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FRET: Validity of a Fall Risk Evaluation Tool for Individuals with Acquired Brain Injuries

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FRET: Validity of a Fall Risk Evaluation Tool for Individuals with Acquired Brain Injuries

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A Culminating Project Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science Occupational Therapy

School of Health and Natural Sciences

Dominican University of California

San Rafael, California

December 2014

This project, written under the direction of the candidates' faculty advisor and approved by the chair of the Master's program, has been presented to and accepted by the Faculty of the Occupational Therapy department in partial fulfillment of the requirements for the degree of Master of Science in Occupational Therapy. The content, project, and research methodologies presented in this work represent the work of the candidates alone.

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Abstract

Objective: The purpose of this study is to evaluate the predictive validity of the Fall Risk Evaluation Tool (FRET) for individuals with acquired brain injuries (ABIs).

Methods: Ten participants were included for the study. Inclusion criteria for participants included: age 18 and older, English speaking, 6-months post ABI, ambulatory with or without an assistive device, and uses a wheelchair less than 25% of the day. Exclusion criteria for participants included: global confusion and degenerative neurological conditions. Following the administration of the FRET, participants recorded falls that occurred over the following 3-month study period.

Results: Data was analyzed using the Pearson's r correlation coefficient. No correlation was found between the FRET score and the participants' reported number of falls during the study period. Correlation between individual subtests within the FRET and actual fall occurrence was also examined. The medication subtest was the only item on the FRET that showed a significant correlation with the participants' falls. A significant correlation was found between the number of falls during 6-months prior to the study and the fall occurrence during the 3-month study period.

Conclusion: There is currently a lack of multi-factorial fall risk assessments specifically designed for individuals with ABIs. The FRET was designed to fill this gap in assessments for individuals with ABIs, although no conclusion can currently be drawn regarding its predictive validity. The study suggests modifications should be made to the FRET to increase the predictive validity the FRET.

Introduction

An ABI refers to any injury to the brain that occurs after birth (Stanford Medicine, 2014). Every year, in the United States, 1.7 million people experience a traumatic brain injury (TBI) and 795,000 people experience a cerebrovascular accident (CVA) (Center for Disease Control and Prevention [CDC], 2013c). Approximately 1.4 million of these individuals are left living with long and short-term effects of the acquired brain injury (ABI) (CDC, 2013c). Consequences of an ABI can include visual difficulties, loss of balance and coordination, and deficits in divided attention, among others (Campbell & Matthews, 2010). These consequences may increase the likelihood of falls in individuals with ABIs.

Falls can affect an individual psychologically and physically. According to the CDC (2013a), regardless of the severity, falls can limit mobility, independence, and participation in activities of daily living. Falls also impose significant costs to the nation. A recent report stated that falls accounted for $30 billion in direct medical costs (CDC, 2013d). Due to the significant effects of falls, it is important to assess and identify individuals at risk for falls. Assessing an individual's fall risk can lead to recognizing the need for further services and can reduce the overall number of injuries from falls (Campbell & Matthews, 2010). Due to the increased risk of falling following an ABI, this is particularly important in the ABI population. Reducing the number of falls can result in a higher quality of life for individuals recovering from ABIs, as well as decreasing the financial burden incurred by falls.

Statement of Problem

While multi-factorial fall risk assessments are used in many populations, there is a limited amount of validated multi-factorial fall risk assessments. In particular, there are no validated multi-factorial fall risk assessments for community dwelling individuals with ABIs. The Fall Risk Evaluation Tool (FRET) was created to fill this gap. The FRET is a multi-factorial assessment that assesses an individual's vision, balance, divided attention, polypharmacy, and fall history to determine an individual's fall risk. The FRET was found to have face validity and possible predictive validity in a pilot study conducted in 2013 (Orgil, Woods & Zemora). This current study was also designed to test the predictive face validity of the FRET.

Literature Review

Falls and the Acquired Brain Injury

TBIs and CVAs are both included in the category of ABIs. An ABI is an injury to the brain that occurs after birth (Stanford Medicine, 2014). A TBI is caused by a jolt to the head or physical penetration of the head or skull that disrupts normal functioning of the brain (Traumatic Brain Injury, 2013). A CVA, commonly known as a stroke, occurs when there is a disruption of blood flow to the brain. The disruption to the brain can be caused when a blood vessel blockage or rupture cuts off the oxygen and nutrients to the brain and causes brain tissue damage (World Health Organization, 2013).

Every year, approximately 1.4 million individuals acquire long and short-term consequences associated with ABIs (CDC, 2013c). An ABI can result in a decrease in function in multiple areas including cognitive, physical, and emotional (Brain Injury Network, 2013). Some of the consequences of ABIs may include: confusion, difficulty

seeing with one or both eyes, difficulty walking, dizziness, and loss of balance or coordination, all of which can lead to an increased risk of falling (Campbell & Matthews, 2010).

Research shows that falls are common in individuals recovering from ABIs. Batchelor et al. (2012) found that 14% - 65% of individuals experience at least one post-stroke fall during hospitalization and between 37% and 73% of those individuals fall within the first 6-months after discharge. The discrepancy reported in fall rates reflected differing inclusion criteria in studies on the subject. The study reporting the highest incidence, 73%, was based on participants 60 years or older (N=108) who had been hospitalized and had some residual disability. More conservative numbers were yielded from studies whose inclusion criteria did not include age limitations and did not exclude participants without a residual disability (Batchelor et al., 2012). Given the grave implications associated with falls, an increased risk of falling is a serious concern for individuals with ABIs. Falls have many consequences that can significantly impact individuals' daily lives. In 2011, there were 9.3 million falls, making falls the leading cause of nonfatal injuries treated in hospital emergency departments (CDC, 2013d). In addition, there are approximately 26,000 fatalities due to falls every year (CDC, 2013d). For the other 9.3 million people who experience a nonfatal fall, life can be difficult due to both physical injuries and fear that can develop after a fall (CDC, 2013b). Developing a fear of falling is common and can cause individuals to self-limit activities, which decreases quality of life (Batchelor et al., 2012). Due to the multiple consequences of falls, it is important to have assessments that can accurately assess an individual's fall risk.

Fall Risk Factors

In order to understand the severity of the risk of falls in the ABI population, it is important to first understand the associated fall risk factors. Impairments in cognition, such as memory, concentration, and divided attention, are common in individuals with ABIs (Campbell & Matthews, 2010; National Institute of Neurological Disorders and Stroke, 2013; Pare, Robin, Fogel & Pepin, 2009). Cognitive impairments, in general, have been linked with an increased risk of falling. In a study with 256 patients who experienced a stroke, those with a cognitive sub-score below 29 on the Functional Independence Measure demonstrated a higher risk of falling (Suzuki, Sonoda, & Misawa, 2005). More specifically, Pare et al. (2009) noted deficits in divided attention, which have been shown to increase the risk of falling, as the most prevalent impairment in cognition post TBI. Using reaction times and accuracy scores on the Test d'Attention Partagee Informatise to measure divided attention, Pare et al. (2009) showed that scores were significantly lower in the 37 individuals with a mild TBI (mTBI) when compared to a non-affected control group.

Due to decreased divided attention, balance deficits have been demonstrated in dual task activities that involve both cognition and mobility (Brauer, Broome, Stone, Clewett & Hertig, 2004). Impaired balance is considered the highest predictor of falls post-stroke and was found to quadruple the risk of falling (Campbell & Matthews, 2010). A literature review written by Batchelor et al. (2012) supported Campbell and Matthew's findings, noting that balance impairment was consistently identified as a fall risk factor in nine peer reviewed articles in post-stroke rehabilitation. The most prominent balance impairment post ABI was postural stability deficits (Brauer et al., 2004). Even when

cognition is not involved, balance complications are still highly predictive of falls. This high prediction was demonstrated in a study where findings showed that in single task balance conditions, individuals with TBIs demonstrated increased difficulty compared to those who did not have TBIs (Brauer et al., 2004).

Along with cognitive and balance impairments, visual field deficits are also common complications after ABIs and can increase the risk of falling (Suchoff et al., 2008). A study done by the Department of Veteran Affairs, found that visual field deficits and contrast sensitivity loss are both common after a TBI. The study found that 66.67% of participants with CVAs and 38.75% of participants with TBIs experienced visual field deficits, totaling 102 of 220 participants with ABIs (Suchoff et al., 2008).

Multiple studies have shown that changes in an individual's visual field increase the risk of falling (Dhital, Pey, & Stanford, 2010). Campbell and Matthews (2010) conducted an integrative literature review of empirical studies that focused on fall risk factors, including visual field deficits in post stroke rehabilitation. They found that preference towards one visual field resulted in increased falls (Campbell & Matthews, 2010). Similarly, in a literature review of visual risk factors for falls in older adults, Lord (2006) identified contrast sensitivity and depth perception as the two key visual components in fall risk.

Aside from cognitive, physical, and visual changes, ABIs can result in a variety of psychological disturbances such as depression or emotional disorders. Psychological disorders common in individuals with TBIs include: mood disorders, anxiety disorders, psychosis, and behavioral problems (Rao & Lyketsos, 2000). Thus, individuals with ABIs frequently use psychotropic medications. Additionally, due to the multisystem

effects of the injuries, individuals are often simultaneously prescribed multiple medications, known as polypharmacy (Rao & Lyketsos, 2000). In a prospective cohort study of 6,928 individuals, the link between fall risk and polypharmacy was examined. The mean age of the participants was 55 years old. Exclusion criteria for the study included individuals who could not provide a fall history and had a mental condition or were diagnosed with dementia. The researchers found that when an identified high-risk medication was among the patient's regimen, the number of drugs taken daily significantly correlated with increased fall risk, $p < 0.001$. This correlation was significantly independent of any other fall risk factors (Ziere et al., 2006).

In a cross sectional study conducted in 2011, polypharmacy was again found to be a significant predictor of falls (Kojima et al., 2011). The participants' fall risk was calculated using three fall risk indices: the fall risk index, the simple screening test, and the one-leg standing balance test. The number of drugs taken was compared to results on each of the three indices. Results showed that, independent from other factors such as age and comorbidity, fall risk was increased significantly when individuals were taking multiple medications, $p < 0.0005$ (Kojima et al, 2011).

Rao & Lyketsos (2000) reported the most common medications prescribed post TBI include: dopaminergic agents, selective serotonin reuptake inhibitors, typical and atypical antipsychotics, and anticonvulsants. Many of these drugs have been shown to increase the risk of falling. In a study of 8,100 elderly women, it was found that medications such as anticonvulsants and antidepressants, which focused on the central nervous system, increased the risk of falling (Ensrud et al., 2002). A meta-analysis was conducted in 2008 that focused on the relationship between psychotropic medications and

falls. Nearly all of the 37 articles that were reviewed showed a positive correlation between antidepressant medications and an increased risk of falling (Cumming, 2008). Thus, because of the types of medications prescribed to individuals with ABIs and the common occurrence of polypharmacy, individuals with ABIs are at an increased risk of falling.

In individuals with ABIs, multiple system deficits can last long after the injury. Deficits specific to individuals with ABIs can increase fall risk in many areas. Cognition, specifically divided attention, is a risk factor that is affected after an ABI. Changes in balance and dual task ability have also been noted in individuals with ABIs and are correlated with an increased risk of falling. Additionally, changes in visual function and high occurrence of polypharmacy, which are both common in individuals with ABIs, have been shown to increase the risk of falling (Campbell & Matthews, 2010).

Fall Risk Assessments

Assessing fall risk post-ABI is a vital step in preventing future injury from falls. Lim, Jung, Kim, and Paik (2012) noted that assessing fall risk was particularly important in higher functioning individuals. Individuals who experience less severe ABIs are more likely to ambulate independently. Statistics show that 5,250,000 (75%) of the total annual TBI incidences are concussions or mTBIs, while about half of stroke incidences are mild strokes (CDC, 2013a). With an increase in ambulation, these individuals have more opportunities to fall compared to those with lasting disabilities that do not allow for ambulation. Thus, creating a need for fall risk assessments to identify risk in these individuals who have the ability to ambulate post ABI.

Nystrom and Hellstrom (2012) reported that fall risk assessments for stroke

patients are lacking. Medley, Thompson, and French (2006) found a similar gap in research regarding fall risk assessments for the TBI population. Due to the lack of assessments specifically designed for individuals with ABIs, tools have been borrowed to assess fall risk in this population. The assessments currently in use are designed for older adults who have similar fall risk factors as individuals with ABIs. Similar to changes experienced by older adults, impairments experienced by individuals with ABIs affect multiple systems such as cognition, balance, and behavior (Parvaneh & Cocks, 2012). Current assessments address each area separately, but a tool that comprehensively evaluates all the fall risk factors found in individuals with ABIs is lacking (Campbell & Matthews, 2010).

Assessments

Single factor clinical balance assessments that are commonly used after an ABI to identify fall risk include: The Tinetti Balance scale, which measures balance and gait; the Berg Balance Scale (BBS) & The Dynamic Gait index, which measure balance impairment in older adults; and the Timed Up and Go (TUG) Test, which measures functional mobility (Medley et al., 2006; O'Dell, Au, Schwabe, Batistick, Christos, P., 2013; Sawacha, Carraro, Contessa, Guiotto, Masiero, & Cobelli, 2013).

Sawacha et al. (2013) noted the multidimensional nature of balance is not reflected in these clinical tests. Sawacha et al. (2013) identified other assessments used more sparsely to assess fall risk post ABI, which include: the Fugl-Meyer scale (FM), the lower Motricity Index (loMI), and the Trunk Control Test (TCT). The FM is a subscale used to measure movement, coordination, and reflex action around the hip, knee, and ankle. The loMI examines lower limb motor impairment after a stroke and assesses six

lower limb movements while the patient is sitting. The TCT assesses three movements and balance in a seated position (Sawacha et al., 2013). Batchelor et al. (2012) also noted three different assessments currently used in community settings for individuals who had a stroke. The names of the assessments were not included. One was described as a balance and history of fall, another focused on the BBS at the time of rehabilitation admission, and the third assessed the affected side, lower limb range of motion, duration of disease, and memory (Batchelor et al., 2012). In their review, Batchelor et al. (2012) noted the necessity for further validation of these tools.

An assessment looking at multiple factors to predict fall risk in stroke patients is the Prediction of Falls in Rehabilitation Settings Tool (Predict FIRST) (Nystrom & Hellstrom, 2012). The Predict FIRST scores five fall risk areas cumulatively; there is a higher risk of falling when there are more areas affected. Risk factors in the Predict FIRST include, "male[s], use of central nervous system medications [depressants and sedatives], a fall in the past year, frequent toileting, and inability to do tandem stance" which is "standing with one foot directly in front of the other foot" (Nystrom & Hellstrom, 2012, p. 474). The Predict FIRST was designed to assess fall risk during inpatient rehabilitation (Nystrom & Hellstrom, 2012). Although the Predict FIRST was designed specifically for individuals with ABIs, it is used in acute inpatient settings so it cannot be generalized to chronic or community-dwelling individuals with ABIs.

An assessment that combines both balance and cognition is the cognitive version of the TUG. The TUG (Cognitive) is a test that measures divided attention between a physical and mental task because the individual must attend to walking and navigating the environment, while also completing a cognitive task. Thus, the TUG (Cognitive) is a

good simulation of mobility in real world contexts. It is also one of the few balance assessments that allows the individual to use an assistive device if he or she normally uses one. The TUG (Cognitive) is a validated fall risk assessment in older adults and has a predictive validity of 87% for that population (Shumway-Cook, Brauer, Woollacot, 2000).

A test that only assesses cognition is the Trail Making Test Part B. It is a cognitive assessment, which has shown to be the most sensitive in differentiating between a control group and those with a mTBI (Demery, Larson, Dixit, Bauer, & Perstein, 2010). The Trail Making Test Part B consists of a paper with 25 circles scattered across the page that have either a number (1-13) or letter (A-L) inside of them. The test measures cognitive functions by requiring the participants to connect the circles starting at "1" then to "A", alternating back and forth between numbers and letters. This assessment looks at visual processing, visual searching, visuospatial skills, working memory, psychomotor coordination, and divided attention (Mertle, Richer, & Scirica, 2012).

The previously mentioned assessments are used to assess fall risk in older adults, as well as in individuals with ABIs. Even though the fall risk assessments are completed with community-dwelling individuals who have experienced ABIs, the assessments do not address the multi-factorial nature of fall risk specific to the ABI population (Medley et al., 2006; Nystrom & Hellstrom, 2012; O'Dell et al., 2013). Due to the multi-factorial complications caused by ABIs, there is a need for a valid multi-factorial fall risk assessment tool for the ABI population.

Validity

Assessment tools that are created must be validated to determine whether they assess the areas they intend to assess, and their accuracy in doing so. There are multiple forms of validity that can be examined when evaluating an assessment tool (Portney & Watkins, 2000). The type of validity used is determined by the data that is available to support the measurement tool. The types of measurement validity include: face validity and criterion-related validity (Portney & Watkins, 2000). Face validity assesses whether the instrument proposes a practical and clear method to measure the desired subject matter. Face validity also determines whether an instrument appears to measure what it is said to measure (Portney & Watkins, 2000). While face validity is considered to be the least rigorous type of validity, it is sometimes the only form of validity that can be used. Such instances include studies evaluating new measurement tools that are one of a kind. In these one of a kind cases, there are no existing valid assessments with which to compare the measure. Thus, face validity must be used (Portney & Watkins, 2000).

There are two types of criterion validity: concurrent and predictive validity. Concurrent validity is measured when a new test and a gold standard test are done parallel to one another. This method is frequently used for determining validity in diagnostic or screening tools (Portney & Watkins, 2000). In contrast, predictive validity evaluates whether a measure can validly predict future outcomes. Predictive validity is determined by completing the target test followed by a period of time before the outcome score is acquired. The predictive validity of the test is determined based on the relationship between the target and the outcome score. Predictive validity is most

commonly used in assessments that evaluate future risks (Portney & Watkins, 2000).

The Fall Risk Evaluation Tool (FRET)

The FRET is a new multi-factorial tool, and at present, it has only been tested in a pilot study in 2013 (Orgill, Woods, & Zamora 2013). The face validity of the FRET was established through in-services to 23 clinicians who practice in ABI rehabilitation (Mertle, Richer, & Scirica, 2012). The pilot study, conducted in 2013, showed possible predictive validity but was limited by a sample size of ten participants (Orgill, Woods, & Zamora, 2013). After the pilot study, no modifications were required since the preliminary results showed possible predictive validity. Because the FRET is aiming to fill the gap in literature, there are currently no multi-factorial fall risk assessments to test it against. Therefore, this study aims to confirm the predictive validity rather than concurrent validity of the FRET.

The FRET is an evidence-based multi-factorial assessment tool that was created specifically to assess the fall risk of individuals post-ABI. The original version of the FRET was called the Fall Risk Evaluation Tool for Traumatic Brain Injury (FRETT). It was created to assess fall risk specifically in community-dwelling individuals with TBIs (Mertle, Richer, & Scirica, 2012). Since CVAs and other ABIs present with similar fall risk factors as TBIs, the target population of the FRETT was expanded to apply to the greater ABI population, excluding neurodegenerative conditions. It was renamed the FRET to reflect this change.

The seven areas the FRET assesses are: 30-day fall history, cognition, visual field, contrast sensitivity, depth perception, balance in dual context tasks, and polypharmacy. The FRET is composed of six assessments, two of which are previously validated fall

assessments: the Trail Making Test Part B and the TUG (Cognitive) test. The FRET also assesses aspects of visual function that can elevate fall risks: peripheral visual field, functional depth perception, and the Hamilton-Veale Contrast sensitivity test. The 30-day fall history of the client and fall risk medications, especially the use of psychotropic medication, are also included in the FRET (Mertle, Richer, & Scirica, 2012).

Summary

Falls have many consequences that can significantly impact individuals' daily lives. After an individual experiences an ABI, there may be long-lasting multiple system deficits, which can increase the individual's risk of falling. Cognition, specifically deficits in divided attention, is a risk factor that can be increased after an ABI. Changes in balance and dual task ability have also been noted in individuals with ABIs and are correlated with an increased risk of falling. Additionally, changes in visual function and high occurrence of polypharmacy, which are both found in individuals with ABIs, have also been shown to increase risk of falling. Although fall risk assessments are currently used with chronic and community-dwelling individuals who have experienced ABIs, the current assessments do not address the multi-factorial nature of fall risks, resulting in a reported gap in literature (Medley et al., 2006; Nystrom & Hellstrom, 2012; O'Dell et al., 2013). Due to the many risk factors that can elevate an individual's fall risk; a valid multi-factorial assessment tool would be beneficial to detect fall risk in the ABI population.

The FRET was created in 2012 to fill the gap in literature regarding the lack of multi-factorial fall risk assessments for individuals with ABIs. The FRET was designed to assess key areas that increase risk of falling and are common in individuals with ABIs,

such as: deficits in balance, cognition, vision, and polypharmacy. In 2013, a pilot study showed possible predictive validity of the FRET; however, it was limited due to a small sample size. This study was designed as a replication of the 2013 study, to increase the data on the FRET. Identical methodology was used so that the two studies could easily be compared and analyzed in hopes of determining the FRET's ability to predict fall risk in individuals with ABIs.

Statement of Purpose

The purpose of this study is to evaluate the predictive validity of the FRET for individuals with ABIs.

Theoretical Framework

Person-Environment-Occupation

The Person-Environment-Occupation (PEO) model was the framework chosen to guide this study. The PEO model explains the interactive relationship between individuals, their occupation, and their environment. In the PEO model, characteristics of the person and characteristics of his or her environment, are constantly interacting with one another and do not exist independently (Dunbar, 2007). If the individual is not at their maximum potential for functional performance, the environment should be open for change (Dunbar, 2007).

There are three components in the PEO model: the person, the environment, and the occupation. The person, as described by the characteristics of the person, include: perception, attention, planning, cognition, physical health, motor, and sensory and perceptual skills. In the PEO model, environment is described as the context where occupational performance occurs. Environmental characteristics must exist outside of the

person, which contrasts the person's intrinsic factors such as motivation. Environmental characteristics include personal, social, and physical contexts. A person's abilities and the characteristics of the environment in which the individual dwells are believed to be predictors of how well that person will perform in his or her occupations. The relationship between a person, his or her environment, and the occupational task is non-linear, non-discrete, and uncontrolled. Neither the person, nor his or her environment, has a direct cause and effect relationship but rather they work interdependently. When an individual acquires a disability, his or her environment can either support the individual or become a barrier (Law et al., 1996). The occupations are activities and functional tasks that have a purpose for the person and are essential for living (Law et al., 1996). A person's daily occupations are important for living a fulfilling life.

The PEO model is dynamic and can be used in various ways. In relation to the FRET study, the purpose of the FRET assessment is to measure the fall risk of an individual with an ABI. The objective of this study was to find out if the FRET assessment is a valid predictor of the likelihood of the participant falling in his or her environment while engaging in his or her routine occupations. From the researchers' perspective, the individual's cognition, balance, visual field, depth perception, and contrast sensitivity abilities represent the characteristics of the person. The environment is the facility where the FRET assessment was administered. The occupation is the standardized manner in which the FRET assessment was performed. Functional performance is maximized when the individual's abilities, environment, and occupation, come together to create the best fit, which result in the optimal scores on the FRET assessment. The investigators on the FRET team aimed to collect accurate data and

facilitated the participant's ability to reach his or her maximum potential by controlling the environment. In order to do this, the room in which the participant was assessed was quiet and had minimal distractions.

From the participant's perspective, the environment and occupation differ with that of the assessor's perspective. The environment includes all the contexts in which the person interacts with during the 3-month study period when fall incidences will be tallied, such as the person's home or community. The occupation includes all the activities and tasks the person engages in within the 3-month study period. When the person's characteristics and the demands of the occupation and environment create a good fit, the person is able to engage in safe functional mobility without falling. If there is a mismatch between the person, environment, and occupation, the person may not perform their occupation at optimal potential. For this study, participants may find a mismatch during the FRET assessment or during daily activities within the 3-month study period. A mismatch during the FRET assessment may affect the participant's FRET scores. A mismatch during the 3-month study period may affect the participant's number of falls. The PEO model is the most suited theoretical framework for this study to assess the correlation between the person's characteristics and the number of falls the person has in his or her environment

Definitions

acquired brain injury (ABI). An ABI refers to any injury to the brain that occurs after birth (Stanford Medicine, 2014).

fall. A fall is defined as an event which results in a person coming to rest inadvertently on the ground or floor or other lower level (World Health Organization, 2012).

polypharmacy. The practice of administering many different medicines, especially concurrently, for the treatment of the same disease (Webster's Third New International Dictionary, 2002).

validity. Validity assesses whether the measurements are accurate and if the assessment is actually measuring what is intended to be measured (Golafshani, 2003).

Methodology

Design

The research design was a single group exploratory longitudinal study. The purpose of the research was to assess the predictive validity of the FRET. The study aimed to discover if there was a correlational relationship between the FRET assessment scores and the number of falls the participants had during the 3-month study period. The purpose of choosing the single group exploratory longitudinal research design is to determine if the FRET accurately predicted fall risks in individuals with ABIs.

The duration of the FRET assessment (see Appendix A) is approximately 30-minutes from start to finish and includes: 30-day fall history, a fall risk medication checklist, the TUG (Cognitive), the Trail Making Test Part B, the Gross Test of Peripheral Visual Fields, the Functional Depth Perception test, and the Hamilton-Veale Contrast Sensitivity Test. The FRET is a standardized assessment and all investigators were trained prior to the start of the study to ensure inter-rater reliability. Subtests of the FRET assessment were all given in similar environments and precautionary measures

were taken to prevent falls during the assessments. The FRET categorizes participants at a low, moderate, or high fall risk. A FRET score of 0-25 indicates low fall risk, 30-45 indicates moderate fall risk, and 50-100 indicates high fall risk.

Subjects

The research study was directed towards the population of high functioning community-dwelling individuals with ABIs. The population consisted of individuals who live within the San Francisco Bay Area in California. Inclusion criteria included: age 18 and older, English speaking, 6-months post ABI, ambulatory with or without an assistive device, and using a wheelchair less than 25% of the day. Exclusion criteria included global confusion and individuals who have degenerative neurological conditions. Being globally confused was identified if the participants incorrectly answered the first three questions on the Saint Louis University Mental Status Examination (SLUMS) (see Appendix B).

Purposeful sampling was used to ensure the participants met the inclusion criteria. Investigators recruited participants by handing out and posting flyers (see Appendix C) at several facilities and events. The flyers contained a brief overview of what the study entailed and the inclusion characteristics for participation. The flyers were posted and handed out at: medical facilities, post-stroke community programs, rehabilitation centers, assisted living centers, and resource fairs. In addition, advertisements were posted on craigslist (see Appendix D). The snowball sampling method of recruitment was also used.

The participants gave informed consent through a signed document (see Appendix E). Participants' bill of rights (see Appendix F) was explained and provided prior to the

participants signing consent and before the FRET was conducted. Participants in the study who had a conservatorship or legal guardianship received a proxy consent form, which was signed by the conservator (see Appendix G), and a proxy bill of rights (see Appendix H). The signed informed consent form verified that the participants were aware of the purpose and procedure of the study, the potential risks and benefits, and their rights to withdraw or discontinue their participation at any time during the study at will.

Once participants initiated contact with the investigators, the investigators screened participants for inclusion and exclusion criteria via telephone calls or emails. The participants were asked if they had a guardian or conservator in the initial screening process in order to obtain either the guardian or conservator's consent for the individual to participate in the study. Inclusion criteria identified through the first screening process included: being 18 years or older, English speaking, using a wheelchair less than 25% of the day, and being at least 6 months post-ABI. The participants that fulfilled the criteria of the study were then scheduled for an in-person assessment of the FRET.

Data Collection

The FRET assessment was conducted at assigned locations throughout the San Francisco Bay Area of California. Upon completion of the consent process, participants were asked to fill out a demographics form (see Appendix I). The next step was conducting the SLUMS assessment, which screened out participants who were globally confused. If the participants incorrectly answered the first three questions on the SLUMS, the FRET assessment was not conducted and the participants were informed that a "Fall Prevention" packet (see Appendix J) would be mailed to their address. If

participants correctly answered the first three questions of the SLUMS, they were not considered globally confused and therefore the FRET assessment was conducted.

The FRET assessment consists of seven assessments. The first assessment gathered information regarding the participants' 30-day fall history. The second assessment identified whether the participants take any medication that increased their risk of falling. The participants were asked to bring a list of current medications they were taking to the assessment. Next, the investigators compared the participants' list of medications with the FRET's list of fall risk medications. The third assessment, the TUG (Cognitive) test, gathered information on the participants' balance in a dual-task context. The fourth assessment, The Trail Making Part B, measured cognitive function. The fifth assessment detected if there was a deficit in the peripheral visual field using the Gross Test of Peripheral Visual Fields. The sixth assessment, the Functional Depth Perception Test, assessed the participants' ability to perceive depth. Finally, the seventh assessment, the Hamilton-Veale Contrast Sensitivity Test, measured the participants' visual contrast sensitivity.

Once the FRET assessment was completed, the participants received fall calendars (see Appendix K), followed by verbal and written instructions as to how to complete the calendars. The participants had the investigators' contact information if they had any questions throughout the 3-month study period. The fall calendars consisted of a stapled packet of three calendars for the consecutive 3-month period after the assessment date and one stamped self-addressed envelope to return the completed calendars to the investigators. The packet had a magnet attached to the back, so the participants could hang the packet on a metal surface, such as the refrigerator. The

participants were asked to keep track of how many times they fell by putting a tally mark for each fall that occurred over the following 3-months. Investigators and assistants contacted participants biweekly throughout the 3-month period via telephone to remind the participants to record their falls in the fall calendars. After the 3-month period ended, the participants returned the fall calendars to the investigators using the self-addressed envelope given to them at the assessment. When the investigators received the calendars, a "Fall Prevention" packet was sent via United States Postal Service to the participants.

Once the FRET assessment was completed, the investigators assigned pseudonyms to the participants. The master key containing the participants' names and assigned pseudonyms was recorded on a password protected word document, and was kept on one of the investigator's password protected desktop computers. Once pseudonyms were assigned, all paperwork only used the participants' pseudonyms. Any paper data forms with identifying information were locked in the investigators' advisor's filing cabinet in a locked office.

Data Analysis

The purpose of the study was to assess the validity of the FRET, as the study aimed to discover if there was a correlational relationship between the FRET assessment scores and the number of falls the participants had over a period of 3-months. Data was analyzed using the Pearson's r correlation coefficient. Pearson's r correlation coefficient is used to measure the linear relationship between two variables; in this case it was used to analyze the data for a correlation between the FRET scores and the number of falls the participants reported. The investigators also individually analyzed the number of reported falls with each of the seven assessments within the FRET, the participants' age,

diagnoses, and gender.

Using data from both the 2013 pilot study and the current study, the FRET scores and fall occurrences were also analyzed in two separate groups, a TBI group and a CVA group. The intention of this was to determine whether diagnosis was a factor in the accuracy of the tool. Investigators were able to use the data from the previous FRET study because the inclusion criteria and data collection were identical in both studies. Additionally, the same advisor trained and oversaw all investigators in both studies.

Limitations

One of the limitations that may occur in a research study is attrition. Attrition may occur if the participants forget to fill out or return their fall calendars. A common sequela of an ABI is impaired cognition, which can lead to incorrect reporting and recall of information. Precautions were taken to guard against limitations by providing biweekly phone calls to the participants from the investigators and the assistants that reminded them to complete their fall calendars. Assistants were provided a phone script to ensure standardized phone calls (see Appendix L). During the biweekly phone calls, participants were reminded how too accurately record falls in their fall calendars. However, during the third week of the study period, one research assistant did not make the assigned calls. As a result, five participants were not reminded to fill out their fall calendars.

Ethical and Legal Considerations

The first action investigators took to ensure procedural justice was receiving the approval from Dominican University of California's Institutional Review Board (IRB). The IRB is a committee designated to protect the rights and welfare of people who

participate in research. The investigators submitted an IRB application describing the study in detail. On February 7th, 2014, the investigators obtained IRB approval, IRBPHP Application #10228 (see Appendix M).

Ethics concerning veracity and the participants' autonomy were addressed through the process of informed consent. The participants gave informed consent through a signed document before the FRET was conducted. Participants in the study who had a conservatorship or legal guardianship received a proxy consent form, which was signed by the conservator or guardian prior to the start of the study. The signed informed consent form verified that participants were aware of the purpose and procedure of the study, the potential risk and benefits, and their right to withdraw or discontinue their participation at any time during the study without consequences. Additionally, participants received a bill of rights form, which explained their rights regarding the study in layman's terms. Participants in the study who had a conservatorship or legal guardianship received a proxy bill of rights form.

To address the confidentiality of the participants' information and identity, the investigators assigned pseudonyms to the participants. The document containing the participants' names and assigned pseudonyms was recorded on a password-protected word document, and was kept on one of the investigator's locked desktop computers. Once pseudonyms were assigned, data only contained the participants' pseudonyms. Any paper data forms with identifying information were locked in the advisor's office. Only the four investigators and their advisor had access to all the participants' names, contact numbers, and assessment data. Two assistants were used to help with the biweekly calls to the participants to remind them to complete the fall calendars. The

assistants were only given access to the names and contact numbers of the participants. The assistants were current students in the Dominican University of California's occupational therapy program and received information on research confidentiality in their research class, OT 5105, prior to their involvement in this study.

Beneficence was an additional ethical concern during this study. The American Occupational Therapy Association describes beneficence as the demonstration of concern for safety and well-being of participants (Reed et al., 2010). During the research study, some participants had difficulty completing the Trail Making Test Part B. Once the maximum amount of time had passed, the investigators did not require the participant to complete the rest of the assessment. Requiring the participants to complete the assessment could have led to psychological effects, such as sadness, frustration, or anger. By stopping the assessment when participants showed signs of mental distress, the investigators protected the participants from becoming overwhelmed or emotionally distraught over their performance. During the assessments that involved safety hazards such as falling, the investigators used the stand by assist technique to eliminate the safety concern.

Results

Ten participants were included in the FRET study. Of the participants, seven were female and three were male. The participants' mean age was 54 (SD = 20.98). Five of the participants were recruited from the Brain Injury Network of the Bay Area (BINBA) and five were recruited through snowball sampling. After the three-month study period, nine out of ten participants returned their fall calendars via United States Postal Service. Verbal confirmation regarding the number of falls was received from the

participant whose fall calendar was not returned to the investigators. Four participants were rated as a low fall risk, three were rated as a moderate fall risk, and three were rated as a high fall risk. Two of the participants who received a low fall risk score fell once during the 3-month period. Zero participants who were ranked at a moderate fall risk fell. Out of the three participants who received a high fall risk score, one participant did not fall, another fell once, and the third fell twice (Table 1).

The investigators used the Pearson's r correlation coefficient to correlate the fall risk of individuals, as determined by the FRET, and the actual number of falls that occurred. The analysis showed no significant correlation (r^2 = .3166, p = .7830). In addition, each of the seven subtests was analyzed individually to determine if there was a correlation between the participants' actual number of falls and their subtest scores (Table 2).

Data from the previous study was also analyzed in conjunction with the current study's results, to determine whether participants' ages, diagnoses, and gender influenced their fall risk. The previous study by Orgill, Woods, & Zamora, included nine participants, whose mean age was 48.5 (SD=11.9) (Table 3). As a whole (N=19), the FRET scores from the combined groups showed a moderate correlation with the actual falls (r^2 = 0.2763, p = .0208) (2013). When demographics such as age, gender and diagnosis were analyzed individually with the actual number of falls, none showed significant correlation with actual falls. Participants' diagnoses of CVAs and TBIs did not show a significant correlation (r^2 = .0035, p = .8276) and neither did their gender (r^2 = .1123, p =.1488).

Discussion

Prior to this study, only one pilot study had been conducted to determine the predictive validity of the FRET (Orgill, Woods, & Zamora, 2013). By using Spearman's rank correlation test, the pilot study showed a significant correlation (r_s, (8) = 0.8227, p <.02), between the FRET score and the actual falls that occurred (Orgill, Woods, & Zamora, 2013). This correlation suggested that the FRET could potentially accurately predict fall risk in individuals with ABIs. In contrast, the analysis of the current study of the FRET showed no significant correlation meaning it was not valid in predicting participants' fall risk. In an attempt to discover what was causing this result, the investigators analyzed each subtest of the FRET individually. The analysis showed the medication is the only subtest with a statistical significant correlation to the number of falls over the 3-month study period. There are several possible reasons the FRET is not a valid tool to assess fall risk in the ABI population in our study.

One possible reason for the FRET not being valid is that The Gross Test of Peripheral Visual Fields, which was used to measure participants' visual field, is not known for its inter-rater reliability. Another possible reason our study did not show predictive validity in the FRET is that a specific depth perception testing procedure was created for the FRET assessment because there is currently no portable standardized assessment for assessing depth perception in a clinical setting. The depth perception test that was created for the FRET has not been tested for its validity. Therefore, it is unclear whether or not the depth perception test provided accurate scores. When the vision subtest scores were analyzed with the FRET scores, no significance was found, yet the

vision portion accounts for a quarter of the entire FRET score. In the future, investigators could consider putting less weight on the vision portion of the FRET.

The FRET consists of seven subtests, and each subtest is weighed differently on the FRET score form. Subtests are weighted higher and lower depending upon the predicted impact on causation of a fall. While the other subtests did not show to be significant, the medication section did show a significant correlation with the number of falls participants had. However, on the FRET, the medications item is worth 15 points out of the highest possible score of 100 points, which may indicate that the medications item is not weighed heavily enough. The FRET may benefit from increasing the weight of the medication on the FRET score sheet.

Another limitation that may have affected the study is that there were five missed calls during the 3-month study period. This may have led to participants forgetting to record falls if they had any that week, which could have greatly affected the final results of the study. Additionally due to consequences of an ABI, specifically memory impairments, participants may have forgotten to record a fall regardless of the reminder calls.

After each subtest was analyzed and discussed, the investigators analyzed information that was not on the FRET score sheet and was gathered through the demographics form. The participants' age, diagnosis, and gender from both the 2013 pilot study and the current study were analyzed to determine whether the participants' demographics had any correlation with the number of times the participants reported a fall. However, all three areas of the demographics were found insignificant. After looking closely at the participants' completed demographics forms, the investigators

analyzed the participants' 6-month fall history with their scores on the FRET. The 6-month fall history was found to be a significant predictor of falls. Therefore, the FRET may benefit from replacing the 30-day fall history with a 6-month fall history.

Other factors that could have affected the fall risk but were unaccounted for in the FRET are the participants' environments and routines. The FRET does not account for the participants' activity level throughout the day. High activity levels may affect a person's risk of falling. Additionally the FRET does not take into consideration if the participant has a caregiver. Having a caregiver may decrease the participants' risk of falling due to caregiver assistance and support. The investigators would suggest including activity levels and caregiver assistance into the scoring of the FRET.

Conclusion

Individuals with ABIs have an increased risk of falling due to the residual effects of an ABI. Physical and mental effects of falls may cause individuals to decrease their participation in occupations and decrease their quality of life. There is currently a lack of multi-factorial fall risk assessment tools for the ABI population. The FRET is a new assessment tool created in 2012 and is in the process of being validated. This current study replicated a pilot study conducted in 2013. Both studies aimed to determine the predictive validity of the FRET. Although the initial pilot study showed that the FRET scores and number of falls over a 3-month period had a significant correlation, the current study showed an insignificant correlation. Given the equal sample size in both studies, the identical methodologies, and the opposing results, no conclusion can be made about the validity of the FRET tool.

While no conclusion can be made regarding validity, this study identified areas in the FRET that could be modified to increase the predictive validity of the FRET. Occupational therapists aim to help clients fully engage in their occupations safely with the least amount of restrictions. Having a multi-factorial fall risk assessment tool for the ABI population can increase the population's accessibility to a treatment intervention that will reduce the risk of falls. Thus, clients will be able to fully engage in their occupations and have a higher quality of life while considering safety precautions identified by the FRET.

Tables

Table 1: Participants' Demographics

Participant	Age	Gender	Diagnosis	Falls in Past 6 Months
1	37	Female	TBI	1
2	31	Female	Multiple concussions, post concussive syndrome, MTBI	0
3	40	Male	Concussions, MTBI, PTSD	2
4	28	Male	Brain Tumor	0
5	44	Female	CVA	0
6	60	Female	CVA	0
7	75	Female	CVA	2
8	84	Female	Unknown ABI	0
9	81	Female	CVA	1
10	62	Male	CVA	1

Table 2: FRET Scores

Participant	Fall Risk Medications	FRET score	Risk of Falling	Number of Falls Over 3 Month Period	Falls in Past 6 Months
1	0	0	Low	1	1
2	0	5	Low	0	0
3	0	0	Low	1	2
4	0	0	Low	0	0
5	0	30	Moderate	0	0
6	0	65	High	0	0
7	0	40	Moderate	0	2
8	0	35	Moderate	0	0
9	4	75	High	1	1
10	2	75	High	2	1

Table 3: 2013 FRET Study

Participant	Age	Gender	Diagnosis	Falls in the last 30 days
1	40	Male	TBI	Yes
2	35	Female	Encephalitis	Yes
3	36	Male	TBI	Yes
4	70	Male	CVA	Yes
5	56	Male	Brain Surgery	No
6	58	Male	TBI	No
7	34	Male	TBI	No
8	51	Male	TBI	No
9	50	Female	TBI	No
10	55	Male	TBI	Yes

(Orgill, Woods, & Zamora 2013)

Appendix A

FRETT

Fall Risk Evaluation Tool for Traumatic Brain Injury

Client Name:
Date:

1. Has client fallen during the past 30 days since onset of TBI?
   - ☐No (score as 0) .....
   - ☐Yes (score as 10) .....

2. Is client taking any fall risk medications?
   - ☐No (score as 0) .....
   - ☐Yes (score as 15) .....

3. Balance & Gait
   - a. TUG cog/*(man) time _____
   - b. Walking aid used _____
   - ☐ < 15 sec *(<14.5) (score as 0) .....
   - ☐ ≥15 sec *(≥14.5) (score as 25) .....

4. Cognition
   - a. TMT B time _____
   - ☐ < 180 sec (score as 0) .....
   - ☐ ≥ 180 sec (score as 25) .....

5. Vision

   WNL

   a. Visual Field
      - ☐Yes (score as 0) .....
      - ☐No (score as 5) .....

   b. Depth Perception
      - ☐Yes (score as 0) .....
      - ☐No (score as 10) .....

   c. Contrast sensitivity
      - ☐Yes (score as 0) .....
      - ☐No (score as 10) .....

   R eye open: Level ____
   L eye open: Level ____
   Both eyes open: Level ____
   *Level ≤ 8 in 1 eye is not WNL – mark "No"
   *Level ≤ 12 in both eyes is not WNL – mark "No"

Low Risk = 0-25 **Mod Risk** = 30-45 **High Risk** = 50 or higher

TOTAL SCORE: _____

SAMPLE

Appendix B

VAMC
SLUMS Examination

Questions about this assessment tool? E-mail aging@slu.edu.

Name_____ Age _____

Is patient alert?_____ Level of education _____

__/1 (1) **1. What day of the week is it?**

__/1 (1) **2. What is the year?**

__/1 (1) **3. What state are we in?**

Department of Veterans Affairs

4. Please remember these five objects. I will ask you what they are later.

Apple Pen Tie House Car

5. You have $100 and you go to the store and buy a dozen apples for $3 and a tricycle for $20.

(1) **How much did you spend?**

__/3 (2) **How much do you have left?**

6. Please name as many animals as you can in one minute.

__/3 (0) 0-4 animals (1) 5-9 animals (2) 10-14 animals (3) 15+ animals

__/5 **7. What were the five objects I asked you to remember?** 1 point for each one correct.

8. I am going to give you a series of numbers and I would like you to give them to me backwards. For example, if I say 42, you would say 24.

__/2 (0) 87 (1) 649 (1) 8537

9. This is a clock face. Please put in the hour markers and the time at ten minutes to eleven o'clock.

(2) Hour markers okay

__/4 (2) Time correct

__/2 (1) **10. Please place an X in the triangle.**

(1) **Which of the above figures is largest?**

11. I am going to tell you a story. Please listen carefully because afterwards, I'm going to ask you some questions about it.

Jill was a very successful stockbroker. She made a lot of money on the stock market. She then met Jack, a devastatingly handsome man. She married him and had three children. They lived in Chicago. She then stopped work and stayed at home to bring up her children. When they were teenagers, she went back to work. She and Jack lived happily ever after.

__/8 (2) **What was the female's name?** (2) **What work did she do?**

(2) **When did she go back to work?** (2) **What state did she live in?**

_____ **TOTAL SCORE**

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SAINT LOUIS UNIVERSITY

SCORING

High School Education		Less than High School Education
27-30	Normal	25-30
21-26	MNCD*	20-24
1-20	Dementia	1-19

* Mild Neurocognitive Disorder

SH Tariq, N Tumosa, JT Chibnall, HM Perry III, and JE Morley. The Saint Louis University Mental Status (SLUMS) Examination for Detecting Mild Cognitive Impairment and Dementia is more sensitive than the Mini-Mental Status Examination (MMSE) - A pilot study. J am Geriatri Psych (in press).

Appendix C

Have you experienced a fall episode or feel like you are at risk of falling?

Will you help with a research study about fall risk?

Students at Dominican University of California are conducting a study on the assessment of fall risk. The study involves: two assessment tests and completing a three-month journal. Upon completion of the study, each participant will receive evidence-based fall risk reduction material.

To participate you must be: 18 years or older, English speaking, and have an acquired brain injury for over one year. Eligible conditions include: cerebral vascular accidents (Stroke), traumatic brain injury, tumors, hypoxia, concussions, and encephalopathy. We look forward to hearing from you!

To participate, contact the FRET at
Phone: (415)-458-3753

Email: fret2014@gmail.com

Appendix D

WEBSITE AD

Have you experienced a fall or feel that you are at risk of falling? We need your help!

Students at Dominican University of California are conducting a study on fall risk and need your help! The study involves participating in a fall risk assessment and completing a 3-month fall journal. At the completion of the 3-months, participants will be provided with a resource packet on fall prevention. To participate you must be 18 years or older, English speaking and have had an acquired brain injury at least 6-months ago. Eligible conditions include: cerebral vascular accidents (Stroke), traumatic brain injury, tumors, hypoxia, concussions, and encephalopathy.

Please contact us at: fret2014@gmail.com or (415) 458-3753

Appendix E

CONSENT FORM TO ACT AS A RESEARCH PARTICIPANT
DOMINICAN UNIVERSITY OF CALIFORNIA

1. I understand that I am being asked to participate as a subject in a research study designed to evaluate the validity of a fall risk assessment. This research is part of Mikaela Conlon, Irene Leung, Desiree Shaver, and Melanie Shea's Capstone research project at Dominican University of California. This research project is being supervised by Dr. Kitsum Li, OTD, OTR/L, Occupational Therapy Department of Dominican University of California.

2. I understand that participation in this research will involve taking part in a 30-minute assessment that will involve cognition, balance, and vision tests as well as a medication review and review of fall history. I understand that it will also include recording any incidence of falls for three months after the initial assessment.

3. I understand that, upon completion of the study, I have the right to request the results of my assessments form by contacting the FRET team at fret2014@gmail.com.

3. I understand that my participation in this study is completely voluntary and I am free to withdraw my participation at any time.

4. I have been informed that, if at any time, I experience difficulty or fatigue during the assessment I can rest or terminate my participation.

5. I understand that if I have any further questions about the study, I may contact the researchers at fret2014@gmail.com or their research supervisor, Dr. Kitsum Li at kitsum.li@dominican.edu, Dominican University of California at 415-458-3753. If I have further questions or comments about participation in this study, I may contact the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with the protection of volunteers in research projects. I may reach the IRBPHS Office by calling (415) 482-3547 and leaving a voicemail message, by FAX at (415) 257-0165 or by writing to the IRBPHS, Office of the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901.

6. All procedures related to this research project have been satisfactorily explained to me prior to my voluntary election to participate.
Risks: Potential risk to the subjects is becoming fatigued, physically and/or mentally, during the FRET assessment. Another potential risk is falling during the TUG assessment. The participants may develop a fear of falling if they perform poorly during the assessment. Poor performance in any area of the FRET may also lead to decreased self-esteem.

Benefits: Participants will be given a sense of fulfillment by contributing to research that may potentially help with fall risk identification in others with similar diagnoses. Participants will gain insight into their personal fall risk. They will be provided information on evidence-based fall prevention strategies upon completion of the study.

I HAVE READ AND UNDERSTAND ALL OF THE ABOVE EXPLANATION REGARDING THIS STUDY. I VOLUNTARILY GIVE MY CONSENT TO PARTICIPATE. A COPY OF THIS FORM HAS BEEN GIVEN TO ME FOR MY FUTURE REFERENCE.

Signature_____
Date_____

Appendix F

DOMINICAN UNIVERSITY of CALIFORNIA
RESEARCH PARTICIPANT'S BILL OF RIGHTS

Every person who is asked to be in a research study has the following rights:

1. To be told what the study is trying to find out;

2. To be told what will happen in the study and whether any of the procedures, drugs or devices are different from what would be used in standard practice;

3. To be told about important risks, side effects or discomforts of the things that will happen to her/him;

4. To be told if s/he can expect any benefit from participating and, if so, what the benefits might be;

5. To be told what other choices s/he has and how they may be better or worse than being in the study;

6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;

7. To be told what sort of medical treatment is available if any complications arise;

8. To refuse to participate at all before or after the study is stated without any adverse effects. If such a decision is made, it will not affect h/her rights to receive the care or privileges expected if s/he were not in the study.

9. To receive a copy of the signed and dated consent form;

10. To be free of pressure when considering whether s/he wishes to agree to be in the study.

11. **Risks:** Potential risk to the subjects is becoming fatigued, physically and/or mentally, during the FRET assessment. Another potential risk is falling during the TUG assessment. The participants may develop a fear of falling if they perform poorly during the assessment. Poor performance in any area of the FRET may also lead to decreased self-esteem.

12. **Benefits**: Participants will be given a sense of fulfillment by contributing to research that may potentially help with fall risk identification in others with similar diagnoses. Participants will gain insight into their personal fall risk. They will be provided information on evidence-based fall prevention strategies upon completion of the study.

If you have other questions regarding the research study, you should ask the researcher or her/his advisor. You may also contact The Dominican University of California Institutional Review Board for the Protection of Human Subjects by telephoning the

Office of Academic Affairs at (415) 257-0168 or by writing to the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA. 94901

Appendix G

PROXY CONSENT FORM TO ACT AS A RESEARCH PARTICIPANT
DOMINICAN UNIVERSITY OF CALIFORNIA

1. I understand that my ward is being asked to participate as a subject in a research study designed to evaluate the validity of a fall risk assessment. This research is part of Mikaela Conlon, Irene Leung, Desiree Shaver, and Melanie Shea's Capstone research project at Dominican University of California. This research project is being supervised by Dr. Kitsum Li, OTD, OTR/L, Occupational Therapy Department of Dominican University of California.

2. I understand that participation in this research will involve taking part in a 30-minute assessment that will involve cognition, balance and vision tests as well as a medication review and review of fall history. I understand that it will also include recording any incidence of falls for three months after the initial assessment.

3. I understand that, upon completion of the study, I have the right to request the results of my assessments form by contacting the FRET team at fret2014@gmail.com

3. I understand that their participation in this study is completely voluntary and my ward is free to withdraw his/her participation at any time.

4. I have been informed that, if any time, they experience difficulty or fatigue during the assessment my ward can rest or terminate his/her participation.

5. I understand that if I have any further questions about the study, I may contact the researchers at fret2014@gmail.com or their research supervisor, Dr. Kitsum Li at kitsum.li@dominican.edu, Dominican University of California at 415-458-3753. If I have further questions or comments about participation in this study, I may contact the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with the protection of volunteers in research projects. I may reach the IRBPHS Office by calling (415) 482-3547 and leaving a voicemail message, by FAX at (415) 257-0165 or by writing to the IRBPHS, Office of the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901.

6. All procedures related to this research project have been satisfactorily explained to me prior to my voluntary election to participate.

Risks: Potential risk to the subjects is becoming fatigued, physically and/or mentally, during the FRET assessment. Another potential risk is falling during the TUG assessment. The participants may develop a fear of falling if they perform poorly during the assessment. Poor performance in any area of the FRET may also lead to decreased

self-esteem.

Benefits: Participants will be given a sense of fulfillment by contributing to research that may potentially help with fall risk identification in others with similar diagnoses. Participants will gain insight into their personal fall risk. They will be provided information on evidence-based fall prevention strategies upon completion of the study.

I HAVE READ AND UNDERSTAND ALL OF THE ABOVE EXPLANATION REGARDING THIS STUDY. I VOLUNTARILY GIVE MY CONSENT FOR MY WARD TO PARTICIPATE. A COPY OF THIS FORM HAS BEEN GIVEN TO ME FOR MY FUTURE REFERENCE.

Signature_____
Date_____

Appendix H

DOMINICAN UNIVERSITY of CALIFORNIA
PROXY RESEARCH PARTICIPANT'S BILL OF RIGHTS

Every person under guardianship who is asked to be in a research study has the following rights:

1. To be told what the study is trying to find out;

2. To be told what will happen in the study and whether any of the procedures, drugs or devices are different from what would be used in standard practice;

3. To be told about important risks, side effects or discomforts of the things that will happen to her/him;

4. To be told if s/he can expect any benefit from participating and, if so, what the benefits might be;

5. To be told what other choices s/he has and how they may be better or worse than being in the study;

6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;

7. To be told what sort of medical treatment is available if any complications arise;

8. To refuse to participate at all before or after the study is stated without any adverse effects. If such a decision is made, it will not affect h/her rights to receive the care or privileges expected if s/he were not in the study.

9. To receive a copy of the signed and dated consent form;

10. To be free of pressure when considering whether s/he wishes to agree to be in the study.

11. **Risks:** Potential risk to the subjects is becoming fatigued, physically and/or mentally, during the FRET assessment. Another potential risk is falling during the TUG assessment. The participants may develop a fear of falling if they perform poorly during the assessment. Poor performance in any area of the FRET may also lead to decreased self-esteem.

12. **Benefits**: Participants will be given a sense of fulfillment by contributing to research that may potentially help with fall risk identification in others with similar diagnoses. Participants will gain insight into their personal fall risk. They will be provided information on evidence-based fall prevention strategies upon completion of the study.

If you have other questions regarding the research study, you should ask the researcher or her/his advisor. You may also contact The Dominican University of California Institutional Review Board for the Protection of Human Subjects by telephoning the Office of Academic Affairs at (415) 257-0168 or by writing to the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA. 94901

Appendix I

DEMOGRAPHIC FORM

Name: _____

Age: _____

Gender (circle one): Female Male

Phone Number: _____

Address: _____

_____

Emergency Contact: _____

Telephone number: _____

Diagnosis/Type of Brain Injury: _____

When did the brain injury occur? _____

Have you fallen in the past six months (circle one)? Yes No

If yes, how many times? _____

Do you use an assistive device(s)? Wheelchair Walker Cane

If you use a wheelchair, how many hours a day do you use it? _____

Appendix J

The FRET Research Team

Fall Prevention Packet

Dominican University of California

FRET Research Team

2014

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Currie, L. (2008). Fall and Injury Prevention. *Agency for healthcare research and quality. CH 10.* http://www.ahrq.gov/professionals/clinicians-providers/resources/nursing/resources/nurseshdbk/index.html Currie L. (Fall and Injury Prevention. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 10. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2653/

Gillespie, L. D., Robertson, M. C., Gillepsie, W. J., Sherrington, C., Gates, S., Clemson, L. M., & Lamb, S. E. (2013). Interventions for preventing falls in older people living in the community (Review). In *Interventions for preventing falls in older people living in the community (Review)*. Retrieved April 13, 2014, from http://eds.a.ebscohost.com.ezproxy.dominican.edu/eds/pdfviewer/pdfviewer?vid=5&sid=e5acffbf-17a5-4dd5-97bb-fcb0a75e5bea%40sessionmgr4001&hid=410

Exercises

Physical Fitness and Ability to Maintain Balance

- One of the most effective ways to lower your chances of falling and create a healthy life style is to exercise. Exercising not only increases physical strength, but also makes you feel better mentally. Lack of exercise decreases muscle mass, which leads to weakness and will increase your chance of falling. Talk with your doctor about what exercises would be the safest for you to participate in (Center for Disease Control and Prevention, 2012).

  Exercise → ⇧Physical strength → 🡻Risk of falling

- Improving your balance is another way to lower your chances of falling. Exercises such as yoga and tai chi help improve balance. Ask your healthcare provider what exercises would be safe for you.
- Research shows that strength and balance exercises and strength and balance retraining can reduce falls by 40% in older adults (Gillespie et al., 2013). In this section, you will find general information on physical fitness and balance, tips on navigating through your environment, and brain exercises to improve cognition.
- Engage in social activities! Studies have shown that loneliness leads to psychological and cognitive decline. Get in touch with your community by joining a group or club!

Center for Disease Control and Prevention. (2012, February 29). What You Can Do to Prevent Falls. *Centers for Disease Control and Prevention*. Retrieved April 19, 2014, from http://www.cdc.gov/homeandrecreationalsafety/falls/WhatYouCanDoToPreventFalls.html

Falls and Older Adults. (n.d.). *NIHSeniorHealth:*. Retrieved , from http://nihseniorhealth.gov/falls/personalchanges/01.html

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Safe Behavior

Environment

- When navigating in the community, watch out for:
  - Uneven surfaces
  - Cracks/bumps in the sidewalk
  - Unpaved roads
  - Curbs
  - Slopes
  - Slippery areas
  - Parking blocks
  - Tree stumps
- Wear proper footwear to prevent slipping and avoid using laces that come untied. Proper footwear tips include: non-skid sole shoes, shoes with a snug fit, avoid using laces that come untied, avoid wearing shoes with heavy/thick soles.
- Always be aware of your surroundings and identify any hazards you may need to navigate around before entering a room.
- Do not rush when the phone rings or when going to answer the door.

Center for Disease Control and Prevention. (2012, February 29). What You Can Do to Prevent Falls. *Centers for Disease Control and Prevention*. Retrieved April 19, 2014, from http://www.cdc.gov/homeandrecreationalsafety/falls/WhatYouCanDoToPreventFalls.html

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Fischer, B. L., Gleason, C. E., Gangnon, R. E., Janczewski, J., Shea, T., & Mahoney, J. E. (2014). Declining cognition and falls: Role of risky performance of everyday mobility activities. *Physical Therapy*, *94*(3), 355-362. doi:10.2522/ptj.20130195

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Medication Awareness

It is known that proper medication management can reduce the risk of falling, but changing your medications without your doctor's permission is dangerous. Here are a few tips that can ensure you are only taking medications that are necessary and that all the medications you are taking are safe to take together.

Ask your doctor:

→ If you were prescribed medication, check with your doctor that you still need to be taking it.

→ Ask your doctor about the current dosage of any psychotropic medications you are taking.

→ Keep a list of all your current medications—bring it with you to all doctor's appointments, especially if you see multiple doctors.

Ask your pharmacist:

→ Ask your pharmacist if the combinations of medications you are currently taking could have adverse side effects.

Information adapted from: The Michigan Fall Prevention Project Department of Community Health

Home Safety Checklist and Information

Home modifications have been identified as one of the key areas in interventions to prevent falls (Currie, 2008). In this section, you will find a checklist of suggested modifications to increase the safety of your home. Priorities will be different depending on the individual, but the checklist is comprehensive enough to include the needs of everyone!

LIGHTING

Proper lighting in all rooms?	Yes No
Proper lighting to entrances of house?	Yes No

FLOOR

Are there any throw rugs?	Yes No
Are there papers, books, towels, shoes, magazines, boxes, blankets, or other objects on the floor?	Yes No
Do you have to walk over or around wires or cords (like lamp, telephone, or extension cords)?	Yes No
When you walk through a room,	Yes No

do you have to walk around furniture?	

STAIRS AND STEPS

Are there papers, shoes, books, or other objects on the stairs?	Yes No
Do you have only one light switch for your stairs (only at the top or at the bottom of the stairs)?	Yes No
Are the handrails loose or broken? Is there a handrail on only one side of the stairs?	Yes No
Is the carpet on the steps loose or torn?	Yes No

KITCHEN

→ Are the things you use often on high shelves? If Yes - Reorganize your cabinets. Keep things you use often on the lower shelves (about waist level).

→ Do you use a step stool? If you must use a step stool, get one with a bar to hold on to. Never use a chair as a step stool.

BATHROOM

→ Is the tub or shower floor slippery? Put a non-slip rubber mat or self-stick strips on the floor of the tub or shower.

→ Do you need some support when you get in and out of the tub? Have a carpenter put grab bars inside of tub.

BEDROOMS

→ Is the light near the bed hard to reach? Place a lamp close to the bed where it is easy to reach.

→ Is the path from your bed to the bathroom dark? Put in a night-light so you can see where you are walking. Some night-lights go on by themselves after dark.

Chase, C. A., Mann, K., Wasek, S., & Arbesman, M. (2012). Systematic Review of the Effect of Home Modification and Fall Prevention Programs on Falls and the Performance of Community-Dwelling Older Adults. *American Journal Of Occupational Therapy*, *66*(3), 284-291. doi:10.5014/ajot.2012.005017

Pynoos, J., Steinman, B. A., Do Nguyen, A., & Bressette, M. (2012). Assessing and Adapting the Home Environment to Reduce Falls and Meet the Changing Capacity of Older Adults. *Journal Of Housing For The Elderly*, *26*(1-3), 137-155. doi:10.1080/02763893.2012.673382

Vision and Fall Prevention

Vision impairments are a common side effect of a brain injury. Vision loss or impairments significantly increase your risk of falling, tripping, and slipping.

Make sure to look at the ground when walking in cluttered areas.
When entering a new place scan the place for safety risks and obstacles in your path.

Adapt your home environment to lower your risk of falling

- ✓ Outline steps with bright tape to give color contrast to stairs.

- ✓ Use bright tape or color contrasting tape in the shower to outline tub threshold, shower chair, and grab bars.

- ✓ Make sure all rooms are well lit. If there is an area of the house that you tend to have trouble navigating, consider adding an additional light.

- ✓ Utilize “Clap-on-Clap-off” lights throughout the home. This enables you to turn on a light before getting out of bed.

- ✓ TAKE YOUR TIME!! Walk at a slower pace while visually scanning path.

- ✓ Visit your eye doctor yearly or when you notice a change in your vision.

- ✓ Ask your doctor if you may be a candidate for Occupational Therapy services related to your loss of vision.

Newton, M., & Sanderson, A. (2013). THE EFFECT OF VISUAL IMPAIRMENT ON PATIENTS' FALLS RISK. *Nursing Older People*,*25*(8), 16-21. doi:10.7748/nop2013.10.25.8.16.e489

Bowers, L. A. (2013). Preventing falls: It's within your power. *Long-Term Living: For The Continuing Care Professional*, *62*(8), 13-15.

Reed-Jones, R. J., Solis, G. R., Lawson, K. A., Loya, A. M., Cude-Islas, D., & Berger, C. S. (2013). Review: Vision and falls: A multidisciplinary review of the contributions of visual impairment to falls among older adults. *Maturitas*, *75*22-28. doi:10.1016/j.maturitas.2013.01.019

In Summary

- ✓ Exercise → ⇧Physical strength & Balance → ⬇Risk of falling
- ✓ Talk with your doctor about what exercises would be safest for you and look for community programs that you can join!
- ✓ When navigating in the community, watch out for uneven surfaces and parking blocks.
- ✓ Be sure you are wearing appropriate footwear, such as non-slip shoes that fit snugly and ensure that they are tied.
- ✓ Have your doctor check your medications regularly and make sure to follow to your medication regimen.
- ✓ Check your home to ensure that your home environment is safe.
- ✓ Store frequently used items in easy to reach locations.
- ✓ Avoid loose fitting or baggy clothing that can touch the floor.
- ✓ If you wear glasses or contacts, make sure you wear them at all times.

Appendix K

Fall Calendar 2014

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

Instructions: Tally one mark per fall on the day the fall occurred.

Appendix L

Standardized Phone Call Reminder Script

Hello Mrs., Miss, or Mr. _____,

My name is _____. I am calling from the fall research study you are participating in. I just want to check in and see if you have been completing your fall journal. Have you fallen recently? (If answers “yes” go to #1; if answers “no” go to #2)

1. If answered yes to falling – I’m sorry to hear! Did you record your fall on your fall calendar? (If answer “yes” go to ‘a’ ; if answer “no” go to ‘b’)

    a. If answered yes to recording the fall(s) – Great! We really appreciate you keeping up with your calendar. (Go to Conclusion sentence)
    b. If answered no to recording the fall(s) - Do you remember what day the fall occurred on? If not, you can mark it on the week. (Go to Conclusion sentence)

2. If answered no to falling – That’s great to hear! Just as a reminder, if you do fall please put a tally mark on the calendar the date the fall occurred. (Go to Conclusion sentence)

Concluding sentence – We will check in with you again in two weeks. Thank you for your time and participation.

Last call:

Hello Mrs., Miss, or Mr. _____,

My name is _____. I am calling from the fall research study you are participating in. Thank you for participating in our study. We will be sending you a fall packet shortly. Please send the fall calendar with the self-addressed envelope that we have provided for you. Thank you!

Appendix M

February 7, 2014

Mikaela Conlon
50 Acacia Ave.
San Rafael, CA 94901

Dear Mikaela:

I have reviewed your proposal entitled *Validity of a Fall Risk Evaluation Tool for Individuals with Acquired Brain Injuries* submitted to the Dominican University Institutional Review Board for the Protection of Human Participants (IRBPHP Application, #10228). I am approving it as having met the requirements for minimizing risk and protecting the rights of the participants in your research.

In your final report or paper please indicate that your project was approved by the IRBPHP and indicate the identification number.

I wish you well in your very interesting research effort.

Sincerely,

Martha Nelson, Ph.D.
Associate Vice President for Academic Affairs
Chair, IRBPHP

cc: Kitsum Li