated the assumption of homogeneity of variance, $F(33,29) = 7.16$, $p = .010$. Therefore, the non-parametric Mann-Whitney *U* Test was used for the analysis of RQ1. The sample met all four assumptions of the Mann-Whitney *U* Test, including: one continuous dependent variable, one dichotomous independent variable, and independence of observations. Since the group distributions were similarly shaped (positively skewed), the fourth assumption was met. This allowed for the comparison of group medians (Laerd Statistics, 2015).

A Mann-Whitney *U* Test was used to examine the difference in TUG times between fallers and non-fallers in an inpatient geriatric psychiatry unit. A significant difference was found, *U* = 737.00, *z* = 3.65, *p* = <.001, *r* = .46. The effect size was medium to large. Fallers took longer to complete the TUG test (*Mdn* = 26.48) than non-fallers (*Mdn* = 13.56). Faller TUG times ranged from 9.16-64.72 seconds. Non-faller TUG times ranged from 8.42-54.03 seconds (Figure 4).

The post hoc power analysis was completed using G*Power version 3.1.9.2 (Faul, Buchner, Erdfelder, & Lang, 2014). For the Mann-Whitney *U* Test, post hoc power was .96. This exceeds the accepted level of power, .80 (Cohen, 1988).

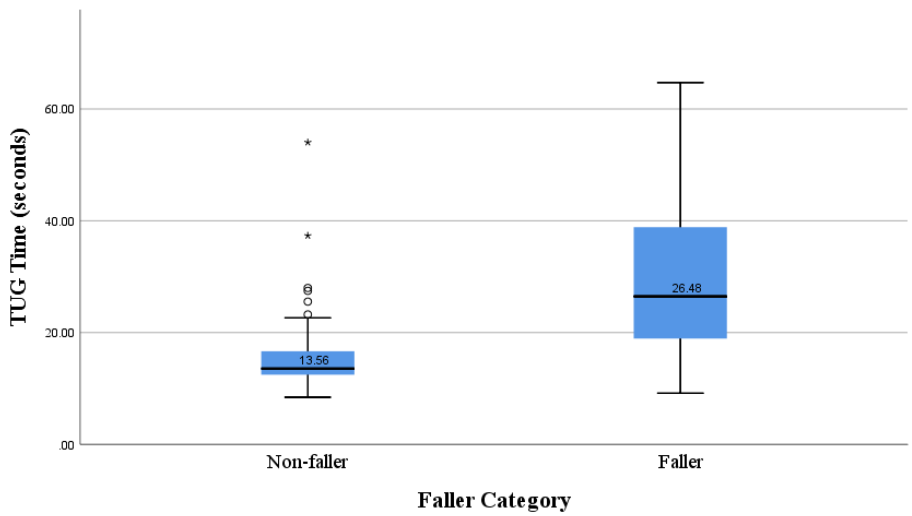

Figure 4. Fallers (*Mdn* = 26.48) took significantly longer to complete TUG testing than non-fallers (*Mdn* = 13.56), *U* = 737.00, *z* = 3.65, p = <.001, *r* = .46. Faller TUG times ranged from 9.16-64.72 seconds. Non-faller TUG times ranged from 8.42-54.03 seconds.

Research Question #2: Does the Timed Up and Go predict falls in inpatient geriatric psychiatry patients?

A binomial logistic regression was performed to ascertain the effect of TUG time on the likelihood that participants were fallers. Linearity of the continuous independent variable with respect to the logit of the dependent variable was assessed via the Box-Tidwell (1962) procedure. A Bonferroni correction was applied using all three terms in the model resulting in statistical significance being accepted when $p < .016667$ (Tabachnick & Fidell, 2014). Based on this assessment, the continuous independent variable was found to be linearly related to the logit of the dependent variable. There was one studentized residual with a value of -4.20 standard deviations, which was kept in the analysis. The logistic regression model was statistically significant, χ^2 (1) =14.08, p = <.001. The model explained 27.1% (Nagelkerke R^2) of the variance in faller category and correctly classified 71.0% of cases. Sensitivity was 58.6%, specificity was 81.8%, positive predictive value was 73.9%, and negative predictive value was 69.2%. The TUG time predictor variable was statistically significant, p =.002 (as shown in Table 3). Increasing TUG times were associated with an increased likelihood of patient falls (OR = 1.10).

Table 3

Logistic Regression Predicting Likelihood of Falling Based on TUG Time

	B	**SE**	**Wald**	***df***	***p***	**Odds Ratio**	**95% CI for Odds Ratio**	
							Lower	Upper
TUG Time	.09	.03	9.71	1	.002	1.10	1.04	1.16

A receiver-operating characteristic (ROC) curve analysis was used as a post-hoc for the significant logistic regression. The most north-west point coordinates of the ROC curve can be used to “establish the optimal cut-off point…(which has the) highest true positive (TP) rate and lowest false positive (FP) rate” (Pintea & Moldovan, 2009, p.54). The selected cut-off point will influence the "sensitivity and specificity of a test" (Florkowski, 2008, p.S84), but also helps a clinician determine, "whether a person with a certain score belongs to one category or another" (Pintea & Moldovan, 2009, p. 49).

Based on the ROC analysis (Figure 5), TUG time adequately discriminated between fallers and non-fallers, AUC = .77, *SE* = .06, *p* < .001, 95CI [0.65-0.89]. The optimal cut-off score was 16.46 seconds, with sensitivity of 79.3% and specificity of 72.7%. The area under the curve (AUC) of .77 is an acceptable discrimination ability (Hosmer et al., 2013). Inpatient geriatric psychiatry patients with TUG times at or above 16.46 seconds are considered more likely to fall.

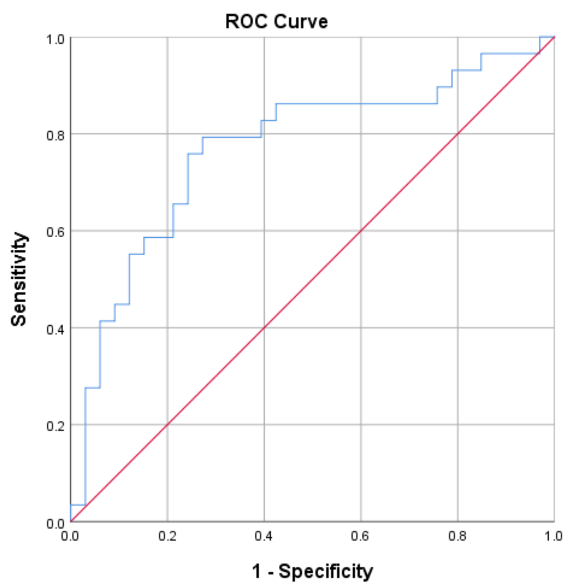

Figure 5. ROC analysis to determine the optimal TUG cut-off time of 16.46 seconds.

Discussion

The purpose of this study was to address a gap in the current literature base, which identified that the TUG has not been tested in the inpatient geriatric psychiatry population. Therefore, the descriptive sample findings from this study could only be compared to those of Shumway-Cook et al. (2000), which is considered the current gold standard for TUG test interpretation, as well as the three previously identified studies (Blair & Gruman, 2006; de Carle & Kohn, 2001; Draper, 2004) that described falls in the inpatient geriatric psychiatry setting.

The final sample size from this study, *N* = 62 exceeded the a priori power analysis required size of *N* = 52. In addition, the sample size was larger than the sample used in Shumway-Cook et al (2000), which had a total sample size of 30.

As previously reported, the sample was homogenous for age between the two groups, non-fallers and fallers. The mean age of non-fallers (*M* = 74.03, *SD* = 7.62) was younger than the mean age of non-fallers in Shumway-Cook et al. (2000) sample (*M* = 78.4, *SD* = 5.8), as well as inpatient geriatric non-faller samples from Blair & Gruman (2006) (*M* = 76.36) and de Carle & Kohn (2001) (*M* = 74.7, *SD* = 7.7). The mean age of fallers (*M* = 75.79, *SD* = 9.60) was younger than the mean age of fallers in the sample of Shumway-Cook et al. (2000) (*M* = 86.2, *SD* = 6.4), but older than the inpatient geriatric psychiatry faller samples of Blair & Gruman (2006) (*M* = 73.6) and de Carle & Kohn (2001) (*M* = 75.6, *SD* = 8.1).

In this study, the samples were also homogenous for gender proportions; both the non-faller and faller group had larger proportions of women. This is consistent with other literature, which also described higher sample female proportions in both non-faller and faller samples of community living elderly (Shumway-Cook et al., 2000) and inpatient geriatric psychiatry (de Carle & Kohn, 2001; Draper, 2004). In addition, the higher female proportion also corresponds with demographic studies which have shown that older women are more likely to have mood and anxiety psychiatric diagnoses (Reynolds et al., 2015), and are also more likely to receive mental health services for depression (NIMH, 2016).

In this sample, non-fallers were more likely to complete TUG testing without an assistive device, while fallers were more likely to use a walker. These findings vary from those of Shumway-Cook et al.(2000), who had a non-faller sample that exclusively completed the TUG without an assistive device (100%, $n = 15$). In the current study, 15.2% of non-fallers used an assistive device (cane = 9.1%; walker = 6.1%).

The proportions of assistive device used by fallers also varied between the current sample and the sample described by Shumway-Cook et al.(2000). In this current study, fallers most often used a walker (48.3%; $n = 14$), followed by no device (41.4%; $n = 12$), then a cane (10.3%; $n = 3$). This is in contrast to Shumway-Cook et al. (2000), who reported the most common device used by fallers was a cane (47%, $n = 7$), followed by a walker (33%, $n = 5$), and no device (20%, $n = 3$).

For the first research question, the research hypothesis can be accepted because there was a significant difference between the TUG time measurements of non-fallers and fallers, $U = 737.00$, $z = 3.65$, $p = <.001$, $r = .46$. Fallers took longer to complete the TUG test ($Mdn = 26.48$) than non-fallers ($Mdn = 13.56$). This finding is similar to that of Shumway-Cook et al. (2000), who also found a significant difference between non-fallers and fallers, $p <.001$. Fallers also took longer to complete the TUG test ($M = 22.2$ sec) than non-fallers ($M = 8.4$ seconds). Of importance to note, TUG times from the current study cannot be directly compared to those of Shumway-Cook et al. (2000) because the non-parametric analysis only permits reporting of medians, not means.

Surprisingly, the observed significant findings in this study were different than those of two studies in *non-psychiatric* geriatric medical units. Neither Lindsay et al. (2004) nor Large et al. (2006) found statistically significant differences between the TUG times of non-fallers and fallers. Lindsay et al. (2004) found no statistically significant relationship between the admission TUG score and fall risk ($p = 0.61$, $n = 141$) (p.250). In addition, Large et al. (2006) reported that "excluding patients unable to complete the TUG failed to detect those with the highest fall rates" (p.425) and suggests "that the value of the TUG lies in the inability to complete the test, rather than the time recorded" (p.426).

The second research question explored in this study sought to determine if the TUG can be used as a predictive tool in inpatient geriatric psychiatry units. Based upon the study findings, the research hypothesis can be accepted because the logistic regression model that used TUG times to identify non-fallers and fallers was statistically significant, $p = <.001$, and increasing TUG times were associated with an increased likelihood of patient falls (OR = 1.10). This finding is similar to the "gold standard" research of Shumway-Cook et al. (2000), who also reported a significant log regression model that predicted fallers to have higher TUG times.

Many studies, including a large meta-analysis (Schoene et al., 2013) have reported that clinicians should not apply "a (TUG) cut point from one study to a different clinical environment…as this could lead to incorrect clinical decision making" (p. 207). Therefore, with a significant log regression analysis, this study also sought to identify the optimal TUG time cutoff point for the patient population of interest, inpatient geriatric psychiatry, since there are no other studies which have reported this to date in the literature.

For this study, TUG time adequately discriminated between fallers and non-fallers, AUC = .77, $SE = .06$, $p < .001$, 95CI [0.65-0.89]. The optimal cut-off score was 16.46 seconds, with sensitivity of 79.3% and specificity of 72.7%. Inpatient geriatric psychiatry patients with TUG times at or above 16.46 seconds are considered more likely to fall.

This cut-off value is slower than the 14 second "gold standard" cutoff as identified by Shumway-Cook et al. (2000). At this time, two possible explanations for this time difference can be proposed. First, it is possible that the unique physical and behavioral issues of this patient population may influence gait speed. However, this study did not analyze the effects of medical comorbidities, psychiatric diagnoses, or patient's behavior during the TUG test (i.e., were they agitated, demonstrating poor safety awareness, etc.) and thus should be explored in future work. The second possible explanation relates to variations in verbal instructions used for TUG testing. In this sample, the hospital physical therapists use the verbal instructions noted in the seminal TUG test development work (Podsiadlo & Richardson, 1991) and instructed patients to walk at a "comfortable and safe pace" (p. 143). This language is consistent with the recommendations of all staff on this unit, who educate patients on safety during admission. However, in the Shumway-Cook et al. study (2000), the researchers instructed patients to walk "as quickly and as safely as possible" (p. 899). It is possible that this difference in TUG instruction between the two studies could account for the difference in the recommended cut-off times. Shumway-Cook's (2000) sample, instructed to walk "quickly," did have a faster cut-off time (14 seconds) than the current sample, who were instructed to walk at a "comfortable pace," resulting in a cutoff time of 16.46 seconds. As evidence based practitioners this observed difference which may be a result of the verbal instruction used forces us to insightfully reflect upon not only the physical actions we employ in therapy but the impact of our verbal instructions on the patient outcomes.

Chapter V

SUMMARY AND CONCLUSIONS

Summary

This study was grounded in the model of functional balance, which emphasizes task and environment constraints, (Huxham et al., 2001) and explored the use of the Timed Up and Go (TUG), a mobility test, to identify patient fall risk in an inpatient geriatric psychiatry unit. The TUG was found to be a predictive tool to identify high fall risk patients in the inpatient geriatric psychiatry setting. A cut-off time of 16.46 seconds is recommended to identify non-fallers from fallers in this patient population.

Limitations

Like all research, this study had limitations in design and analysis. The non-experimental approach used an attribute independent variable to compare groups, make predications and summarize the data (Gliner, Morgan, & Leech, 2009, p. 46). Thus, threats to both internal and external validity must be presented.

Internal validity considerations. Internal validity comprises both equivalency of groups and contamination. First, although subjects were not randomly assigned to groups, both groups were similarly matched for age and gender variables. This provided a medium level of group equivalency. However, the study was highly contaminated. As a retrospective clinically-based study, the environment was not well controlled. While all patients were tested on the same unit, it is likely that the overall unit milieu (for example noise levels, presence of other patients in testing area) varied for each subject. In addition, there were other extraneous variables that were not controlled for or analyzed, including the subjects' psychiatric diagnoses, behaviors, medical comorbidities or medications (Gliner, Morgan, & Leech, 2009, p. 106).

External validity considerations. Population external validity was reduced because of a sampling bias; subjects were included only if they were referred to physical therapy during admission. It is possible, then, that the final sample was not a good representation of the theoretical population, which includes all patients on inpatient geriatric psychiatry units in the United States. This limits the generalizability of the findings. However, as a clinically-based study, this research did have medium to high levels of ecological external validity. The retrospective chart reviews were completed on patients who were tested in the natural conditions of this one inpatient geriatric psychiatry unit (Gliner, Morgan, & Leech, 2009, p. 129).

Conclusions

This study sought to address a literature gap that has real-world clinical implications. Although inpatient geriatric units have high fall rates (Fischer et al., 2005; Draper et al., 2004; de Carle & Kohn, 2001), clinicians working in these specialized units do not have well-validated fall risk assessments that match the unique risk factors of this patient population (Bunn et al., 2014). The findings from this study support the use of the Timed Up and Go (TUG) test as an evidence-based tool to identify inpatient geriatric psychiatry patients who are a high risk for falls during admission and allow better allocation of fall prevention resources (Degelau et al., 2012). As we move forward to meet the Joint Commission mandated fall risk assessments requirements (TJC, 2016), the TUG can be used as the tool of choice in this population and may aid in preventing patient falls and post-fall sequelae of increased healthcare costs (Wong et al., 2011; de Carle & Kohn, 2001).

Future Research

This was the first study to test the predictive validity of the Timed Up and Go (TUG) in the inpatient geriatric psychiatry setting. The results presented here form the foundation for additional studies, and future research should address the known limitations of this study design. While a prospective design would have ethical limitations (that is, waiting to see if a patient fell during an admission), it is important to determine if a patient's TUG time did predict a fall during the actual inpatient admission. This could be completed using a retrospective analysis of both the medical and adverse patient event records. In this design, fallers would be those subjects who sustained a fall while admitted on the inpatient geriatric psychiatry unit, rather than before admission to the unit.

It is also recommended for future studies to have larger sample sizes. This would improve the likelihood that analyses would meet normality assumptions and allow for the use of the more powerful parametric statistical tests. Larger samples could be achieved through the use of: (1) broader inclusion criteria, ideally all patients admitted to an inpatient geriatric psychiatry unit, not just a sub-set, and (2) multiple inpatient geriatric psychiatry units, especially those in varying geographic regions of the United States.

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Appendix A

NewYork-Presbyterian Hospital/Weill Cornell Medicine IRB Approval

Weill Cornell Medicine

Institutional Review Board
Mailing Address :
1300 York Avenue Box 89
New York, NY 10065

Telephone: 646-962-8200
E-mail: irb@med.cornell.edu

September 26, 2017

Danielle Struble, DPT

Submission Type:	Expedited New
Protocol Number:	1708018435
Protocol Title:	Exploring the Use of the Timed Up and Go Test to Identify Patient Fall Risk in an Inpatient Geriatric Psychiatry Unit
Risk Level:	Minimal Risk
Expedited Review Category:	5

Dear Dr. Struble:

The Institutional Review Board (IRB) has conducted an expedited review and approved the abovementioned protocol via expedited review procedures as per 45CFR46.110, including the following documents:

- CSEC Approval Letter – 8/29/2017
- Complete HIPAA Waiver

The protocol and its relevant documents stand approved for the following period:

Approved: 9/15/2017 **Expires:** 9/14/2018

Please do not hesitate to contact the IRB office staff if you have any questions or need assistance in complying with the terms of this approval.

Sincerely,

Alayy Sos, M.S.
Director, Institutional Review Board

Please note the following important information about this approval:

- No investigators on this study, who also serve as members of the Weill Cornell Medicine IRB, participated in thereview, discussion or vote of this submission.
- Billing Compliance: This approval is contingent upon continued adherence with institutional billing compliance policies.
- Immediate Reporting: Investigators must follow the Immediate Reporting Policy at http://weill.cornell.edu/research/research_integrity/institutional_review_board/irb_adv.html. Failure to comply with IRB directives within specified time frames may result in federally mandated penalties, up to and including suspension or termination of IRB approval and mandatory reporting to the Federal government.
- Human Gene Transfer: If this is a human gene transfer protocol, it is a term and condition of IRB approval that the principal investigator obtains Institutional Biosafety Committee (IBC) approval of all amendments prior to initiation, reportable adverse events as per WCMC policy, and annual reports as per M-I-C-3 of the NIH Guidelines for Research Involving Recombinant DNA Molecules. View the IBC website at

http://weill.cornell.edu/research/research_integrity/ibc.html or contact ibc@med.cornell.edu if you require assistance in complying with these requirements.

- Other reporting: The reporting requirements of various regulatory bodies may differ with regard to both what must be reported and when. You are responsible for acquainting yourself with and abiding by all applicable federal and state regulatory reporting requirements.
- Changes to this protocol: If you want to change this research in any way or if any unanticipated hazardous conditions emerge affecting the rights or welfare of the human subjects involved in it, you must submit an amendment detailing these changes to the IRB for review and approval prior to implementing those changes. If the CTSC is used, the changes must also be submitted to the Translational Research Advisory Committee (TRAC). It is your responsibility to obtain approval for any such changes prior to initiating them.
- Continuing approval: You will receive a reminder via email for continuing review of this protocol in advance of the expiration date. The continuing review forms must be filed with the IRB sufficiently early to permit timely review and approval if the project is to continue beyond the period for which it was approved. Please note, no study related activities can continue beyond the WCMC IRB expiration date, including subject recruitment, enrollment, intervention and data analysis.
- If your research study involves human tissues: In addition to IRB approval, Section 4.4 of the hospital By-Laws "**Specimens Removed During Resective Surgery**" requires that all specimens removed during surgical diagnostic procedures that will be used for research must be approved by Pathology Service. Information about Pathology review can be found online at http://www.med.cornell.edu/research/for_pol/forms/Pathology_Review_Instructions.pdf
- If the IRB is requiring that you obtain informed consent from subjects: The signed IRB approved consent forms must be kept in the subject's hospital chart. If the subject has no New York Presbyterian Hospital chart, you are responsible for retaining such signed forms in your research files.
- Information about the WCMC IRBs: The Weill Cornell Medical College (WCMC) Institutional Review Board (IRB) is constituted as required by the Federal Office for Human Research Protections (OHRP). WCMC holds a Federalwide Assurance (FWA) with OHRP. The FWA number is FWA00000093. The WCMC IRB is registered on that FWA. The registration number for the IRB is: General IRB #1 IRB00009417, General IRB #2 IRB00009418, Cancer IRB#1 IRB00009420, Cancer IRB#2 IRB00009421 and Expedited IRB IRB00009419. Should you need additional information about the terms of the WCMC FWA or the WCMC IRBs, please refer to http://weill.cornell.edu/research/research_integrity/institutional_review_board/index.html.
- Note that new federal legislation took effect April 7, 2008, (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html), requiring that all peer-reviewed journal articles resulting from NIH supported research be deposited in PubMed Central, the NIH free digital archive of biomedical and life sciences journal literature, and be made publicly available within twelve months of publication. The Library and RASP have prepared general information which you can see at: http://library2.med.cornell.edu/FacPub/nihpolicy.html
- **ClinicalTrials.gov: To comply with applicable requirements (HHS, NIH, and/or ICMJE), you must register prior to the first subject enrollment for studies that meet the following criteria:**
  - Interventional investigator-initiated NIH-funded WCM studies
  - Interventional investigator-initiated WCM studies evaluating at least one FDA-regulated drug, biological, or device product (except for phase 1 and small device feasibility studies)
  - Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes

  Updating of the record is required every 6 months, with results reporting required for some studies 12 months after study completion. **Failure to publicly post results may incur civil monetary penalties of up to $10,000/day.** Email registerclinicaltrials@med.cornell.edu with full name, CWID and phone number to set up a ClinicalTrials.gov account. More information is available at http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html.

Appendix B

Seton Hall University IRB Approval

SETON HALL UNIVERSITY
1856

November 28, 2017

Danielle Struble-Fitzsimmons

Dear Ms. Struble-Fitzsimmons,

The Seton Hall University Institutional Review Board has reviewed the information you have submitted addressing the concerns for your proposal entitled "Exploring the Use of the Timed Up and Go Test to Identify Patient Fall Risk in an Inpatient Geriatric Psychiatry Unit: A Retrospective Chart Review". Your research protocol is hereby approved as revised through expedited review until **September 14, 2018**. The IRB reserves the right to recall the proposal at any time for full review.

Enclosed for your records are the signed Request for Approval form.

The Institutional Review Board approval of your research is valid for a one-year period from the date of this letter. During this time, any changes to the research protocol must be reviewed and approved by the IRB prior to their implementation.

According to federal regulations, continuing review of already approved research is mandated to take place at least 12 months after this initial approval. You will receive communication from the IRB Office for this several months before the anniversary date of your initial approval.

Thank you for your cooperation.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

Sincerely,

Mary F. Ruzicka, Ph.D

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Genevieve Pinto Zipp

Office of Institutional Review Board
Presidents Hall • 400 South Orange Avenue • South Orange, NJ 07079 • Tel: 973.313.6314 • Fax: 973.275.2361 • www.shu.edu

A HOME FOR THE MIND, THE HEART AND THE SPIRIT

Please review Seton Hall University IRB's Policies and Procedures on website (http://www.provost.shu.edu/IRB) for more information.
Please note the following requirements:

Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Amendments: If you wish to change **any** aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.

Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.

Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Renewal: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your initial approval anniversary date. **Note:** No research may be conducted (except to prevent immediate hazards to subjects), no data collected, nor any subjects enrolled after the expiration date.

REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

All material must be typed.

PROJECT TITLE: Exploring the Use of the Timed Up and Go Test to Identify Patient Fall Risk in an Inpatient Geriatric Psychiatry Unit: A Retrospective Chart Review

CERTIFICATION STATEMENT:

In making **this application**, I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects. I (we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Director of the Institutional Review Board, Seton Hall University, South Orange, NJ 07079.

[signature] 9/25/17

RESEARCHER(S) Danielle Struble-Fitzsimmons DATE

Please print or type out names of all researchers below signature. Use separate sheet of paper, if necessary.

My signature indicates that I have reviewed the attached materials of my student advisee and consider them to meet IRB standards.

[signature] PT, EdD 9/25/17

RESEARCHER'S FACULTY ADVISOR [for student researchers only] DATE

Genevieve Pinto Zipp, PT, EdD

Please print or type out name below signature

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research at the Nov 2017 meeting.

The application was approved ✓ not approved ___ by the Committee. Special conditions were _____ were not ✓ set by the IRB. (Any special conditions are described on the reverse side.)

Mary F. Ruzicka, Ph.D 11/28/17

DIRECTOR, DATE

SETON HALL UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

Seton Hall University
3/2005

Appendix C

Chart Review Form

Timed Up and Go: Chart Review

Medical Record Number	
Age	
Gender (Male, Female)	
Faller Category (Non-Faller, Faller)	
Assistive Device Used for Testing (Walker, Cane, None)	
Timed Up and Go Time (in seconds)	