VIRTUAL REALITY-BASED THERAPY FOR THE TREATMENT OF BALANCE DEFICITS IN PATIENTS RECEIVING INPATIENT REHABILITATION FOR TRAUMATIC BRAIN INJURY

by

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Balance deficits are one of the most commonly occurring and physically limiting sequela that result from more severe traumatic brain injury (TBI). The purpose of this study was to evaluate the effectiveness and applicability of using a commercially available virtual reality (VR) system as a treatment of these deficits for patients receiving inpatient rehabilitation for a primary diagnosis of TBI by conducting analyses of data collected as part of a pilot randomized controlled trial. The aims of this thesis were: (1) to examine the relationships between treatment received (VR or Extra Standard of Care) and static and dynamic balance changes over time; (2) to assess the predictive validity of the VR game scores on static and dynamic balance; and (3) to investigate dose response relationships between study treatments and changes in static and dynamic balance.

Results indicate that patients receiving either treatment demonstrated significant balance improvements over time; however, neither treatment condition was found to be significantly better than the other. Scores from the VR balance games were found to have some moderately strong associations with the standardized assessment of static balance, with less strong relationships between VR scores and standardized assessments of dynamic balance. The results did not suggest the existence of any relationship between the amount of treatment received and changes in standardized assessments of balance. These data provide an essential first step in the establishment of the use of
commercially available VR systems as effective tools for treating balance deficits for patients with TBI.

The form and content of this abstract are approved. I recommend its publication.

Approved: Cynthia Harrison-Felix
DEDICATION

I would like to dedicate this thesis to my wife, Kimberly, who has kept our home in order, our family together and our lives moving forward as I have focused much of my efforts on completing my doctoral work and my employment. Without her, this thesis would have never have been completed. I would like it be known that her sacrifices have not gone unnoticed, and that this work is a testament to both of our resolves over the years past.

I would also like to dedicate this thesis to the mentoring professionals who I have had the pleasure to work with and for, who have shown faith and support to me as I endeavored to undertake my doctoral education. In particular, I would like to thank David Gray for believing in me as a researcher, and helping me find belief in myself. I would like to thank Gale Whiteneck for prodding me to pursue my education, and providing enough time in my day to get it done. Finally, I’d like to thank Cindy Harrison-Felix for her priceless advice and guidance, and for never turning a deaf ear to my endless knocking on her door.
ACKNOWLEDGEMENT

I would like to acknowledge my coworkers in the Craig Hospital research department and for the physical therapy staff at Craig Hospital. These groups were integral in accomplishing the randomized controlled trial detailed in this thesis, and without all of their aid and cooperation, the goals of this project might not have been realized.

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<table>
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<td>AOC</td>
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<td>BBS</td>
<td>Berg Balance Scale</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>FGA</td>
<td>Functional Gait Assessment</td>
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<td>LOC</td>
<td>Loss of Consciousness</td>
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<td>Medical Model of Disability</td>
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<td>National Institutes of Health</td>
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<td>PT</td>
<td>Physical Therapy</td>
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<td>Post Traumatic Amnesia</td>
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<td>Social Model of Disability</td>
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<td>United States</td>
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CHAPTER I
INTRODUCTION

1.1. Overview

The Centers for Disease Control and Prevention (CDC) define traumatic brain injury (TBI) as a post-natal traumatic event that interrupts normal functioning of the brain, as a result of the head hitting an object, an object hitting the head, or an object penetrating the skull.[1] TBIs are a major public health concern in the United States (US), as these injuries account for nearly one third of all injury-related civilian deaths and have an estimated annual economic cost of over $76 billion.[2] Each year, at least 1.7 million Americans will incur a TBI, of which 275,000 will be severe enough to require hospitalization.[1] For those hospitalized with TBI, approximately 52,000 will die as result of injury,[1] and those who survive will have an elevated risk of long-term physical and neurological deficits, cognitive impairment, disability, and reduced lifespan.[3]

It is estimated that ninety percent of yearly hospital admissions for TBI are for persons 16 years of age or older.[4] TBIs have been particularly detrimental for late teens and adults, with this group demonstrating poorer resilience to and recovery from TBI, as compared to younger cohorts.[1] Of all late teens and adults hospitalized for TBI in the US, approximately 20,000 will be discharged to inpatient rehabilitation annually for the treatment of deficits that result from injury.[5] Upon inpatient rehabilitation admission, these deficits can be categorized into four overarching domains: physical, cognitive, behavioral and emotional.[6] Within the Physical domain, balance deficits are the one of the most common and physically limiting impairments resulting from TBI.[7, 8]
Balance can be described as the ability to maintain an upright position by keeping the body’s center of gravity over its base of support as the body performs stationary or dynamic activity. [9, 10] Previous research has suggested that upon admission to inpatient rehabilitation, almost 60% of patients with TBI will demonstrate impairment on the most basic of balance activities (sitting upright) and more than 75% will demonstrate impairment in slightly challenging balance activities (rising from sit to stand). [10] These impairments are often the result of diminished abilities of one of the many systems involved in balance and posture maintenance, [11] which can be attributed to physical damage to the brain and central nervous system, sensory disruption in receiving information from the body systems involved in balance, [12] muscle wasting from long periods of bed rest [10] and medications used to treat co-occurring issues. [12-15]

Balance deficits are of particular importance in regards to the treatment of patients after TBI. Diminished balance ability has been shown to be associated with longer inpatient rehabilitation length of stay, [7, 10] increased risk of falling, [16] slowed recovery, increased medical complications [10] and gait abnormalities. [17] Despite improvements in balance that have been found to occur from 0 to 6 months post injury (the time during which inpatient rehabilitation most often takes place), [8] balance impairments have been shown to persist long past inpatient rehabilitation, and are one of the most commonly noted chronic deficits in this population, with distinct impairments noted in research examining patients with TBI at one, two, five and more than 20 years post injury. [8, 18, 19] These long term deficits have been associated with decreased mobility and functional abilities after inpatient rehabilitation discharge, and have been shown to hinder community participation, including decreased ability to ambulate in the
community, navigate surfaces with minor obstacles, safely cross streets, enter or drive automobiles, board public transportation and participate in leisure activities.[8, 19-22] Coinciding with these functional limitations is an increased risk of falls and decreased quality of life.[12, 23, 24] In total, balance deficits experienced after TBI are a severe detriment to participation in life activities, both during and after formal rehabilitation.

The treatment of balance deficits in the inpatient rehabilitation setting is predominantly provided by physical therapists. These professionals are involved in the assessment of balance deficits, determining etiology, and developing comprehensive treatment plans to address the specific type of balance deficit and the underlying cause. To elicit recovery, physical therapists will apply evidence-based principles for motor learning (which stem from theories of neurological recovery and reorganization) to the use of traditional equipment (e.g. balance beams, rocker boards, uneven surfaces, varied surface composition) and activities (e.g. varied leg stances, varied locomotion speeds, varied visual input and tasks involving divided attention) available in the therapy setting.[25-27] However, despite the well-established methodologies for assessing and determining the etiology of balance deficits, little evidence is available to demonstrate the effectiveness of physical therapy-based treatment of balance deficits for persons with TBI.[6, 25, 28, 29] Recent literature reviews have demonstrated the dearth of literature for these treatments, with a systematic review published in 2011 finding that only two studies of adequate sample size and complexity (meaning that these studies acquired an n large enough to determine true differences between treatment groups, and that they were conducted using methodologies adequate for associating study results with study
treatments) have been completed in order to inform the field on effective treatment of balance impairments (of which one study demonstrated a null result).[6]

The impetus for completing well designed research studies to establish evidence-based therapies for the treatment of balance deficits for patients with TBI is evident; however, the strategy for testing new therapies should be systematic and logical. One strategy for addressing these evidence gaps is to assess treatments shown to be effective for improving balance for populations with neurological conditions and deficits similar to TBI and to systematically evaluate these treatments for patients with TBI. Using this framework, one treatment modality that has demonstrated positive results for which there is a substantial and growing literature base is Virtual Reality (VR)-based treatment.

VR systems are computer-based processes which provide a simulated environment with which a person can respond and interact with the environment in real-time.[30, 31] These systems range from extremely complex, in which an environment is broadcast across a 360 degree viewing field, to extremely simple, in which a commercially available gaming system (e.g., Nintendo Wii) is used to simulate a virtual environment on a flat panel television.[30] These systems not only provide the opportunity to implement many of the principles of motor learning, but also provide activities and games that allow participants to interact in environments or activities that are personally meaningful or otherwise inaccessible (e.g. simulated outdoor tennis game for a patient unable to leave an inpatient rehabilitation facility).[32] Research on the use of VR-based therapy to treat balance deficits for populations with similar neurological deficiencies has shown improvements in several aspects of balance, and enhanced
participant enjoyment (compared to the application of traditional equipment and activities), even in instances in which only simple VR systems have been utilized.[33, 34]

A small sample of VR-based therapeutic interventions for patients with TBI has been reported in the literature;[30, 35-37] however, these studies have predominantly involved cognitive rehabilitative efforts, as opposed to physical rehabilitation. In regards to balance, one small randomized controlled trial has been completed, comparing a physical therapist led activity-based balance exercise program with a program utilizing a highly complex VR-system in which participants completed balance exercises in front of a blue screen that were projected onto a large television on which the patient appeared to be completing the movements in an environment outside the rehabilitation facility.[38] While this study did not find a significant difference between groups, it did demonstrate that both groups improved their balance, and that participants receiving the VR-based treatments enjoyed their therapy experience more than those in the standard care group.[38, 39] While these data do not clearly demonstrate that the VR-based therapy was advantageous to standard care, they do suggest that VR-based interventions may be effective in treating patients with TBI who are receiving rehabilitation for balance deficits.

1.2. Conceptual Framework

The theoretical model selected to guide the overarching conceptual framework of this thesis was the International Classification of Functioning, Disability and Health (ICF) model of disability. This model, a revision of the model first developed by the World Health Organization in 1980, provides a conceptual foundation by which all manner of health and disability can be defined and measured.[40] The ICF model of
disability was specifically designed to be a flexible tool, and can be used across clinical, research and political contexts, and can be applied at the individual, institutional and social level.[40, 41]

The ICF was developed as an amalgamation of two models, the Medical Model of Disability (MMD) and the Social Model of Disability (SMD), as neither of these models alone was completely adequate to address function following disability.[40, 42] By itself, the MMD labeled disability as a characteristic of an individual that was the result of a disease, condition or traumatic event. While this model was exceptionally good for defining limitations due to injurious events and to call for treatments directly related to these, it lacked the ability to address resulting limitations that stemmed from environmental causes (e.g. buildings lacking accessible design features), and provided little ability to track progress for improvements in function, unless the disabling event was completely resolved. The SMD defined disability as a problem not of the individual, but as a lack of fit between an individual and the social and physical environment resulting in reduced function. This model was particularly well suited for determining environmental influences that diminished a person’s overall function; however, it provided almost no basis for improving the abilities of the individual. In an effort to capture the strengths of these models, they were combined to create a model that addressed biological, individual and social factors, sometimes referred to as a biopsychosocial model.[40]

The basic model of disability developed by the ICF accounts for three levels of function which are displayed throughout the middle of the model, presented in Figure 1.[40, 41] These include function at the most basic level of human anatomy and organ
systems (Body Structure & Functions), at the level of the individual executing a desired task (Activity) and at the level of performance as a member of society (Participation). The three levels of function interact with two overarching factors, including personally limiting problems (Health Conditions) and contextual factors (Personal and Environmental Factors).[40, 41] Definitions of each of these constructs are listed in Table 1. The interplay of all of these constructs creates a context in which a person experiences the world given their own characteristics, and if a limitation occurs at any of the three levels of function, a disability is said to exist. Disabilities that stem from the Body Structure and Function level are labeled Impairments; those that stem from the Activity level are labeled Activity Limitations; and, those that stem from the Participation level are labeled Participation Restrictions.[40-42]
Table 1: Construct definitions of ICF Model of Disability

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Health Condition</td>
<td>Any disease, disorder or injury experienced by an individual</td>
</tr>
<tr>
<td>Body Function</td>
<td>Physiological functions of all body systems</td>
</tr>
<tr>
<td>Body Structure</td>
<td>Human anatomy, from cellular level to limb</td>
</tr>
<tr>
<td>Activity</td>
<td>Volitional completion of movements or tasks</td>
</tr>
<tr>
<td>Participation</td>
<td>Volitional involvement in life situations</td>
</tr>
<tr>
<td>Environmental Factors</td>
<td>Physical, social and attitudinal environment of an individual</td>
</tr>
<tr>
<td>Personal Factors</td>
<td>Characteristics and experiences of an individual</td>
</tr>
</tbody>
</table>

For this thesis, the ICF model was adapted to provide a framework to guide a randomized controlled trial (RCT) to compare two interventions for improving balance deficits resulting from TBI. The product of this adaptation is listed in Figure 2. The adapted model outlines the method by which the systematic assessment of an intervention that compared two Activity-level balance treatments that were derived from balance deficits noted at the Body Structure and Function level could be accomplished. It was hoped that improved balance would then drive improved Participation, and participants in the RCT would be better able to participate in society (e.g. be out and about in the community and be socially engaged); however, for the purposes of this thesis, measurement occurred only at the level of Activity.

In order to minimize confounding from extraneous influences, inclusion and exclusion criteria (listed in section 3.2.3) were set so that participants would have largely homogenous characteristics. In regards to Health Condition, only patients who had incurred a TBI severe enough to require inpatient rehabilitation were included.
Figure 2: ICF model of disability adapted for an RCT for the treatment of balance deficits following TBI

Moderate & Severe Traumatic Brain Injury Requiring Inpatient Rehabilitation
Primary diagnosis of TBI
No additional major injuries or illnesses

Balance Intervention
VR or Extra Standard Care for
4 Weeks of Balance Therapy

Balance Systems
Biomechanical Constraints
Stability Limits/Verticality
Anticipatory Postural Adjustments
Postural Responses
Sensory Orientation
Stability in Gait

Balance Activities
Static balance as measured by the BBS at (0, 2 & 4 weeks)
Dynamic balance as measured by the FGA (0, 2 & 4 weeks)

Environmental Factors
Therapy day (8 hours)
Therapist/social interactions
Meal times
Sleep/wake times
Medication dispensing
Days from injury to enrollment
Days of acute care

Personal Factors
Age
Race
Gender

Participation
Out and about in community
Productive
Socially Engaged
Furthermore, only patients who had a primary diagnosis of TBI with no additional significant injury [e.g. Spinal Cord Injury (SCI), Amputation] and who were within six months of injury onset at the time of study enrollment were included. To standardize the Environmental Factors, recruitment was limited to patients receiving inpatient rehabilitation at Craig Hospital who would require at least three additional weeks of inpatient therapy at the time of enrollment. This limitation ensured that all participants included in the research project would reside within the same physical environment, and be subject to the same social environment. Limiting enrollment to patients receiving inpatient rehabilitation for a primary diagnosis of TBI at Craig Hospital standardized numerous potentially confounding environmental characteristics, including hours of therapy per day, social interactions, meal times, quiet hours, sleep and wake times and medication adherence. Some environmental factors could not be standardized, and as such were abstracted from the medical record for later analytical purposes. These variables included time from injury to enrollment, TBI severity and days of acute care. Personal Factors, including age, race and gender, also could not be controlled, thus these were captured from the medical record for later analyses. All recruited patients were also required to be experiencing balance deficits that required at least some balance-focused physical therapy intervention as part of their inpatient rehabilitation program. Balance deficits are conceptualized as any deficits in the six synergistic systems required for the maintenance of balance as proposed by Horak [11] and colleagues (listed in Figure 3). The six systems and the primary neurological centers that comprise them include: Biomechanical Constraints (motor cortex), Limits of Stability/Verticality (parietal cortex), Anticipatory Postural Adjustments (basal ganglia), Postural Responses.
Figure 3: Systems Model of Balance (presented by Horak et al, Physical Therapy, 89 (5), page 486)[11]
(cerebellum), Sensory Orientation (vestibular system) and Stability in Gait (brain stem).[11] While explicit information of deficits at the system level were not available for capture as part of the RCT, licensed physical therapists at Craig Hospital confirmed that each patient selected to approach for recruitment had deficits in at least one system.

The intervention and assessment aspects of the RCT are both placed within the Activity level of the balance-adapted ICF model. Patients recruited and enrolled in the RCT were randomly assigned to receive one of two types of balance-therapy as an addendum to the therapy day. Both of these therapy types included repetitive trials of both stationary and movement-oriented balance tasks; however, one group received these therapies via a VR device (Nintendo Wii), while the other group received therapies using standard equipment and activities found in the therapy gym. Standardized assessments of overall stationary and dynamic balance were assessed at three intervals that included baseline (prior to intervention onset), at 2 weeks (mid-intervention) and at 4 weeks (intervention completion). Using this framework, analyses were conducted that addressed static and dynamic balance changes, the ability of two therapy types to influence standardized assessment scores, and the cumulative effect of participation in each of the addendum therapies.

1.3. Purpose

The purpose of the overarching RCT from which this thesis is derived is to obtain data to determine the sample size for a larger sufficiently powered efficacy study. The purpose of this thesis is to extend the overarching study by performing extended analyses of the balance measures, collected as part of the overarching study, and thesis-specific measures, including Wii balance board game scores and treatment adherence data. The intent of these additional analyses is to enhance the knowledge base of effective
strategies for the treatment of balance deficits for patients receiving inpatient rehabilitation with a primary diagnosis of TBI. This thesis will further extend the evidence base by:

a. assessing the relationship between the therapy type (VR or extra standard) and change over time for standardized assessments of static and dynamic balance,
b. determining if a dose-response relationship exists between therapy type and static and dynamic balance changes over time, and
c. identifying the predictive validity of scores taken directly from the VR system.

1.4. Problem Statement

Balance impairments are one of the most common deficits that result from TBI and significantly impact short and long term recovery. In an inpatient rehabilitation setting, these deficits are most often addressed by physical therapists, who will endeavor to identify the specific type(s) and cause(s) of balance deficits experienced by a patient, and design a rehabilitation plan to address these specific factors. The standard PT practice for treating balance deficits in patients with TBI involves using equipment and activities commonly available in an inpatient therapy gym; however, little evidence exists to support the use of these standard modalities for the improvement of balance in this population. One modality that has shown promise in improving balance for populations with similar neurological deficits is VR. No study to date has systematically evaluated the use of these VR modalities for the treatment of patients with balance deficits associated with TBI during inpatient rehabilitation.
CHAPTER II

REVIEW OF THE LITERATURE

2.1. Literature Review

The literature review that follows begins with a description of the methodology employed to search and review literature relevant to TBI, balance deficits that typically follow these injuries and the treatment of these deficits. This chapter provides a general discussion of TBI followed by a review of pathology and etiology of balance deficits that commonly occur after these injuries, the evaluation of these deficits, current treatments for balance deficits, and the need for new and more effective treatments, including the possible use of virtual reality (VR) as a therapeutic modality. A summary of the findings of this review, limitations of the literature and the impetus for the current study concludes this chapter.

2.1.1. Literature Search Strategy

Four databases, including CINAHL, PsychINFO, MEDLINE and Pubmed, were searched to acquire all available published research regarding TBI and balance, including epidemiology, pathology, etiology, evaluation and treatment, and the use of VR for patients with TBI (for deficit or disabilities). The onset of this literature search began October 15, 2011, with a final search completed June 30, 2012. The databases selected for review were chosen as they were deemed the best resources for medical and rehabilitation literature.

To ensure that all articles relevant to the research topics were found, broad-based searches were conducted for each topic of interest. Singular sub-topics were then applied
to these larger searches in order to identify all articles pertinent to this thesis. At the completion of each sub-topic search, the title of each article identified was reviewed for inclusion, and for those deemed relevant to the topic, abstracts were reviewed to confirm inclusion. For those abstracts deemed relevant to the sub-topics of interest, full article reviews were completed. References from each article reviewed were also searched for additional relevant citations. Articles identified via this methodology were evaluated using the identical inclusion process of title, abstract and complete article review. Table 2 provides an overview of the literature search conducted, including citations identified, and titles, abstracts and articles reviewed.

Relevancy of each article was determined by the focus of each article. Articles were first assessed to determine their application to TBI. Those found to relate only to conditions other than TBI were excluded. Articles were then assessed for population age. Only articles focused on late teens or adults were included. For balance related issues, including pathology, etiology, and treatment, only articles that related directly to cases of adult TBI were maintained. Literature that included cases of TBI as part of a cohort of varying disabilities for which information specific to patients with TBI could not be determined were excluded. For articles regarding VR for the treatment of balance deficits, a wider search was conducted, as few interventions involving this modality for patients with TBI were available. Thus, articles related to VR and balance treatment for populations with balance deficits that stem from etiologies similar to TBI (SCI, Parkinson’s disease, and stroke) were deemed relevant.
Table 2: Literature search terms with combined results from designated databases

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<th>Search Terms</th>
<th>Total Citations</th>
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<th>Abstracts Reviewed</th>
<th>Full Articles Reviewed</th>
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<td>2.</td>
<td>Balance; or Posture; or Vestibular; or Gait</td>
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<td>1 &amp; 2</td>
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<td>1 &amp; 5</td>
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2.1.2. Traumatic Brain Injury Overview

Traumatic brain injury (TBI) is defined as any damage to brain tissue after birth that results from an external force to the head and is denoted by one of the following disruptions of normal brain functioning:

- post traumatic amnesia (PTA), referring to state of confusion following an acute head injury in which a person is unable to recall events either before or after the injury;
alteration of consciousness (AOC), referring to mental state following an acute head injury in which a person is alert but does not process environmental stimuli in a timely or appropriate manner;

- loss of consciousness (LOC), referring to a mental state following an acute head injury in which a person does not respond to any stimuli, or;

- positive medically documented neurological deficits as determined by physical or mental status examination.[43-45]

Each year, an estimated 1.7 million civilians sustain a TBI in the US, most frequently as a result of falls, motor vehicle collisions, violence, and sports injuries. The public health impact of these injuries is immense, as they contribute to almost one-third (30.5%) of all injury-related deaths (52,000), and have an annual economic cost of more than $76 billion.[2]

The incidence of TBI across the US population demonstrates a bimodal distribution, with the highest rates in children age 0 through 4 (839 per 100,000) and adults aged 75 and older (599 per 100,000).[1] Of these injuries, approximately 80% will be treated and released from an emergency medical facility, 16% will involve a hospital admission and 4% will result in death; however, these percentages are based on cases in which patients seek care for their injuries, and as such do not include instances of TBI that go untreated.[1] The preponderance of patients with TBI requiring hospitalization is individuals over the age of 15. The CDC estimates that approximately 90% of people who have incurred a TBI that are discharged alive from an acute hospitalization each year are 16 years of age or older.[4] Furthermore, the epidemiology, medical management
and prognosis following TBI has been shown to be markedly different between children and adults, with adults demonstrating less resilience to and recovery from injury.[1] As such, this group deserves differentiated investigation and intervention.

Each occurrence of TBI can be classified in terms of severity as mild, moderate or severe by the sequelae following injury. The most common type is mild TBI (MTBI).[1, 46] These account for 80% of all TBI, and are typified by the manifestation of:

- a brief LOC (30 minutes or less), and/or;
- PTA less than 24 hours, and/or;
- AOC less than 24 hours.

Previous research has demonstrated the potential of these injuries to result in long-term deficits; however, most often they do not result in hospitalization, persistent impairment or permanent disability.[1, 46] Moderate, severe and penetrating injuries account for the remaining 20% of TBI, which account for more than 240,000 adult hospitalizations in the US annually.[1] TBIs considered to be moderate in severity are classified by:

- LOC greater than 30 minutes but less than 24 hours, and/or;
- AOC of 24 hours or more, and/or;
- PTA lasting between 24 hours and 7 days.

Finally, those injuries classified as severe TBI result in:

- LOC greater than 24 hours, and/or;
- AOC of 24 hours or more, and/or;
- PTA lasting more than 7 days.
It is important to note that there is significant overlap between moderate and severe injuries, with definitions of these categorizations differing across professionals and organizations. To circumvent the dichotomization of these severities, for the purpose of this thesis, moderate, severe and penetrating TBI will be referred to with the common term more-severe TBI, and relate to those injuries that require hospitalization, and are likely to result in long term issues. Beyond mere hospitalization, an extensive literature base has established the association of more-severe TBIs with long term or permanent physical and neurological deficits, cognitive impairment, functional limitation, disability, and reduced lifespan.[3] In order to reduce the impact of these injuries, well managed and implemented acute care and long term rehabilitation is paramount.

Despite the need for long-term rehabilitation following more-severe TBI, not all patients with these injuries receive this care. Recent research by Cuthbert et al using three large archival datasets found that of persons with moderate, severe or penetrating TBI who were discharged alive from acute care, only 13% to 29% were admitted to inpatient rehabilitation, with all other cases being discharged home (57% to 65%) or some form of sub-acute care (10% to 18%). Beyond injury severity, factors influencing discharge to rehabilitation included age, race, and acute care payment source.[47] Research using similar methodologies in both national and international samples has demonstrated similar results, with relatively small percentages of patients with more severe TBI being discharged to inpatient Rehabilitation.[48-50] Due to the large proportion of patients with more severe TBI who are discharged from acute care with no additional medical follow-up, there are likely large public health needs that stem from
these un-followed injuries; however, these needs are unknown.[47] Estimates from here forward will apply only to those patients who receive inpatient rehabilitation, though it is likely that estimates of deficiency and disability will be underestimates.

The incidence of admission to inpatient rehabilitation for late teen and adult patients with a primary diagnosis of TBI has recently been estimated at approximately 20,000 per year in the U.S. This population demonstrates a bimodal distribution, with a peak in the younger age group of 20 to 29 (12.7%) and a subsequent peak in the older age group 80 to 89 (19.5%). These patients tend to be male (64.3%), married (41.0%) or never married (30.7%), and predominantly white (77.4%). At admission, the group has an average Functional Independence Measure (a measure of independence in activities of daily living) total score of 54.8 (out of 126) with a standard deviation of 21.9 points. The average length of stay for inpatient rehabilitation is 17.5 days with a standard deviation of 15.2 days. The primary methods of payment for these services are private insurance (33.6%), Medicare (46.3%) and Medicaid (8.6%).[5, 51]

2.1.3. Balance Deficits Following TBI

Adults admitted to inpatient rehabilitation after TBI typically demonstrate limitations within four gross domains: physical, cognitive, behavioral and emotional.[52] Within the domain of physical function, a myriad of deficits have been identified as being the result of TBI, including reduced ability to appropriately perform or control voluntary movements, muscle strength, muscle tone, stamina, reflex, reaction and balance.[53] Of these issues, balance deficits are one of the most commonly occurring [54] and physically limiting issues associated with TBI.[7, 54] Balance deficits are of particular importance
as they heavily influence the rehabilitative process,[7] are predictive of inpatient rehabilitation length of stay,[7, 10] and have been shown to affect mobility, physical function and independence long beyond discharge.[19, 20, 54]

Balance is defined as “the ability to maintain an upright position unassisted without falling and the ability to alter that base of support and maintain equilibrium in reaction to a variety of conditions”.[10] Balance is required for basic motor functions, such as sitting upright, as well as more complex functions, such as rising from sit to stand, running and jumping. In order to achieve functional balance (the ability to maintain balance required for completing desired activities of daily living), a person must be able to volitionally maintain a position in space, stabilize the body for a desired movement, and react to external movement. Voluntary movement requires a person be able to move their center of gravity relative to their base of support while adjusting their posture to maintain or restore the center of gravity to the base of support.[9, 10] For balance to be maintained, several neurological systems must function interactively.

In an effort to provide a cohesive description of the overall process required to maintain posture and balance, Horak and colleagues defined balance in terms of interactive neurological systems. Each component of balance was evaluated, and the neurological areas involved in each system were defined. The result was a model of motor control which included six interactive systems, defined as: (1) Biomechanical Constraints, (2) Limits of Stability, (3) Anticipatory Posture Adjustments, (4) Postural Responses, (5) Sensory Orientation and (6) Stability in Gait.[11] Each of these systems is independent from the other and each involves specific neural area(s), pathways and
functions. Despite the autonomy of each system, all of the systems must be able to function independently and communicate with and react to the other in order for balance to be maintained. The Biomechanical Constraints system includes both the motor cortex and the musculature controlled by this brain area that are involved in the mechanical components of balance, including the muscles of the foot, ankle, hip, trunk and arms. The Limits of Stability system involves the parietal cortex and its oversight of the automated reflexes for maintenance of the center of gravity over the base of support. The Anticipatory Postural Adjustments system includes the basal ganglia and brain stem areas that provide the impetus to move the body dynamically. The Postural Responses system includes the cerebellum and the sensory pathways that detect perturbations in balance and provide automatic corrective responses to these disturbances. The Sensory Orientation system includes the vestibular system and the temporoparietal cortex which provide spatial orientation via visual and tactile input. The Stability in Gait system includes the spinal locomotor and brainstem postural sensorimotor pathways which adjust the center of gravity as the base of support moves through space.[11]

Within patients with more-severe TBI, many of these systems can be disrupted. The etiology of system disruption associated with TBI can be categorized into four types: physical damage, sensory disruption,[12] muscle wasting [10] and medication related.[12-15] Physical damage associated with TBI can involve trauma to any of the primary neurological centers of balance maintenance, including the motor cortex, parietal cortex, brain stem, vestibular system, basal ganglia and/or the cerebellum,[12, 19, 55] and can also include damage to other body systems that occur at the same time as the TBI,
including contusions, bone fractures, and spinal cord injury. Sensory deficits include the reduction of information from the primary sensory systems involved in balance, including the visual, vestibular or proprioceptive systems, or an inability to appropriately utilize this sensory information.[12, 19, 20, 55] Balance deficits due to muscle wasting include instances in which a patient’s muscles have deteriorated due to excessive bed rest or from denervation of the muscles involved in postural control. Medication related balance issues are those that result from the pharmacological treatment of TBI.[10] Deficits that are associated with medication use are most often due to antipsychotic use for the treatment of behavioral issues.[14, 15]

2.1.4. Balance Deficit Evaluation

In order to provide an effective treatment, not only must the balance system(s) that has been disrupted be evaluated, but so must the underlying cause of the disruption. Within rehabilitation, the most common method of evaluating balance is an initial gross balance and posture assessment by a physiatrist (medical doctors specifically trained to treat and improve physical deficits and quality of life that have been affected by a physically disabling condition). In general, these assessments involve clinical observation of sitting and silent standing (standing with eyes open and forward and arms in an anatomical position) for patients for whom these test are clinically feasible and medically appropriate. A multicenter study by Greenwald and colleagues provided a standardized taxonomy (grossly normal, mildly impaired, grossly impaired, and untestable) for the findings of these gross balance evaluations of patients admitted to 17 Traumatic Brain Injury Model Systems (TBIMS) facilities between 1989 and 1998.[10]
Among the 908 patients deemed as ‘testable’ within the sample, 40.3% were found to have mildly impaired sitting balance, while 19.4% were found to have gross impairment. In regards to standing balance, 37.2% were found to have mild impairment and 37.4% were determined to have gross impairment.[10]

Following a gross assessment, the next method of evaluating balance in patients with TBI is through the use of standardized clinical assessments,[56] which can be completed either by a physician or a physical therapist. Clinical balance measures provide insight into the balance system(s) which has been disrupted, the current balance ability of the patient, their risk of falling, the protective and/or corrective responses to balance perturbations and their need for balance (re)training. These measures will likely include assessments of balance in both stationary (static) and movement-oriented (dynamic) tasks that involve both seated and standing bases of support. Using these measures, it is estimated that almost all persons with TBI admitted to inpatient rehabilitation have some form of balance impairment, with 68% [16] to 73% [8] demonstrating significantly decreased physical capacity to maintain balance, decreased functional balance and elevated risk of falling.[8, 16] Some of the more common measures of balance include the Four Step Square Test,[57] the Berg Balance Scale,[9] the Dynamic Gait Index,[58] the Functional Gait Assessment,[59] and the Timed Up and Go Test.[60] All of these assessments involve patients completing specific movements and tasks on which a therapist can rate the abilities of the patient.

To assess the more detailed aspects of balance, multi-system analyses[61] and computer based assessments, including posturography,[56, 62, 63] stabilometry and
pressure plate analyses may be implemented.[62-65] The results of multi-system analyses provide information regarding the underlying cause(s) of balance deficits.[61]

For the highest level of precision, the evaluation of the physical and proprioceptive aspects of balance is most accurately completed using computerized analysis. These tests provide insight into the most subtle aspects of balance which often cannot be elucidated with standard testing,[66] including postural sway, standing symmetry, weight shifting, balance maintenance strategies, gait pattern and gait speed. Numerous studies utilizing computerized testing have been conducted and demonstrate the deficits following TBI. Stationary standing or sitting irregularities identified by these methodologies include increased sway (including lateral and antero-posterior),[56, 64, 65, 67] standing asymmetry,[64, 68] slowed weight shifting,[64] and inappropriate or insufficient balance maintenance strategies.[56, 68] Dynamic deficiencies have also been described by these methods, and include slowed, maligned or hemiparetic gait,[54, 67, 69] balance losses during normal gait [54, 67] and difficulty stepping over objects during normal gait.[70] Some assessment devices, such as the SMART Balance Master, include several of the aforementioned computerized evaluations as part of one device, and are used by therapists to qualify, quantify and track balance abilities and deficits throughout the rehabilitative stay. The results of all of assessments, no matter the complexity, are shared throughout a multidisciplinary team (i.e. physiatrists, physical therapists, occupational therapists, speech language pathologists and neuro-psychologists) so that a comprehensive treatment plan can be implemented.
2.1.5. Need for Effective Balance Interventions Following TBI

For patients who incur more-severe TBI, balance deficits are common and lasting, and negatively impact short and long-term outcomes. [7, 10, 19, 20, 54] Physical therapy (PT) interventions designed to address balance deficits are frequently provided during inpatient rehabilitation for patients with TBI; however, following completion, many individuals with TBI do not receive long-term outpatient or in-home PT, despite evidence of chronic balance deficiencies.[8, 18, 19] Furthermore, the time available to provide these interventions within inpatient rehabilitation is shrinking, with the average length of stay decreasing from an average of 23 days to 16 days between 2000 and 2008.[71] As such, it is likely that patients discharged from rehabilitation will have unmet balance needs.[72] In order to alleviate the burden of lasting balance deficiencies and their accompanying functional limitations, development of evidence-based rehabilitation modalities for the treatment of these issues is essential.

2.1.6. Effect of Balance Deficits

Balance abnormalities significantly impact the inpatient rehabilitation course of stay and discharge. For patients with TBI, balance deficiencies that limit the ability to sit or stand have been shown to slow recovery and be strongly associated with occurrence of significant medical complications, including respiratory failure, pneumonia, urinary tract infection and soft tissue infection.[10] Gait abnormalities that result from decreased balance, including reduced step size and velocity, have also been noted to slow the rehabilitative process.[17] Deficient balance has also been shown to be a strong indicator
of increased length of stay,[10] and predictor of motor and overall functional ability at discharge from rehabilitation.[7]

Despite the efforts of inpatient rehabilitation professionals, balance deficits continue to persist long term in this population, and have a marked negative impact. A study by Walker and colleagues involving 102 veterans with severe TBI found that balance deficiencies were the most commonly diagnosed movement-related abnormalities during basic neurological examinations at both one and two years post injury.[54] During these general evaluations, approximately 25% of this population was found to demonstrate loss of balance while attempting tandem gait (heel-toe stepping), and approximately 11% used a hemiparetic gait pattern (a gait pattern in which one leg swings normally while the other is moved in a half-circular motion away from the base of support in an attempt to move the leg forward) at two years post-injury.[54] A study by Hiller and colleagues examined balance issues five years post-injury for 67 patients with predominantly moderate and severe TBI, finding that balance deficits were the second most commonly self-reported physical limitation.[19] Physical examinations of a subset of this group (n=23) involving only patients with moderate or severe TBI showed that over 40% of the cohort demonstrated complete dependence in running, hopping on either leg, jumping, and driving a car, while approximately 25% of the group was completely dependent at climbing stairs without railings and in boarding and offloading public transportation.[19] These balance deficiencies can dramatically limit participation in the community due to impaired speed of movement, inability to alter base of support especially with unexpected terrain changes, and inability to walk while maintaining gaze
on objects, pick up objects, or change directions.[18, 70, 73] Such deficiencies are of particular importance, as they have been shown to negatively impact the ability to participate in daily community activities (e.g. getting in a car, crossing the street and utilizing public transportation), increase the risk of falls and subsequent injury and negatively impact quality of life long term.[12, 19, 23, 24]

2.1.7. Current Treatment for Balance Deficits Following TBI

In an inpatient rehabilitation setting, the treatment of injury can be best addressed by an interdisciplinary team including physiatrists, nurses, occupational therapists, neuropsychologists and physical therapists.[74-76] The goal of this team will be to treat remaining medical issues, minimize deficits due to injury, promote recovery of impairments, maximize remaining function, and teach compensatory strategies for diminished abilities so that upon discharge, the patient can return to life at the highest possible level of independence. Within the team, physical therapists will be expected to provide the preponderance of balance-based rehabilitative efforts. Physicians and nurses will address the appropriate medical and pharmaceutical management of balance related issues. Occupational therapists will provide therapies geared to improve functional balance, and specifically target limitations that result from visual and vestibular impairments. Neuropsychologists will address patient’s insights and their ability to use their sensory systems in order to improve their physical performance. Physical therapists will provide the assessment of all remaining balance issues, particularly those related to the proprioceptive and physical aspects of balance. Based on the results of these
assessments, they will develop a treatment plan geared to improve sitting, standing, gait and higher level motor functions.

Within inpatient rehabilitation, physical therapists are expected to provide the majority of direct balance-based rehabilitative treatments. These treatments do not follow a specific script; rather, theories and evidence based principles for eliciting of motor learning to elicit functional recovery (via re-learning of motor abilities or compensatory strategies) are adapted and applied to a patient’s specific deficits using equipment available within the therapy setting and are fit within a continuum of activities set forth by the American Physical Therapists Association guidelines for treatment for TBI.[25, 27] Principles that may be applied include repetitive practice, mental imagery, imitating another person’s movements, viewing one’s self completing movements and biofeedback.[35] Balance deficits that stem from TBI have been shown to improve post-injury; however, these results may be obfuscated by gains made as a result of natural recovery following TBI as opposed to systematic rehabilitation.[64] Regardless of the drivers of these improvements, at the completion of rehabilitation, both basic and higher level balance deficits often remain.[8, 64]

While the underlying principles for the rehabilitation of balance deficits have an established evidence base, several comprehensive reviews of general physical therapy practices have shown that little to no evidence exists to support the application of the ‘standard’ equipment and activities used to address balance deficits for patients with TBI.[6, 28, 29, 77] A systematic review specifically focused on balance-based PT for patients with TBI published in 2011 found that limited evidence exists to support any
modality used for balance related PT (including those applied using traditional equipment and activities), and that only two studies of adequate complexity and sample size were completed to appropriately inform clinical practice.[6] The results of these studies suggested that body weight supported treadmill training may be effective in improving gait, while Tai Chi was found to be ineffective in improving balance. To address these evidence gaps, it may be advantageous to develop future research utilizing therapeutic applications shown to be effective in populations similar to TBI.

2.1.8. Emerging Techniques for Balance Treatments: Virtual Reality

An emerging evidence-based treatment for balance deficits in patient populations with neurological impairments similar to TBI, including spinal cord injury, stroke, and Parkinson’s disease, is virtual reality (VR).[35, 36] VR systems are computer-based processes that allow an individual to view a simulated environment, and provide the ability to dynamically respond and interact within this environment in real-time.[30, 31] These systems range in complexity from ‘non-immersion’ in which a user views a two dimensional image on a flat panel television and interacts with the environment with their body movements or a stimulus device, to ‘full immersion’ in which a user views a three dimensional 360 degree image of an environment using either VR goggles or dome projection and interacts with movements captured by sensors directly placed on the body. In recent years, ‘non-immersion’ systems have become more commercially available, and are no longer accessible only to researchers or academic institutions, with basic units marketed as gaming consoles that can be purchased at retail outlets (XBOX, Wii). These non-immersion products are cost-effective ($179 - $300)[78] when compared to the full
immersion systems used in laboratory based research ($5,000 – $350,000)[79] and while they lack the complexity and nuances available in more costly systems, they maintain the ability to provide environments and activities that have been shown to be effective in physical rehabilitation.[33, 34, 80]

The use of VR has several advantages over traditional inpatient rehabilitation activities. These systems provide the ability to generate standardized, replicable, ecologically valid settings in which to treat patients.[32] Furthermore, they can be used to allow a patient to participate in virtual activities or locations deemed to be enjoyable by the patient which may be inaccessible or dangerous in reality (e.g. a simulated kitchen in which a patient with behavioral instability is able to use knives and a gas stove), all while maintaining the safety and location. In regards to balance, VR provides an avenue to implement many of the therapy strategies that have been established for physical and neurological recovery, including repetitive practice, self-observation, biofeedback and imitation of others movements.[35] An extensive evidence base has been established demonstrating the positive effects of utilizing VR for the treatment of balance deficits in neurologically similar patients, including stroke,[81-92] Parkinson’s disease [80, 93, 94] and spinal cord injury.[35, 36, 95, 96] Studies of varying levels of complexities in these populations have shown that groups utilizing VR have improved gait speed, standing endurance, and score higher than groups receiving the ‘standard of care’ on measures of posture, standing and higher level balance.[35, 36]

Despite the broad use of VR-based therapy for balance-focused rehabilitation in neurologically similar populations, the use of VR for the physical rehabilitation of
patients with TBI has been limited,[35-37, 97] with the majority of research focusing on cognitive rehabilitation.[31, 98-106] Applications of VR have sparsely been used for physical rehabilitation [37] and functional training, including completing kitchen activities,[32, 98] using automatic teller machines,[107] driving[108-110] and way-finding.[111] In regards to balance, VR has been investigated as a tool to assess deficits post injury in athletes with mild TBI,[112-114] and as a therapeutic technique to treat long-term balance deficits in patients more than six months post TBI.[39] It should be noted that while the latter study failed to show statistically significant group differences, it did show that persons receiving VR-based treatment did improve their balance as much as a group receiving standard PT.[39] Acceptance or enjoyment of the use of VR has been assessed across several of these studies, all of which have reported positive feedback from participants.[38, 39, 108]

Despite the overall positive results of VR interventions, these processes are not without limitation. One major drawback of using these interventions is the possibility of inducing adverse events. ‘Cyber sickness’ is a form of motion sickness that is elicited by viewing moving three-dimensional imaging, which has occurred with previous VR interventions.[36, 115] Symptoms of this illness include nausea, headaches, balance disturbances and hand-eye coordination disruption. While the likelihood of ‘cyber sickness’ is less likely when using non-immersive VR systems, inducing this condition remains a possibility.[36] Also of issue is the ability to transfer tasks learned in the virtual environment to the real environment, and if this transfer is as effective and lasts as long as real-world practice. Previous research has demonstrated a some transfer of
learning from the virtual to the real world, with tasks that closely relate to real-word equivalents faring better than those that do not.[116] A final issue with off-the-shelf VR interventions is task selection. Commercially available VR games designed for gaming systems are designed for entertainment, and as such, they may not address any or all of an individual’s deficits. These games may be too difficult for a person with disabilities to complete, or they may reinforce maladaptive or undesired movement patterns.[34, 117] Furthermore, users of these games who score poorly may be given negative visual or auditory feedback as a result of their performance, which may in turn reduce the desire to complete the activity or change movements in order to achieve a better result, regardless of the appropriateness of these actions.[33]

2.2. Summary of Findings, Limitations and Importance

The need for the development of effective evidence-based treatments for balance deficits of patients with more-severe TBIs is of great importance. The review of the literature has demonstrated that balance deficits are both an immediate and long term problem for patients with TBI. At current, an insufficient literature base has been established for the treatment of these deficits, with only two studies of adequate complexity and sample size completed to inform the field. One effective strategy in developing new balance therapies for this population may be to pull from the literature base of neurologically similar conditions. The evidence base of these fields has shown that VR-based therapy can be an effective modality in treating balance issues. One small study of a balance therapy program for patients with moderate or more severe TBI that utilized a VR-based treatment has been completed; however, this modality has not been
systematically evaluated for safety or feasibility for patients with TBI, particularly in an
inpatient setting and for non-immersive commercially available systems. Addressing
limitations of VR interventions during research design, including VR game selection,
adverse event monitoring, and providing feedback regarding actual performance instead
of game score will augment the veracity of the study results. The dearth of knowledge
regarding the use of VR for the treatment of balance deficits for patients with TBI who
are receiving inpatient rehabilitation provides a strong rationale for the proposed
systematic research endeavor.
CHAPTER III

STUDY HYPOTHESES, METHODS AND ANALYSIS PLAN

3.1. Research Questions and Specific Aims

The purpose of this thesis was to extend the completed overarching RCT by performing extended analyses of the secondary data to evaluate the effect of a VR-based therapy intervention to improve balance for adult patients receiving inpatient rehabilitation for a primary diagnosis of TBI. Three specific aims including a total of six research questions were established for this thesis.

3.1.1. AIM 1: To Investigate the Relationship Between Study Treatment Received and Balance Changes Over the Course of Treatment.

Research Question 1a. After completing treatment, is there a difference in static balance, as measured by the Berg Balance Scale (BBS), between groups of patients receiving

a. virtual-reality based non-traditional balance therapy (Nintendo Wii-based therapy) in addition to standard balance therapy, or;

b. extra traditional balance therapy in addition to standard balance therapy?

Research Question 1b. After completing treatment, is there a difference in dynamic balance, as measured by the Functional Gait Assessment (FGA), between groups of patients receiving

a. virtual-reality based non-traditional balance therapy (Nintendo Wii-based therapy) in addition to standard balance therapy, or;

b. extra traditional balance therapy in addition to standard balance therapy?
3.1.2. AIM 2: To Assess the Predictive Validity of Wii Balance Board Game Scores On Actual Standardized Assessments of Balance.

Research Question 2. Within the group receiving the Wii intervention, do Wii balance game scores correlate with scores on a standardized assessment of

a. static balance, as measured by the BBS?

b. dynamic balance, as measured by the FGA?

3.1.3. AIM 3: To Investigate the Existence of a Dose-Response Relationship Within Each Study Arm On Balance Changes.

Research Question 3. Over time and within each intervention group, is there a relationship between the number of treatment sessions completed and the change in

a. static balance over time, as measured by the BBS?

b. dynamic balance over time, as measured by the FGA?

3.2. Study Methodology

These aims and research questions were addressed as part of a pilot study, designed as an inpatient, blinded, randomized, controlled, clinical trial (RCT) conducted at Craig Hospital for which the author of this dissertation was the project manager. The purpose of this study was to obtain data requisite to determine the sample size for a larger sufficiently powered efficacy study. Outcomes included in this thesis were comprised of standardized balance assessments (BBS and FGA), VR game-based balance scores (Wii balance board scores) and treatment adherence data. Assessments of static (BBS) and dynamic balance (FGA) were collected by two trained and licensed blinded physical therapist evaluators as part of the study. Wii balance board game scores were abstracted
from the memory of the Wii units. Treatment adherence was gleaned from study notebooks kept by therapists involved in providing treatment as part of the study protocol. These latter measures were collected solely by the author.

The RCT involved a four week PT intervention protocol. Patients receiving inpatient rehabilitation at Craig who meet study criteria and consented to participate in the trial were randomized to one of two treatment conditions: Extra Standard Care, or VR-based Therapy (utilizing the Nintendo Wii). All patients included in the trial received therapy as per the therapeutic guidelines established by the respective departments at Craig Hospital; however, in addition to these therapies, patients enrolled in the trial received 15 minutes of additional balance-focused physical therapy, delivered by a trained and licensed physical therapist, at the end of the therapy day. The study protocol provided for study-related therapies to be provided four times per week for a total of four weeks.

3.2.1. Treatment Protocol

Patients randomized to the Extra Standard of Care treatment group received 15 minutes of balanced-focused PT using a standard range of balance equipment and activities available in the PT gym at Craig Hospital. Patients randomized to the VR-based therapy arm received 15 minutes of therapy utilizing the Nintendo Wii, for which specific games have been selected for use in this trial. In order to reduce confounding from non-therapeutic VR system use, patients enrolled in the trial were excluded from use of VR systems (Nintendo Wii and Xbox Kinect) for all delivered therapeutic
activities across all professions and all recreation activities for the duration of the study assessments. A diagram of all study related activities is presented in Figure 4.

Figure 4: Tasks involved in the RCT of Wii-based balance therapy

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<th>Timeline</th>
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<td>VR Treatment Group</td>
<td>VR-based Therapy 15 Minutes Per Day 4 Times Per week</td>
<td>Mid Intervention Test</td>
<td>VR-based Therapy 15 Minutes Per Day 4 Times Per week</td>
</tr>
<tr>
<td>Medical Record Screen</td>
<td>Consent</td>
<td>PT Screen</td>
<td>Randomize</td>
</tr>
<tr>
<td>Extra Standard Care Group</td>
<td>Extra Standard Care 15 Minutes Per Day 4 Times Per week</td>
<td>Mid Intervention Test</td>
<td>Extra Standard Care 15 Minutes Per Day 4 Times Per week</td>
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3.2.2. Case Consenting

The author was responsible for screening all new TBI rehabilitation admissions to Craig Hospital to determine eligibility throughout the duration of the RCT. Those patients meeting minimum inclusion criteria, including injury severity, age, planned rehabilitation length of stay, a BBS score of 15 or higher (indicating that staff therapists were actively engaging in balance-based therapy and that these patients had adequate balance function to safely participate in balance therapy) and PTA status, were approached by a study research assistant for consent to screen for and participate in the
trial. All consents completed by proxy were accompanied with a verbal assent from the patient. After consent was obtained, patients were evaluated for study appropriateness by a physical therapist using a 10-minute trial that encompassed basic use of the Wii Fit and Wii Sport activities. If the patient was able to complete this trial without exhibiting extreme negative physical/behavioral reactions or unsafe postural instability, they were randomly assigned to one of the two study groups: Extra Standard Care, or VR-based Therapy (here forward referred to as Wii-based Therapy). Random assignment was 1:1, with the randomization schedule provided by the overarching RCT statistician.

3.2.3. Case Inclusion

Potential participants were enrolled in the study if they, or their family member/proxy, provided consent to undergo a study screen within 21 days of admission to Craig Hospital, and met the following inclusion criteria as determined by review of the medical record, including injury information and clinician specific notes (PT and SLP), and a brief screen:

1. Had a diagnosis of TBI as defined as “damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness or post traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination,”[118]

2. were continuously hospitalized from time of injury until admission for rehabilitation;

3. enrolled in the study within 6 months of TBI;
4. were admitted for initial inpatient rehabilitation at Craig Hospital;
5. were able to sign informed consent, or have a family member or proxy available to provide consent;
6. scored a minimum of 15 on the BBS, signifying sufficient motor function required for participation in the intervention, as assessed by a Physical Therapist;
7. completed a Wii trial for a minimum of 10 minutes using the identical activities that were to be employed in the study if the participant was randomized to this study arm. A successful trial required screening personnel to observe no negative physical or behavioral reactions during or within one hour after the trial was completed. Negative reactions included: extreme fatigue; insufficient balance or cognition for safe use, even with direct supervision; increased spasticity, visual disturbances, pain, or vestibular dysfunction; or increased combative, labile, or agitated behaviors. These negative reactions were also monitored by the Craig rehabilitation team, and were reported to the author before inclusion in the study.

Individuals were excluded from participation in the study if they:

1. displayed agitated or other behavioral issues that would interfere with participation in Wii treatment, as determined by the rehabilitation study team;
2. had spasticity, tone, or reflexes that interfered with participation in Wii treatment, as determined by the rehabilitation study team;
3. had concurrent medical diagnoses/issues that interfered with participation in or assessment of Wii treatment, including lower extremity weight-bearing
limitations, combination TBI/SCI patients, or any condition that, in the judgment of the investigators, precluded successful participation in the study;

4. had a scheduled inpatient stay that was predicted to be less than ¾ of the intervention window;

5. were Non-English speaking;

6. had significant difficulty communicating, due to speech and/or cognitive dysfunction, that precluded understanding of verbal or demonstrated directions for Wii use, as determined by the rehabilitation study team;

7. had a Revised Galveston Orientation and Amnesia Test (GOAT-R) score of less than 11 or Orientation Log score less than 25, indicating that they were still in PTA;

8. were participating in another clinical trial.

3.2.4. Sample Size

The study in which this thesis was couched was an unpowered pilot study, the purpose of which was to obtain data required to design and power an efficacy trial for a population of patients receiving rehabilitation for a primary diagnosis of TBI. The study was supported by a small grant fund provided by the Craig Hospital Foundation. The sample size selected for this study was 20 participants, with 10 participants per treatment arm. This sample was selected as it was deemed feasible to obtain within a one year period, would provide data from multiple participants across multiple time points which could thereby be used to establish at least some level of evidence for proceeding with
more sophisticated research of the selected intervention and to determine sample size for a larger sufficiently powered efficacy study, and would not overtax the minimal budget.

3.2.5. Study Treatments

Participation in the trial was four weeks. Following successful screening, enrolled patients had study treatments added to their inpatient rehabilitation schedules at the end of their therapy day (typically at 4pm or 4:30pm). Throughout study enrollment, the author monitored the participant schedule to ensure that study treatments were not overbooked by additional therapeutic or medical activities, and rescheduled therapies in the event of these occurrences. Efforts were made to inform the patient and rehabilitation study team of these adjustments so that participation and intervention in the trial were maximized. A standard schedule for study participation included treatments on Monday through Thursday, allowing Friday for rescheduled treatments. Weekend treatments did not occur unless requested by an enrolled participant. Patients were allowed to refuse treatment at their own discretion; however, any participant that refused treatment more than four sessions was dropped from the study, with an additional participant enrolled to replace this subject. Treatments missed for reasons beyond the control of the participant, including holidays, equipment failure, and early discharge were tracked, though not counted as treatment refusals. Attempts were made to reschedule these therapies at times when both treating therapists and patients were available; however, no treatments were rescheduled on days which standardized assessments were collected.

Treatment assignment was revealed to participants on the first date of study treatment, with treating staff alerted the day prior. Each study treatment was
administered by a physical therapist trained specifically for the administration of the study. Treating therapists for each participant varied throughout the study, with each treatment session guided by the notes provided by the previous treating therapist and clinical judgment. The treatment protocol established for both treatment arms are described below.

*Extra Standard Care.* This group received an additional 15 minutes of balance-specific therapy, four times per week, at the end of the therapy day using the activities and equipment available in the Craig Hospital therapy gym. The types of balance activities were individualized for the patient’s specific balance needs, and included: balance beams, tilt boards, rocker boards, altered surfaces (e.g. foam), altered bases of support (wide, narrow, tandem), altered visual inputs (e.g. eyes open/closed, bright/darkened rooms), altered head positions (head turns with balance activities), dual attention activities (cognitive or physical distractions in addition to balance tasks), and interactive dynamic standing activities (e.g. ball toss, reaching, stepping).

*Wii-based therapy.* This group received an additional 15 minutes of balance activities utilizing the Wii Fit and Wii Sport interactive games. Prior to the commencement of the first Wii treatment session, an avatar (virtual participant) was created for each study participant for the purposes of tracking game progress, improving immersion and enhancing participant enjoyment. The treatment consisted of eight minutes of Wii Fit balance board games, and seven minutes of Wii Sport games, four times per week. Specifically, the Wii activities were utilized as follows: Day one and
three - eight minutes of Table-Tilt, seven minutes of Tennis; Day two and four - eight minutes of Penguin Slide, seven minutes of Bowling

3.2.6. Data Collection

Standardized assessments were completed at baseline, and at the completion of two and four weeks of therapy, or in the instance of an early rehabilitation discharge, within two days of the discharge date. Data collection for these assessments occurred at the same time that study balance treatments were provided (the end of the therapy day) to minimize bias related daily fatigue fluctuations and to minimize interference with regularly scheduled therapies. These assessments were completed by two blinded evaluators who are also licensed physical therapists employed by Craig Hospital. Training to standardize administration of each of the assessments was provided prior to data collection. All additional thesis data was collected by the author, from data abstracted from the medical record, the Wii units utilized during the study (Wii balance game scores) or from the therapy logs (treatment adherence) at the completion of the RCT.

Per exclusion criteria four, it was anticipated that all enrolled patients would complete the intervention; however, when a patient was discharged prior to the study completion, participation was considered complete at the time of discharge, and all outcome assessments were collected within 48 hours of the discharge date.

3.2.7. Study Assessments

Demographics and Injury Information. Demographic and injury severity information was abstracted from the medical record. Demographic variables collected
included gender, age, and race. Injury data included the etiology of injury, the number of days from injury to acute care discharge, the number of days from injury onset to study enrollment, the number of days from inpatient rehabilitation admission to discharge and the Glasgow Coma Scale score (indicating TBI severity) on admission to acute hospitalization.

**Static Standing Balance.** Static standing balance was assessed using the Berg Balance Scale (BBS).[9] The BBS is a 14-item functional skills test of functional balance. Responses are scored on a 5-point ordinal scale (0-4). The total score for this scale is calculated by summing each of the included items and has a range of 0-56, with higher scores indicating greater balance.[119] The scale has demonstrated high intra- and inter-rater reliability (ICC 0.98 and 0.97-0.99 respectively).[120, 121] The scale also has well established validity[122] and has been shown to be sensitive to treatment changes.[123-126] A copy of this measure is presented in Appendix 1.

**Dynamic Balance.** Dynamic balance was evaluated with the Functional Gait Assessment (FGA). The FGA is a clinical tool for evaluating performance in walking, consisting of a 10-item gait assessment based on the Dynamic Gait Index, with each item scored on a range of 0-3. Total scores for this scale are calculated by summing each of the items, and have a range of 0-30, with higher scores representing more functional gait ability.[59] This scale has demonstrated high reliability[59] and validity,[127] and has been shown to be sensitive to treatment effects in previous research involving patients with TBI.[128] Patient performance on the FGA can be compared with age-referenced
norms for expected performance.[129] A copy of this measure is presented in Appendix 2.

_Wii Balance Game Scores._ Wii balance game scores were taken from the Wii-therapy balance board games that the participant used and for which scores are stored longitudinally (Table-Tilt and Penguin Slide), not a level or per-opponent result (Bowling, Tennis). Scores for each participant during each treatment session were recorded; however, as the number of games played per session varied across participants and sessions, the average of the top two scores in the sessions that were most proximal to the standardized assessments of balance were retained. Scores for all of these participants were abstracted from the Wii at the completion of the study.

_Treatment Adherence._ Session attendance was tracked by review of the study notebooks. Each session attended was tallied, as was the total number sessions the patient was available for therapy. Adherence was calculated as both the total number of sessions attended, and as a proportion of sessions attended (labeled Treatment Compliance). Each missed therapy and the reason for the absence was recorded. Therapies missed without reason or outright refusal were classified as ‘skipped’; however, not all therapies missed were assigned this designation. As some treatment schedules fell during weeks that included national holidays, treatment sessions were not held, as no therapists were available to provide either study treatments or any other scheduled therapies. Furthermore, some patients with medically complex conditions who were required to return to acute hospitals for surgeries (e.g. craniotomy flap replacement) were enrolled in the study. Missed therapies that related to off-site medical procedures were classified as
‘Not Applicable’ and were not counted toward the total number of possible therapies for the denominator of the proportion of Treatment Compliance. Therapies classified as ‘Not Applicable’ were attempted to be rescheduled; however, for those that fell during weeks which assessments took place, rescheduling was not always possible.

3.3. Analysis Plan

The analysis plan for each study aim is described in the following section. Descriptive analyses were completed to demonstrate the demographic and injury-related composition of each treatment arm, and tests for significance for group differences were assessed using Wilcoxon Ranked Sum Tests for continuous variables and Fishers Exact Tests for categorical variables. Final analyses included covariate adjustment for those variables found to be at minimum near statistically different at baseline (cutoff of p=0.15) which could theoretically influence the study outcomes; however, covariate inclusion was capped a priori to two variables so that degrees of freedom would be available to complete the outcome analyses. Unadjusted tests of significance were completed for all stated research questions using the methods specified below. In an effort to minimize repetition, analytic plans are provided for each overarching aim, with the methods described therein applied to the corresponding research questions provided under each aim.

Data collected for this study were completed as part of a pilot trial for which no a priori data were available from which to estimate a sample size. As such, all results, including those with non-significant results will be presented, so that all interesting
scientific findings that may be useful in future research can be discussed. All analyses conducted will be completed as intent-to-treat analyses.

3.3.1. Aim 1: Analysis

The research questions stated under this aim were evaluated using linear mixed effects repeated models, using the BBS and FGA measures as outcomes, respectively. Measures from each of the three time points collected for these outcomes were entered into models specific to each outcome. Estimates, including treatment group differences, change over time, and treatment group difference by change over time were obtained from these models. The primary estimate of interest was the group difference in change over time. A variance components correlation structure was utilized. As the timing of assessments differed across patients (due to patients discharging from inpatient rehabilitation earlier than anticipated), time was treated as a continuous variable, and equated the number of days from baseline assessment to final assessment. A graph demonstrating the treatment effects over time for each group was produced for each outcome.

3.3.2. Aim 2: Analysis

The research questions stated under this aim were evaluated with Spearman correlations, and only included participants randomized to the Wii-based therapy condition. Four total correlations were completed. Average scores for each Wii balance board game (Tilt Table and Penguin Slide) were calculated for three time points, including baseline (scores obtained during the first use of the Wii balance board games), mid-treatment (scores obtained most proximal to the two week standard assessment date),
and treatment completion (scores obtained most proximal to the final standard assessment date). These average scores were correlated with both standardized assessments (BBS and FGA) measured at each of the corresponding intervals. Correlations between these measures are used to identify if a relationship between raw scores from the Wii balance board and standardized measures of balance exist.

An additional correlation was completed for change scores from both Wii and standardized assessments. Change scores for each Wii balance board game were calculated by subtracting the average scores obtained during first use from the average scores obtained most proximal to treatment completion. Change scores for the standardized assessments were calculated by subtracting baseline assessment from final assessment. Change scores across each Wii balance game were independently correlated with changes for each standardized balance measure. These analyses were used to provide guidance as to whether changes over time in the Wii balance activities associate with changes in standardized balance measure score, and whether these changes are similar in direction and magnitude. Ninety-five percent confidence intervals and scatter-plots of all of these relationships are provided to more closely inspect the correlational relationships (or lack thereof).

3.3.3. Aim 3: Analysis

The research questions stated under this aim were evaluated using Spearman correlations, and included all enrolled subjects. Change scores were calculated for each standardized balance measure (BBS and FGA) by subtracting the final outcome measure from the baseline measure. These change score were then correlated with both measures
of treatment adherence (overall number of treatments completed, and the number of treatments completed divided by the number of treatment opportunities). Independent analyses were computed for each treatment group, using Spearman correlations. Ninety five percent confidence intervals and scatter-plots of the relationships between change scores and treatment compliance for both the Wii-based therapy and Extra Standard Care groups were produced to more closely inspect the relationship (or lack thereof) between treatment adherence and overall change in standardized measures of balance.
CHAPTER IV
RESULTS OF ANALYSES

4.1. Participant Characteristics

Participants enrolled in the trial were predominantly male \( (13/20 = 65\%) \), Caucasian \( (17/20 = 85\%) \), injured in motor vehicle incidents \( (14/20 = 70\%) \) and had GCS severity scores of Severe \( (15/20 = 75\%) \). The average age of participants was 36 years, average time between injury and admission to inpatient rehabilitation at Craig Hospital was 29 days with a standard deviation of 17 and average inpatient rehabilitation length of stay was 61 days with a standard deviation of 18. No significant differences were found between the two study arms for any characteristic. As such, none of these variables were included in subsequent analyses as covariates. Comparisons of all patient demographic, injury information and study participation characteristics, including the type of significance test and accompanying results, are presented in Table 3.

4.2. Analytic Discussion

As with the analytic plan for this thesis, results will be discussed as they pertain to each overarching study aim. At the onset of each section, the Aim will be presented, with the description of results that follow divided by study question. This style of presentation is done in an effort to reduce repetition.

4.2.1. Aim 1: Results

Model data, including estimates, 95% confidence interval (95% CI), standard error and p-values from the linear mixed models used to assess the treatment by time
Table 3: Characteristic comparisons of Wii-based therapy and Extra Standard Care groups

<table>
<thead>
<tr>
<th>Demographics, Injury Characteristics, Baseline Balance Scores</th>
<th>Fishers Exact Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Wii</td>
<td>7</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>6</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>8</td>
</tr>
<tr>
<td>Hispanic</td>
<td>9</td>
</tr>
<tr>
<td>Black</td>
<td></td>
</tr>
<tr>
<td>Mechanism of Injury</td>
<td></td>
</tr>
<tr>
<td>Motor Vehicle</td>
<td>7</td>
</tr>
<tr>
<td>Fall</td>
<td>2</td>
</tr>
<tr>
<td>Sports</td>
<td>1</td>
</tr>
<tr>
<td>Violence</td>
<td></td>
</tr>
<tr>
<td>Mechanism of Injury</td>
<td></td>
</tr>
<tr>
<td>Wilcoxon Ranked Sum Tests</td>
<td></td>
</tr>
<tr>
<td>Age at Injury</td>
<td>Median</td>
</tr>
<tr>
<td>Wii</td>
<td>31.5</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>31.0</td>
</tr>
<tr>
<td>Days of Acute Care Stay</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>23.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>23.5</td>
</tr>
<tr>
<td>Days from Injury to Enrollment</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>56.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>95.0</td>
</tr>
<tr>
<td>Days of Rehabilitation Stay</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>65.5</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>58.5</td>
</tr>
<tr>
<td>Days of Study Enrollment</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>28.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>27.0</td>
</tr>
<tr>
<td>Baseline BBS Score</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>49.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>51.5</td>
</tr>
<tr>
<td>Baseline FGA Score</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>17.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>18.5</td>
</tr>
<tr>
<td>Treatment Sessions Attended</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>13.5</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>13.5</td>
</tr>
<tr>
<td>Treatment Compliance (Sessions Attended/(Session Attended + Skipped)</td>
<td></td>
</tr>
<tr>
<td>Wii</td>
<td>100.0</td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td>96.7</td>
</tr>
</tbody>
</table>
effect for the BBS (static) balance outcome are presented in the upper portion of Table 4. Participants in the Extra Standard Care group demonstrated an improvement of 0.15 points per day, while those in the Wii-based therapy group had a 0.19 point improvement per day; however, only the rate of change for the Wii-based therapy group was shown to be statistically significant. Differences in change over time between the Extra Standard Care and the Wii-based therapy groups over the 28 day study period were found to be negligible (-1.13) and had a p-value of 0.70. Figure 5 presents a graphic representation of these results.

Results from the linear mixed models used to assess group differences in treatment by time interactions for the FGA (static) balance outcome is presented in the lower portion of Table 4. Both study treatment conditions demonstrated positive change over the course of the study, with the Extra Standard Care group showing a daily improvement of 0.20 points, while the Wii-based therapy group had a daily improvement of 0.23 points. As with the previous model, differences across groups for total treatment by time interactions were negligible (-0.91) with a 0.73 p-value. Figure 6 presents a graphic representation of these results.

4.2.2. Aim 2: Results

Results of the Spearman correlations, including the Spearman rho statistic and 95% CI, between each Wii balance board game and the corresponding BBS measures are presented in Table 5. Relationships between the Wii balance game Tilt Table was found to have a moderately strong association with BBS measures taken at corresponding time points. Spearman rho coefficients ranged from 0.28 to 0.68, with a significant
Table 4: Linear mixed models results comparing Berg Balance Scores and Functional Gait Assessment Scores across the study period

<table>
<thead>
<tr>
<th>Mixed Model Estimates</th>
<th>Estimate (95% CI)</th>
<th>Standard Error</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Berg Balance Scale Total Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47.68 (43.07, 52.28)</td>
<td>2.27</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>49.79 (45.82, 53.77)</td>
<td>1.96</td>
<td></td>
</tr>
<tr>
<td>Study Completion</td>
<td>51.90 (47.09, 56.71)</td>
<td>2.37</td>
<td></td>
</tr>
<tr>
<td>Treatment by time</td>
<td>0.15 (-0.03, 0.33)</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>Wii-based therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47.21 (42.60, 51.82)</td>
<td>2.27</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>49.89 (45.94, 53.84)</td>
<td>1.95</td>
<td></td>
</tr>
<tr>
<td>Study Completion†</td>
<td>52.57 (47.87,57.26)</td>
<td>2.32</td>
<td></td>
</tr>
<tr>
<td>Treatment by time</td>
<td>0.19 (0.02, 0.337)</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td><strong>Total treatment by time difference</strong></td>
<td>-1.13 (-8.17, 5.91)</td>
<td>3.48</td>
<td>0.70</td>
</tr>
<tr>
<td><strong>Functional Gait Assessment Total Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra Standard Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>17.76 (13.62 ,21.89)</td>
<td>2.04</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>20.55 (16.80, 24.30)</td>
<td>1.85</td>
<td></td>
</tr>
<tr>
<td>Study Completion</td>
<td>23.34 (19.07, 27.61)</td>
<td>2.10</td>
<td></td>
</tr>
<tr>
<td>Treatment by time</td>
<td>0.20 (0.06, 0.34)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>Wii-based therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>16.36 (12.22, 20.50)</td>
<td>2.04</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>19.61 (15.87, 23.34)</td>
<td>1.84</td>
<td></td>
</tr>
<tr>
<td>Study Completion†</td>
<td>22.85 (18.66, 27.05)</td>
<td>2.07</td>
<td></td>
</tr>
<tr>
<td>Treatment by time</td>
<td>0.23 (0.10, 0.36)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td><strong>Total treatment by time difference</strong></td>
<td>-0.91 (-6.20, 4.39)</td>
<td>2.61</td>
<td>0.73</td>
</tr>
</tbody>
</table>

†This time point is equivalent to the last measurement taken, which most often 28 days, though had a range of 13 to 29 days.
Table 5: Spearman correlations between Wii balance board game scores and corresponding BBS and FGA measures

<table>
<thead>
<tr>
<th></th>
<th>Berg Balance Scale</th>
<th>Functional Gait Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rho (95% CI)</td>
<td>rho (95% CI)</td>
</tr>
<tr>
<td>Tilt Table</td>
<td>Baseline</td>
<td>Week 2</td>
</tr>
<tr>
<td></td>
<td>0.28 (-0.42, 0.77)</td>
<td>0.68* (0.09, 0.92)</td>
</tr>
<tr>
<td>Penguin Slide</td>
<td>Baseline</td>
<td>-0.02 (-0.64, 0.61)</td>
</tr>
<tr>
<td></td>
<td>0.35 (-0.36, 0.80)</td>
<td>0.41 (-0.30, 0.82)</td>
</tr>
<tr>
<td></td>
<td>0.35 (-0.71, 0.53)</td>
<td>-0.03 (-0.65, 0.61)</td>
</tr>
</tbody>
</table>

* Significant at the 0.05 level
† This time point is equivalent to the last measurement taken, which most often 28 days, though had a range of 13 to 29 days.
Figure 5: Scatterplot and mixed model regression lines of Wii-based therapy and Extra Standard Care groups BBS scores
Figure 6: Scatterplot and mixed model regression lines of Wii-based therapy and Extra Standard Care groups FGA scores
association between Tilt Table scores and BBS assessment score taken at week two (rho = 0.68; p = 0.03). Total change during study participation on Tilt Table scores and BBS measures were shown to have a poor relationship (0.23). Relationships between Penguin Slide scores and BBS measures taken at corresponding time points initially demonstrated poor association (-0.02 for initial games and baseline BBS), with strengthening associations at two weeks (0.27) and at final measurement (0.69). Correlations at the final measure were significant at the 0.05 level. Change over time on Penguin Slide scores and BBS measures were shown to have a moderately strong, yet not significant, negative association (-0.39). Scatterplots of each of these relationships are presented in Figures 7 and 8.

Relationships between Tilt Table scores and corresponding FGA measures were found to be less strong than those with the BBS. Spearman rho coefficients for these relationships ranged from 0.22 to 0.41. Total change over time between Tilt Table and FGA scores did not indicate an association, with a Spearman rho of -0.01. Correlations between Penguin Slide scores and FGA measures taken at baseline and week two suggested association; however, a moderate relationship (0.52) was found between the final Penguin Slide scores and FGA measure (0.52). Change scores between these assessments were mild. Scatterplots of each of these relationships are presented in Figures 9 and 10.

4.2.3. Aim 3: Results

Spearman correlations between both measures of treatment adherence, including Sessions Attended and Treatment Compliance, were found to have moderate inverse
Figure 7: Scatterplots of Tilt Table scores with corresponding BBS measures
Figure 8: Scatterplots of Penguin Slide scores with corresponding BBS measures
Figure 9: Scatterplots of Tilt Table scores with corresponding FGA measures
Figure 10: Scatterplots of Penguin Slide scores with corresponding FGA measures
relationships between changes in BBS scores for the group receiving Wii-based treatments. No relationships, however, were found between measures of treatment adherence and changes in FGA scores. Data for these analyses are listed in the top portion of Table 6, and graphic representations of these data are presented in Figure 11.

Moderate to strong inverse relationships were demonstrated by Spearman correlations between measures of treatment adherence and changes in BBS scores for the group receiving extra standard therapy. As with the Wii-based therapy group, the analysis suggests no evidence of a relationship between measures of treatment adherence and changes in FGA scores. Data for these analyses are listed in the lower portion of Table 6 and graphic representations of these data are depicted in Figure 12.

Table 6: Spearman correlations between measures of treatment adherence and changes in BBS and FGA measures

<table>
<thead>
<tr>
<th></th>
<th>BBS Change rho (95% CI)</th>
<th>FGA Change rho (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wii-based therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Session Attended</td>
<td>-0.28 (-0.77, 0.42)</td>
<td>-0.17 (-0.72, 0.51)</td>
</tr>
<tr>
<td>Treatment Compliance</td>
<td>-0.27 (-0.77, 0.43)</td>
<td>0.08 (-0.58, 0.68)</td>
</tr>
<tr>
<td><strong>Extra Standard Care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Session Attended</td>
<td>-0.31 (-0.81, 0.44)</td>
<td>-0.01 (-0.67, 0.66)</td>
</tr>
<tr>
<td>Treatment Compliance</td>
<td>-0.65 (-0.92, 0.03)</td>
<td>-0.09 (-0.71, 0.61)</td>
</tr>
</tbody>
</table>
Figure 11: Treatment adherence scatterplots with changes in standardized measures of balance for the Wii-based therapy Group
Figure 12: Treatment adherence scatterplots with changes in standardized measures of balance for the Extra Standard Care Group
CHAPTER V
CONCLUSIONS

5.1. Conclusions: Aim 1

The results of the mixed model analysis of treatment group differences in regards to the daily rate of change for BBS demonstrated that only the group receiving the Wii-based therapy intervention had a significant daily rate of improvement over time (0.19 points per day, p = 0.03); however, when comparing differences between groups over the 28 day study period, the Wii-based therapy group was found to have only a 1.13 point higher improvement in BBS scores as compared to the group receiving Extra Standard Care, which was not significant (p=0.70). Mixed model analyses of treatment group differences in daily FGA change demonstrated that both groups had a significant daily rate of improvement (Extra Standard Care = 0.20, Wii-based therapy = 0.23). Again, comparisons of total change over the study period demonstrated no significant differences in total changes in these scores over the total study period. These results do not suggest that the Wii-based therapy intervention is more advantageous in improving static or dynamic balance as compared to Extra Standard Care. As the purpose of the overall trial was pilot work to obtain data required to design and power a larger efficacy trial, the lack of significant results is not surprising. Furthermore, these non-significant findings are similar to the results of a previous randomized controlled trial of an outpatient-based virtual reality intervention for the treatment of balance deficits in people at least six months post-TBI in which a six-week intensive PT-based exercise program and a blue-screen modulated VR were compared. Findings from this study also
suggested that both VR and comparator treatments improved balance over an interventional period, though neither was found significantly better than the other.

Despite the lack of significant group differences, the results of this study are not without merit. To the author of this thesis’ knowledge, this represents the first randomized controlled trial comparing a VR-based intervention to PT standard of care treatment for patients with TBI who are receiving inpatient therapy. Though a null result was found in this pilot trial, the results from the data from this trial can be used in establishing a more methodologically and statistically rigorous RCT of these interventions on a larger population to assess if balance outcomes are influenced differently by these treatment types. These results can also be of use to physical therapists that treat patients with TBI in an inpatient setting. This is the first trial to demonstrate that VR-based interventions may be effective in eliciting balance improvements over time for patients with TBI receiving care in an inpatient setting, as evidenced by the Wii-based therapy group having significant daily improvement on both their BBS and FGA scores. While these results are not definitive, they do provide some rationale for the use of VR in the treatment of balance deficits for this population, as the analyses performed here demonstrate that the Wii-based therapy group improved just as much, if not slightly more, than the group who received Extra Standard Care.

While the findings from this study are important, they are not without limitation. One major confounder for this study is that both interventions under investigation were done in adjunct to the therapy day, meaning that patients enrolled in the study were already receiving between 3 and 8 hours of rehabilitative therapies (including those that addressed balance) as part of their inpatient stay. As such, the results of this study may
be an artifact of the overall rehabilitation that patients enrolled in the trial were receiving or natural recovery that is known to occur early on following TBI, as opposed to the four weeks of add-on therapy of either Extra Standard Care or Wii-based therapy. In order to determine if these adjunct therapies are truly advantageous in improving balance following TBI, an additional study comparing these treatments that includes a study arm in which patients receive no adjunct therapy is recommended. Such an arm was not included in this trial, as the funding source for the trial was obtained via a private donation to the Craig Hospital Foundation which explicitly stated that financial support would only be provided for research regarding the direct provision of an intervention, and that funds could not be used for solely observational purposes. Also limiting the results of this trial is variability in treatments completed by each participant. As this study was completed in an inpatient setting, enrollment was based on projected lengths of stay; however, these projections were not always accurate, with nine of 20 enrolled patients being discharged prior to completion of the full study protocol, one of whom was discharged only two weeks after enrollment. To address this issue in a future study, it would be recommended to utilize a shorter study length, more frequent assessment, or a study design of longer length in which balance could be assessed beyond the inpatient rehabilitation stay. While the latter suggestion could be compromised by the lack of standardization (e.g. setting, intervention, etc.) beyond the inpatient rehabilitation setting, it would allow for the assessment of balance gains made beyond the relatively short length of stays associated with inpatient rehabilitation. One of the balance measures included as part of this trial also limits the results. The BBS has a known low ceiling effect, meaning that patients often reach the top of this scale quickly.[121] In this trial,
one patient reached the ceiling of the scale prior to their final outcome assessment and six additional participants were within two points of the high score, meaning that for these patients, treatment effects over time could at most be minimally demonstrated, as these participants could no longer improve on this scale. In future study, use of a static balance scale that is not affected by a ceiling effect (e.g. a time single leg stance test or a computerized measure of postural sway) is recommended.

5.2. Conclusions: AIM 2

Spearman correlation analyses between time matched Wii balance board game scores and the BBS suggest moderate positive relationships between these measures. The rho coefficients between the Wii balance board game Tilt Table and the BBS ranged from 0.28 to 0.68, with the measures taken at 14 days post enrollment demonstrating a significant positive relationship (p = 0.03). Analyses of the relationship between the Wii balance board game Penguin Slide and the BBS demonstrated similar relationships, with rho coefficients ranging from -0.02 to 0.69. For this game, the final assessments were found to be significantly positively correlated, with a p-value of 0.03. The majority of these relationships suggest that as scores improve on Wii balance board games overall static balance as measured by the BBS improves. While it is impossible to determine from these data if these measures are assessing the same construct (static balance), the strong relationships between Wii balance board game and BBS scores suggest that Wii balance board game scores may provide a surrogate for standardized tests of static balance. This association may provide therapists with a new modality for informally evaluating stationary balance beyond standardized assessments and more expensive technological methodologies (e.g. pressure plate analyses). The ability to incorporate the
use of a VR device for these purposes may also provide a method for enhancing current therapy practices. As these devices have the ability to provide tasks and environments that patients may find personally relevant or enjoyable that are otherwise unavailable within the inpatient therapy setting,[32] therapists may be able to select or design VR games which maximize client-specific interests thereby enhancing patient participation effort in balance therapy and evaluation. Previous research has demonstrated that patient effort is one of the key factors of maximizing rehabilitation outcomes, particularly functional outcomes at discharge from inpatient rehabilitation.[130] In today’s healthcare climate, in which TBI rehabilitation lengths of stay have been drastically reduced,[71] providing therapies which maximize patient effort within the window of rehabilitation is essential. Furthermore, if these results were to hold true beyond an inpatient setting, they could play a valuable role in providing a low-cost and highly accessible method for the evaluation and treatment of static balance abilities for patients with TBI who have been discharged from inpatient care. However, these relationships would first need to be evaluated in an outpatient population.

Examination of the strength of relationships between the BBS and both Wii games across time points shows that measurements taken at the onset of the study had the least robust correlations, with rho’s of 0.28 and -0.02 for the Tilt Table and Penguin Slide games, respectively. These results are unsurprising, as there was a steep learning curve involved in the use of the Wii system for this patient population, and often patients focused more on learning to interface with the system as opposed to game play. Measures taken beyond the initial time points show stronger associations (0.27 to 0.68), suggesting that after 14 days of use, use of the VR equipment is less likely to negatively
influence game play. Measures of satisfaction with treatment, taken outside of this thesis, support this hypothesis, as treatment satisfaction scores for the Wii-based therapy group show markedly improved scores as time enrolled in the study progressed.

Spearman correlations between FGA scores and Wii balance games were neither as strong nor all in the same direction as those found with the BBS, with rho coefficients ranging from -0.03 to 0.52. These results suggest that changes in Wii balance board game scores do not reflect changes in dynamic standing balance as well as they do for changes in static balance; however, the results not completely without merit. The diminished relationships between these assessments and dynamic balance as compared to static balance are logical and expected, as Wii balance board games only utilize weight shifting and body positioning (which are essential components of the BBS), as opposed to full body movements that require the maintenance of balance over a moving center of gravity, which make up the core of the FGA. Based on the study results, using the Wii balance board as a surrogate method to informally assess or treat dynamic balance would not be as strongly recommended as for static balance. If a standardized method for data collection of scores from dynamic games (e.g. Tennis) could be derived, it is likely that these would better predict scores on standardized measures of dynamic balance; however, for this study, no method of score standardization could be determined.

Despite the interesting findings of these analyses, interpretation of these data should be approached cautiously. First, the balance board scores obtained as part of this study were obtained while patients were under close supervision of a physical therapist. These therapists ensured not only that each patient was performing the balance board tasks safely, but that their objectives were to address issues of balance that were
personally relevant to the patient, stressing the use of correct movement strategies and form, as opposed to tasking the participants to attempt to attain high scores. For this type of therapeutic activity to be effective beyond inpatient rehabilitation, it would be necessary for the end user to act under these conditions (focusing on function and form as opposed to high score), which runs counter to how many people approach VR game play. It should also be noted that some of the strongest relationships between the Wii balance board games and the standardized assessments were associated with the BBS. As mentioned in the conclusion section of AIM 1, the BBS has a known ceiling effect.[121] As such, these findings may be limited to the evaluation and treatment of static balance in instances in which a patient has not reached the ceiling of this measure. As was found in this study, many patients had reached the ceiling of the BBS before leaving the inpatient setting, which may limit the applicability of these findings. Therapists or researchers that wish to use VR-based balance treatments to improve static balance as measured by the BBS or replicate these results will need to limit their applications to patients who have not yet achieved a ceiling score on the BBS, which may severely limit patient enrollment. In order to properly evaluate the ability of the Wii system to associate with the construct of stationary balance, a study that includes more advanced assessments of this construct is warranted. Finally, it should be noted that BBS and Wii balance board game change scores did not associate well with one another. These results are not completely unexpected, however, as study participants had difficulty in their first uses of the VR system, thereby negatively influencing their scores, and some reached the ceiling of the BBS early on in the study and could no longer continue to show improvement.
5.3. Conclusions AIM 3

Analyses of the correlational relationship between measures of treatment compliance and changes in standardized measures of static and dynamic balance failed to show association across all comparisons for both treatment conditions. These results suggest that performance on both of the standardized assessments of balance was not driven by participation in either of the adjunct therapies. The lack of relationship between these measures is likely the product of numerous factors. First, there was little variability in treatment compliance, as most participants attended almost all of the treatment sessions available to them. This high rate of participation was the result of participant’s being highly motivated (or their family members were highly motivated) to participate in the study, as it presented a means by which they could receive additional PT services at no additional costs. Also driving participation was the ability of the treating therapists to find the participant and suggest to them that they should participate in the adjunct therapy. As this was a study in an inpatient setting, patients enrolled in the trial were housed within a few feet of the treatment area. Given this proximity, therapists would often search out patients who did not initially attend sessions and provide them the opportunity to participate (this was done both for motivation, and because patients with TBI often have difficulty managing their appointments). In order to miss a treatment session, a patient would be required to convince a therapist that he or she was unwilling to participate in therapy, or remove him or herself from the inpatient setting.

Also complicating the relationships between these measures was the adjunct nature of the treatments under investigation. All of the participants enrolled in the trial had been diagnosed with balance deficits as part of the standard of therapeutic care at
Craig Hospital. By nature of these diagnoses, each of the participants had active PT goals that involved balance activities, and substantial portions of the physical rehabilitation they received while in the inpatient setting was focused on improving balance. Thus, improvement in standardized assessments of balance is likely regardless of compliance or participation in the trial. Finally, these analyses involved change scores. As with discussion of both previous aims, the ceiling effect of the BBS is likely to have obscured the relationship between treatment adherence and compliance and changes in static balance. Since little or no change for this measure could be detected beyond two weeks for 35% of the study population, detecting association between these measures was extremely unlikely.

5.4. Overall Study Conclusions

This study represents the first RCT of a VR-based intervention for the treatment of balance deficits in patients with a primary diagnosis of TBI who are receiving inpatient rehabilitation for these injuries. The data presented within this thesis helps extend the knowledge base of physical rehabilitation for patients receiving inpatient rehabilitation for TBI, as these data have provided evidence, albeit small, that VR-based interventions may be efficacious for the treatment of balance deficits for this population, particularly for improving static balance post injury. Furthermore, these data help to provide support for the growing trend of using VR-based activities in physical rehabilitation, as the VR intervention applied here utilized many of the theories of neurological and physical recovery that have driven this trend, including repetitive practice, self-observation and biofeedback.[35] Applying these strategies within a VR-based intervention in which a
patient can be motivated by self-selected activity or setting may prove to be an invaluable treatment modality as the time for treatment in an inpatient setting shrinks.

While these data are certainly preliminary, they clearly suggest the need for additional study, using more complex methodologies, larger sample sizes and extended outcome assessments. The time by treatment effect estimates computed as part of this thesis provide data that can be used to design and power a more rigorous trial of these interventions, in which both treatment conditions can be assessed in relation to a no treatment arm. Results of this trial can then be used to determine if Extra Standard Care or Wii-based therapy is truly advantageous to no additional treatment, and if so, if either is more effective than the other. Not only can these estimates be used to power the future study, but they can also be used to justify the study, as in this trial both treatment conditions were shown to improve aspects of balance for patients with TBI in an inpatient setting, with the Wii-based therapy having slightly better results than the comparator treatment. The correlations between the standardized assessments of balance and the scores taken from the Wii balance board games also provide justification for future study. In particular, moderately strong positive relationships were found between the Wii balance board games and the standardized measure of static balance, the BBS. The associations between these game scores and the BBS suggest that this treatment modality is well fit for evaluating and addressing static balance deficits in patients with TBI, particularly early after injury. However, the overall lack of relationships between change over time on Wii balance board games and the standardized measures of balance provides some caution for assigning too much meaning to the scores gleaned from the Wii. The learning curve involved in learning to use these devices may mask ability during initial
use and be the result of equipment unfamiliarity, thus reducing the applicability in overall change in balance game scores. Regardless of this limitation, the research study was a success, as it has provided the data by which a larger trial can be designed, powered and justified.

### 5.4.1. Overall Study Limitations

There are overarching limitations that should be applied across all of the study results and conclusions. The sample size for this trial was small, and as such, the analyses completed may not represent the true population characteristics of patients with TBI who demonstrate balance deficits in an inpatient rehabilitation setting. Tests for significant group differences may have been influenced by this small sample. The limited amount of study-based therapies provided to patients in both treatment conditions also restricts the interpretation of the study data. The median number of sessions attended for both treatments groups was 13.5, which amounts to a total of 202 minutes of balance therapy across a possible 4 weeks of enrollment; thus, eliciting statistically significant improvements or group differences that were directly related to the investigational treatments was unlikely.

Also limiting all of these results is the lack of a control group that received no treatment. The absence of this group draws into question the improvements and associations that were noted as part of this study and raises the possibility that the results presented here reflect the patient’s advancement through the overall therapeutic process, as opposed to resulting from the Extra Standard Care or Wii-based therapy treatments. Another possible confounder of the study findings was the lack of control of the Extra Standard Care group. In practice, physical therapists match therapies to the specific
needs of their patients, based on injury type, deficits expressed, and goals of the client. Within this trial, therapists were allowed freedom in their selection of therapeutic balance activities as they would normally, so long as their selected modalities did not include VR applications. While this freedom was well-received by the therapists participating the trial, it does raise the possibility that disparate treatment types and intensities may have been applied across patients. As such, the Extra Standard Care group may have experienced greater variability in standardized balance outcomes, as a result of differently applied therapies. In regards to the Wii-based therapy condition, the intervention was tightly controlled, with therapists not free to select games that they thought would best match the abilities and interests of each patient. As such, the improvement (or lack thereof) of participants assigned to the Wii-based therapy group may not have been as marked as could be obtained if therapists could have tailored their VR interventions to patient’s specific deficits and interests.

Generalizability of the data from this thesis, as is the case with many RCTs, is limited by the strict inclusion criteria and population enrolled in the trial. Enrolled patients were limited to those meeting TBI severity, age, language, behavioral and cognitive function criteria. Within the total population of patients receiving inpatient rehabilitation for more-severe TBIs, patients meeting all of these criteria may be uncommon, particularly during inpatient rehabilitation. Furthermore, the patients enrolled in this trial were receiving care at a full time inpatient rehabilitation facility, whose main focus is to provide care to patients with TBI and SCI. As such, the conceptualization, intensity and provision of ‘standard care’ to those enrolled in the trial may vary quite drastically from what is practiced at other more general rehabilitation
facilities, the patient population at other rehabilitation facilities may not have as severe TBIs or the standardized physical and social environment as was present here. Finally, blinding in this study was applied only to the two physical therapists performing standardized outcomes and to the analysts involved in the larger study. The ability to keep these individuals from knowing the treatment assignment of the study participants was not assessed as part of the trial, so it is unknown if the blinding was truly effective. The effectiveness of blinding was further limited in this thesis, as the analyses included within were completed by an un-blinded individual.
REFERENCES


APPENDIX A

THE BERG BALANCE SCALE

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. ( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item

#4. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. ( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. ( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds
REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches) ( ) 2 can reach forward 5 cm
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( ) 4 able to stand independently and complete 8 steps in > 20 seconds
( ) 3 able to complete 4 steps without aid with supervision
( ) 2 able to complete > 2 steps needs minimal assist
( ) 1 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject’s normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on. ( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently ( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)
APPENDIX B

THE FUNCTIONAL GAIT ASSESSMENT

Appendix.
Functional Gait Assessment

Requirements: A marked 6m (20 ft) walkway that is marked with a 30.48 cm (12 in) wide.

1. GAIT LEVEL SURFACE

Instructions: Walk off your normal speed from here to the next mark 6 m (20 ft).

Oiling: Rate the highest category that applies.

1. Normal—Walks 6 m (20 ft) in less than 5.5 seconds, no excessive devices, good speed, no evidence for imbalance, normal gait pattern, deviates no more than 15.24 cm (6 in) outside of the 30.48 cm (12 in) walkway width.

2. Mild impairment—Walks 6 m (20 ft) in less than 7 seconds but greater than 5.5 seconds, uses assistive devices, slower speed, excessive deviations, or deviates 15.24—38.1 cm (6—15 in) outside of the 30.48 cm (12 in) walkway width.

3. Moderate impairment—Walks 6 m (20 ft) in less than 10 seconds, excessive deviations, excessive gait pattern, evidence for imbalance, or deviates 38.1—76.2 cm (15—30 in) outside of the 30.48 cm (12 in) walkway width.

4. Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 76.2 cm (30 in) outside of the 30.48 cm (12 in) walkway width or requires 7 seconds to ambulate 6 m (20 ft).

2. CHANGE IN GAIT SPEED

Instructions: Begin walking at your normal pace for 1.5 m (5 ft). When I tell you to, walk as fast as you can for 1.5 m (5 ft). When I tell you to, walk 1.5 times as slowly as you can for 1.5 m (5 ft).

Oiling: Rate the highest category that applies.

1. Normal—Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal, fast, and slow speeds. Deviates no more than 15.24 cm (6 in) outside of the 30.48 cm (12 in) walkway width.

2. Mild impairment—Is able to change speed but demonstrates mild gait deviations, deviates 15.24—38.1 cm (6—15 in) outside of the 30.48 cm (12 in) walkway width, or no gait deviations but unable to achieve a significant change in velocity, or uses an assistive device.

3. Moderate impairment—Note only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations, deviates 38.1—76.2 cm (15—30 in) outside of the 30.48 cm (12 in) walkway width, or changes speed but loses balance or balance is able to recover and continue walking.

4. Severe impairment—Cannot change speeds, deviates greater than 76.2 cm (30 in) outside of 30.48 cm (12 in) walkway width, or loses balance and has to reach for wall or be caught.

3. GAIT WITH HORIZONTAL HEAD TURNS

Instructions: Walk from here to the next mark 6 m (20 ft) away. Begin walking at your normal pace. Keep walking straight after 3 steps, turn your head to the right and keep walking straight while looking to the right. After 2 more steps, turn your head to the left and keep walking straight while looking left. Continue alternating looking right and left after every 3 steps until you have completed 2 repetitions in each direction.

Oiling: Rate the highest category that applies.

1. Normal—Performs head turns smoothly with no change in gait. Deviates no more than 15.24 cm (6 in) outside of 30.48 cm (12 in) walkway width.

2. Mild impairment—Performs head turns smoothly with slight change in gait velocity (deg), minor disruption to smooth gait path, deviates 15.24—38.1 cm (6—15 in) outside of 30.48 cm (12 in) walkway width, or uses an assistive device.

3. Moderate impairment—Performs head turns with moderate change in gait velocity, slows down, deviates 38.1—76.2 cm (15—30 in) outside of 30.48 cm (12 in) walkway width, loses balance, stops, reaches for wall.

4. Severe impairment—Performs task with severe disruption of gait (deg), stumbles 38.1 cm (15 in) or outside of 30.48 cm (12 in) walkway width.

4. GAIT WITH VERTICAL HEAD TURNS

Instructions: Walk from here to the next mark 6 m (20 ft). Begin walking at your normal pace. Keep walking straight after 3 steps, tip your head up and keep walking straight while looking up. After 3 more steps, tip your head down, keep walking straight while looking down. Continue alternating looking up and down every 3 steps until you have completed 2 repetitions in each direction.

Oiling: Rate the highest category that applies.

1. Normal—Performs head turns with no change in gait. Deviates no more than 15.24 cm (6 in) outside of 30.48 cm (12 in) walkway width.

2. Mild impairment—Performs task with slight change in gait velocity (deg), minor disruption to smooth gait path, deviates 15.24—38.1 cm (6—15 in) outside of 30.48 cm (12 in) walkway width, or uses an assistive device.

3. Moderate impairment—Performs task with moderate change in gait velocity, slows down, deviates 38.1—76.2 cm (15—30 in) outside of 30.48 cm (12 in) walkway width, but recovers, can continue to walk.

4. Severe impairment—Performs task with severe disruption of gait (deg), stumbles 38.1 cm (15 in) outside of 30.48 cm (12 in) walkway width, loses balance, stops, reaches for wall.

5. GAIT AND DROITUR TURN

Instructions: Begin walking at your normal pace. When I tell you to, turn and stop, turn as quickly as you can to face the opposite direction and stop.

Oiling: Rate the highest category that applies.

1. Normal—Performs turn safely within 3 seconds and steps quickly with no loss of balance.

2. Mild impairment—Performs turn safely within 3 seconds and steps quickly with no loss of balance, or performs turn safely within 3 seconds and steps with mild imbalance, requires small steps to catch balance.

3. Moderate impairment—Turns slowly, requires verbal cueing, requires several small steps to catch balance following turn and stop.

4. Severe impairment—Cannot turn safely, requires assistance to turn and stop.

6. STEP OVER OBSTACLE

Instructions: Begin walking at your normal pace. When you come to the shoe box, step over it, not around it, and keep walking.

Oiling: Rate the highest category that applies.

1. Normal—Able to step over one stacked shoe boxes (deg), (4.5 cm (2 in) total height) without changing gait speed, no evidence of imbalance.

2. Mild impairment—Able to step over one shoe box (11.3 cm (4.5 in) total height) without changing gait speed, no evidence of imbalance.

3. Moderate impairment—Able to step over one shoe box (1.4 cm (4.5 in) total height) but must slow down and adjust steps to clear box safely, may require verbal cueing.

4. Severe impairment—Cannot perform without assistance.

(Continued)
Appendix.

7. GAIT WITH NARROW BASE OF SUPPORT
Instructions: Walk on the floor with arms folded across the chest, feet aligned head to toe in tandem for a distance of 2.6 m [8 ft]. The number of steps taken in a straight line are counted for a maximum of 10 steps.

Grading: Mark the highest category that applies.

(1) Normal—Is able to ambulate for 10 steps head to toe with no staggering.
(2) Mild impairment—Ambulates 7-9 steps.
(3) Moderate impairment—Ambulates 4-6 steps.
(4) Severe impairment—Ambulates less than 4 steps head to toe or cannot perform without assistance.

8. GAIT WITH EYES CLOSED
Instructions: Walk at your normal speed from here to the next mark (6 m [20 ft]) with your eyes closed.

Grading: Mark the highest category that applies.

(1) Normal—Walks 6 m (20 ft), no assistive devices, good speed, normal gait pattern, deviates no more than 15.24 cm (6 in) outside 30.48 cm (12 in) walkway width.
(2) Mild impairment—Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24 - 25.4 cm (6 - 10 in) outside 30.48 cm (12 in) walkway width. Ambulates 6 m (20 ft) in less than 7 seconds.
(3) Moderate impairment—Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4 - 38.1 cm (10 - 15 in) outside 30.48 cm (12 in) walkway width. Requires more than 9 seconds to ambulate 6 m (20 ft).
(4) Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48 cm (12 in) walkway width or will not attempt task.

9. AMBLULATING BACKWARDS
Instructions: Walk backwards until I tell you to stop.

Grading: Mark the highest category that applies.

(1) Normal—Walks 6 m (20 ft), no assistive devices, good speed, no evidence for imbalance, normal gait pattern, deviates no more than 15.24 cm (6 in) outside 30.48 cm (12 in) walkway width.
(2) Mild impairment—Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24 - 25.4 cm (6 - 10 in) outside 30.48 cm (12 in) walkway width.
(3) Moderate impairment—Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4 - 38.1 cm (10 - 15 in) outside 30.48 cm (12 in) walkway width.
(4) Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48 cm (12 in) walkway width or will not attempt task.

10. STEPS
Instructions: Walk up these stairs as you would at home (i.e., using the rail if necessary). At the top turn around and walk down.

Grading: Mark the highest category that applies.

(1) Normal—Alternating feet, no rail.
(2) Mild impairment—Alternating feet, must use rail.
(3) Moderate impairment—Two feet to a stair, must use rail.
(4) Severe impairment—Cannot do safely.

TOTAL SCORE: ___________ MAXIMUM SCORE 30

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