Inpatient Rehabilitation for Patients with Traumatic Brain Injury: Process and Content

by

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Abstract

The goals of this thesis were to a) compare the content and process of inpatient rehabilitation (IR) between patients with Traumatic Brain Injury (TBI) who were treated in one Canadian and nine US facilities, b) investigate the association of therapeutic factors with short-term functional outcomes, and c) describe the functional recovery from admission to nine months post-discharge at 4 time points as well as explore the predictive value of therapeutic and post-discharge determinants to explain the variation in long-term outcomes in patients with TBI who were admitted to a Canadian facility.

This thesis was based on three studies. The results of the first study showed that there are significant differences between components of IR for patients with TBI who were treated in Canadian versus US facilities. These findings provide informative data for practitioners and researchers about variations in service provision for patients with similar profiles. The findings of the second study revealed that level of effort was associated with higher discharge cognitive scores. Additionally, more intensity of time spent in complex occupational and physical therapy activities were significant predictors of better discharge motor scores. These findings provide evidence to consider patient level of effort and intensity of specific activities in the process of goal setting. The results of the third study demonstrated that after three months post-discharge, patients did not show significant variations in functional outcomes. Also, the number of post-discharge health issues was negatively associated with both cognitive and motor scores at nine months post-discharge, and a greater intensity of time spent in complex occupational therapy activities was a predictor of better motor scores at nine months follow-up. These findings inform health care providers about the temporal influence of IR and the necessity of investigating the association of continuous treatments with long-term outcomes after IR discharge.

In summary, this thesis provides valuable information for stakeholders to consider the effect of variations of pattern and content of care on short and long-term outcomes following IR and to direct the resources for providing adequate and appropriate level of care.

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List of Abbreviations

ACRM	American Congress of Rehabilitation Medicine
ADL	Activity Daily Living
CDC	Center for Disease Control and Prevention
CER	Comparative Effectiveness Research
CM	Case Manager
CPI	Clinical Practice Improvement
CSI	Comprehensive Severity Index
DRS	Disability Rating Scale
ED	Emergency Department
FAM	Functional Assessment Measure
FIM	Functional Independent Measure
GCS	Glasgow Coma Scale
GCS-E	Glasgow Coma Scale-Extended
GOS	Glasgow Outcome Scale
HMO	Health Management Organization
IADL	Instrumental Activity Daily Living
ICD 9th	International Classification of Disease, 9^{th} Revision
ICU	Intensive Care Unit
IR	Inpatient Rehabilitation
IRFs	Inpatient Rehabilitation Facilities
IQR	Inter Quartile Range
LoS	Length of Stay
MCO	Managed Care Organization
MoCA	Montreal Cognitive Assessment
MPAI	Mayo Portland Adaptability Inventory
MVCs	Motor Vehicle Collisions
OT	Occupational Therapy
PART-O	Participation Assessment with the Recombined Tools-Objective
PBE	Practice Based Evidence

PTA	Post Traumatic Amnesia
PT	Physical Therapy
RCT	Randomized Controlled Trial
RLoS	Rehabilitation Length of Stay
RITS	Rehabilitation Intensity of Therapy Scale
RM-ANOVA	Repeated Measure-Analysis of Variance
SD	Standard Deviation
SLPs	Speech Language Pathologists
SW	Social Work
SWLS	Satisfaction with Life Scale
SNFs	Skilled Nursing Facilities
TBI	Traumatic Brain Injury
VIF	Variance Inflation Factor
WHO	World Health Organization

Chapter 1
Traumatic Brain injury

1 Introduction and Background

1.1 Epidemiology Overview and Clinical Outline

Traumatic Brain Injury (TBI) is a critical public health problem globally and is projected to remain the major cause of disability from neurological disorders until 2030 (1). Worldwide estimates suggest that TBI leads to the hospitalization and mortality of up to 50 million people annually (1). According to the Center for Disease Control and Prevention (CDC) approximately 2.8 million Emergency Department (ED) visits and hospitalization or deaths occurred in the US following TBI in 2013 (2). Population-based incidence rates for the United States (US) is reported to be about 823.7 per 100,000 persons per year (1).

The prevalence of this injury in Canada is expected to continue to be the neurological condition with the greatest number of patients experiencing severe disability by 2031 (3). The incidence of TBI in Canada is estimated to be approximately 979.1 per 100,000 persons per year (1).

While a previous study revealed that hospitalization is significantly higher in males than females and in individuals younger than 40 years of age with the main cause being Motor Vehicle Collisions (MVCs) (4), recent evidence suggest new trends in the epidemiological pattern of TBI (5). According to *The Lancet Neurology Commission,* while the incidence of TBI due to road traffic is increasing in low-income countries, the frequency of falls is increasing in the 0-14 and 55-75 age groups particularly in high-income countries (5). Also, the rate of TBI hospitalization in females among all age groups, except the 5-14-year age group, is growing mainly due to falls (5-7).

The total cost associated with head injury is in excess of $400 (USD) billion annually nation-wide in the US (1), making TBI both a substantial health and economic burden. The indirect economic costs due to working age disability in hospitalized TBI in Canada is projected to increase from $7.3 (CAD) billion in 2011 to 8.2 in 2031(3). In Ontario, the annual medical costs of hospitalization are approximately $120.7 (CAD) million for all patients with TBI and the cost of inpatient rehabilitation (IR) for this population is noticeably higher per patient compared with those who were discharged to other destinations from acute care ($93,340 versus $25,394 CAD) (8).

1.1.1 Definition and Diagnosis

TBI is defined as “an alteration in brain function, or other evidence of brain pathology, caused by an external force” (9). Alteration is described as “any period of loss of or a decreased level of consciousness, any loss of memory for events immediately before (retrograde amnesia) or after the injury (post traumatic amnesia-PTA); neurologic deficits or any alteration in mental state at the time of the injury (confusion, disorientation, slowed thinking, etc.)” (9, 10).

The World Health Organization (WHO) describes TBI as “ a silent epidemic injury that is caused by an external mechanical force where the brain will be displaced inside the skull and can be injured against the solid meningeal membrane, the dura, or against the inside of the neuro-cranium” (11, 12). Besides these definitions, the International Classification of Disease (ICD) codes are used as “the standard diagnostic tool for epidemiology, health management, and clinical purposes” to identify patients with TBI in healthcare administrative databases (12, 13).

From the clinical perspective, the Glasgow Coma Scale (GCS) score is one of the most common measurements to classify injury severity. This scale was developed to assess alterations in consciousness using motor responsiveness, verbal performance, and eye opening (14). A mild, moderate and severe TBI, involves GCS score of 13-15, 9-12, and 3-8 respectively (14).

However, the GCS is criticized due to the lack of enough sensitivity to detect mild TBI where patients are classified as normal by GCS yet experienced varied symptoms (15-18). The American Congress of Rehabilitation Medicine (ACRM) defined a patient with mild TBI as “a person who has had a traumatically induced physiological disruption of brain function, as manifested by one or more of the following: a) any period of loss of consciousness for up to 30 minutes, b) any loss of memory for events immediately before or after the accident for as much as 24 hours, c) any alteration of mental state at the time of the accident (e.g., feeling dazed, disoriented, or confused), d) focal neurological deficit(s) that may or may not be transient” (15).

1.2 Canadian and American Health Care Perspective

The Canadian healthcare system operates within a national legislative framework through *the Canada Health Act* (19). In Canada, responsibilities for health care system are shared between federal, provincial, and territorial governments (19). The founding principle of the Canadian health care system is "accessing health care based on need rather than ability to pay" (20). According to *the Canada Health Act*, provincial and territorial health care insurance has to meet the principal standards of *public administration, comprehensiveness, universality, portability, and accessibility* (19). This concept of universal health care system delivery is recognized as a national value and contributes to Canadian identity.

The primary health care system– known as *Medicare* – is a tax-based public insurance that covers all medically necessary hospital services including inpatient rehabilitation, diagnostics, and physician services free of charge for eligible Canadians (20). Given the differences in-tax revenue among provinces, access to health care services is varied (21). Another group of services such as outpatient prescription drugs, home care, institutional long-term care, and mental health care are financed through a combination of public and private (supplemental) insurance and may be provided differently among provinces as they are not governed under a national frame work. Other services such as outpatient rehabilitation (i.e., physical therapy (PT), occupational therapy (OT)), vision care, and complementary medicine are largely financed through both governmental and supplemental private health insurance considering the type of settings (e.g., governmental rehabilitation center or private clinic) (19, 20). About 75% of Canadians have access to supplemental insurance through their employers and government-sponsored insurance plan (20, 22). However, approximately one quarter to one third of Canadians do not have supplemental insurance and have to pay out of pocket for services that are not financed by public coffers (20, 22, 23).

Health care in the United States (US) is multilayered and includes both public and private insurance which is not structured based on a universal and a single nationwide health care system approach (24). In 2017, approximately 37.7% of Americans have health care coverage through public insurance which includes *Medicare, Medicaid, and Military Health care* (24-26). Older adults and some disabled patients who receive social security benefits are eligible to receive *Medicare* for hospital services, care in Skilled Nursing Facilities (SNFs), outpatient care, doctor's visit, and medical tests. *Medicare* is the main health insurer in the US that is administered by the federal government (25). It contains compulsory and supplemental sections (25, 27). Compulsory health insurance covers inpatient hospital care, very limited nursing home and some home-based services, while supplemental plans provide benefit of physician services, outpatient hospital visits, laboratory, and radiography services (25, 27). Health care for low-income people, pregnant women, low-income older adults, and people with disabilities are eligible for *Medicaid* that is financed by federal and state governments and is managed by each state. Hence, some states receive a better package of insurance from Medicaid than others (25, 28). About 67.2% of US population is covered by any private health insurance including employment based and direct-purchase. However, about 8.8% of the population is estimated to be uninsured (24, 26).

1.2.1 Traumatic Brain Injury and Inpatient Rehabilitation in Canada and the United States

The pathway of care for patients with TBI typically starts with a pre-hospital incident where emergency medical services are summoned. It then involves emergency room/acute care, often followed by a stay in the Intensive Care Unit (ICU). A range of discharge settings are possible from acute care, including home with/without supports, Inpatient Rehabilitation Facilities (IRFs), SNFs and long/short-term care settings (1, 17, 29, 30).

Inpatient rehabilitation (IR) or post-acute rehabilitation is one of the main approaches of care for patients with TBI where patients who are medically stable can benefit from a comprehensive rehabilitation program (17, 21). It is based on an inter-professional collaborative approach in a hospital environment where patients receive comprehensive interventions from providers such as OTs and PTs, speech language pathologists (SLPs), and physicians (21, 31).

Rehabilitation is defined by the WHO as "a set of interventions designed to optimize functioning and to reduce disability in individuals with health conditions in interaction with their environment and to maximize people's ability to live, work, and learn to their best potential" (32). The principal aim of IR for patients with TBI is to improve physical, cognitive, and psychological performance in order to attain functional independence necessary in their personal and social life such as activities of daily living, social functioning, quality of life, and ability to participate in the community (17).

TBI rehabilitation is comprised of therapies that are generally categorized as cognitive, physical as well as mental health related interventions. According to the CDC, cognitive rehabilitation includes a group of interventions used to manage deficits, thought processes and behavior (e.g., comprehension, perception, and learning) and physical rehabilitation focuses on improving physical factors such as strength and endurance, as well as providing assistive devices that facilitate independence (17).

However, admission to IRFs could be affected by different factors in North America. A recent systematic review of predictors of discharge location from acute care in this population showed that the type of insurance coverage is one of the main factors in determining the next level of care for these patients (33). As mentioned above, differences in health care systems between Canada and US may contribute to variability in accessing IR for patients with TBI. While in Canada medically eligible patients who meet the admission criteria will have the possibility of taking benefits from IRFs with having equal access to universal health care, in the US only medically stable patients with an appropriate insurance coverage will be admitted to IRFs (25).

Published evidence on patients who are treated in Canadian and US-IR facilities have shown that rehabilitation length of stay (RLoS) is longer for Canadians patients (34-36). Further, IR delivery in the US follows *the Medicare Benefit Policy* in which the intensity of services is typically demonstrated based on a recommended 3 hours per day to provide at least 15 hours rehabilitation per week for patients (37), while in Canadian facilities, there is often not a specific policy for intensity of IR that applies to all provinces. In Ontario, according to the Great Toronto Rehab Network, the IR intensity is about 15-30 mins of therapy, 3x/day to 3 hours/day for 7 days/week, based on patient's tolerance. Additionally, a recent study revealed that age, behavior, cognitive abilities, endurance, medical status, improvement in acute care, pre/post-injury functional status, patient and family expectations are the main factors that affect occupational therapists' perception of brain injury patients' potential to be referred to rehabilitation facility (38).

Review of the literature reveals that some attention has been given to comparisons of health care systems between developed nations (25, 39). The WHO has marked an international collaboration to gather data on patients with disabilities as one of the core objectives of their global action plan for 2014-2021, focusing on strengthening rehabilitation programs for this population (40). However, there are few comparison studies on rehabilitation delivery in developed countries for patients with neurological impairments, particularly patients with TBI. For instance, McNaughton et al. has compared rehabilitation services for patients with stroke between New Zealand and the US. They found that US patients had a shorter RLoS and better outcomes at discharge and received more intensive therapy from OTs and PTs (41). In another study, Hart et al. conducted an international investigation of the differences in RLoS and intensity of therapy between Denmark and the US. They found that Danish facilities provided a longer RLoS and more functional and emotional treatments during the first year after TBI. Although Danish patients experienced a greater level of functional impairment at admission compared to US patients, there was no significant difference between patients in these countries with respect to discharge functional and emotional outcomes after controlling for baseline factors (42).

The Lancet Commission in their recent report on the importance of clinical management and research strategy reported the lack of availability of consistent strong evidence in rehabilitation therapies due to the limitation of Randomized Controlled Trial (RCT) methodology in the field of rehabilitation. Therefore, international collaboration studies were recommended using the Comparative Effectiveness Research (CER) based methodology to capture the diversity of TBI and system of care, and to enable assessment of therapies in real world conditions (1). They indicated that high quality non-randomized and observational studies could be as valuable as RCTs. They can mitigate the limitation of RCTs' generalizability while providing valuable practical information in combination with the CER methodology (1). CER is "the generation and synthesis of evidence to compare the advantages and disadvantages of different approaches in delivery of care, diagnosis, monitor and treat clinical conditions" (1). Horn et al, has introduced a methodology known as the Practice-Based Evidence (PBE) for Clinical Practice Improvement (CPI) methodology (PBE-CPI) as a sophisticated research method for CER (43). They defined the PBI-CPI as a type of observational study that includes all patients, treatment process/content, and outcome variables from heterogeneous practice settings (43, 44). Results of PBE-CPI studies can be used to evaluate existing treatments and develop evidence, based on clinical data (43).

1.2.1.1 Research Gaps

Comparing the process and content of health care delivery continues to be of great interest in both Canada and the US, considering similarities and differences in cultural values while using a client-centered approach. Horn et al. in 2015 used the PBE methodology to collect comprehensive information from patients with TBI who were admitted to 10 IR facilities (1 from CA and 9 from the US). While they derived a large amount of data on the profile of patients with TBI and content of IR, they did not compare characteristics and treatments between Canadian and US patients (45, 46).

Chapter 2 of this thesis addresses this research gap by comparing the process and content of IR between patients who were admitted to Canadian and US facilities by focusing on: 1) demographic characteristics, 2) clinical features, 3) treatments, and 4) cognitive and motor scores at discharge, three- and nine-months post-discharge using data that were collected via PBE methodology.

1.3 Short-Term Functional Outcomes and Therapeutic Factors

1.3.1 Intensity of Rehabilitation and Short-Term Functional Outcomes

General effectiveness of rehabilitation has been shown in a large number of studies (47-52). Further, many prognostic studies have aimed to describe the mechanism of successful rehabilitation by exploring the influence of demographic and clinical factors on functional outcomes in patients with moderate to severe TBI. Results of these studies have shown that age (45, 49, 52, 53), race/ethnicity (45), sex (45), education (54) were the most studied demographic variables that were associated with IR discharge cognitive scores (55, 56). Among clinical and injury related factors, severity of injury (45), comorbidities (45), PTA (57), admission cognitive function (45, 52), onset-admission interval (52), insurance payer (45), LoS (52) were predictors of cognitive outcome. Almost all these studies applied the cognitive component of the Functional Independence Measure (FIM™) to explore the association of these factors with cognitive outcome.

Prior literature has also revealed that motor function is influenced by demographic determinants such as age (45, 49, 52, 53), and race/ethnicity (45, 58). Further, days from injury to rehabilitation admission (45), severity of injury (53), presence of comorbidities (45), admission motor function (52), LoS (52), and insurance status (58) were recognized as clinical factors that contribute to the variation in motor outcomes. The majority of these studies used the motor component of the FIM to assess the predictive value of these factors.

Studies that utilized a holistic approach to assess the level of function in this population revealed that PTA (48, 59), early admission to rehabilitation (48, 60), RLoS (48, 61, 62) and existing comorbidities (48) were significant predictors of functional level in these patients. These studies used total FIM scores (48, 59), the Disability Rating Scale (DRS) (48, 59, 60), the Supervision Rating Scale (60), and the Community Integration Questionnaire (60) as outcome measures.

Although some attention has been given to the correlation of functional outcomes with rehabilitation intensity, evidence is still sparse in this field and results are inconsistent in the use of definitions for rehabilitation intensity (62-66). Studies that defined intensity as total therapy time concluded that patients who received more intensive therapy were more likely to achieve a greater level of function (62-66). Sheil et al. examined the effect of increased intensity of rehabilitation therapy provided to patients with moderate to severe TBI. They found that receiving more intensive therapy (580 minutes per week vs. 402 minutes per week), facilitated more rapid acquisition of independence and reduced LoS (56 days vs. 84 days)(64). In another study, Peiris et al. investigated the influence of receiving more therapy time on functional outcomes in patients with neurological impairments who received additional Saturday rehabilitation (6 days a week, about 60 minutes more time of rehabilitation per week) versus a routine program (with 5 days a week) using RCT methodology. They revealed that the intervention group who received more therapy time showed higher improvements in FIM scores at discharge with a shorter LoS by 2 days (62). However, these studies did not control the effect some factors such as motivation or patient admission function.

Few studies examined the association of therapy intensity by rehabilitation disciplines for patients with moderate to severe TBI and their results were not consistent. Heinemann et al. studied the intensity of OT, PT, SLP, and psychological interventions (total hours) and concluded that while intensity of psychological services may affect cognitive function, intensity of other disciplines did not make significant variation in cognitive and motor function after controlling for demographic and clinical factors (67). In another study, Cifu et al. indicated that lower intensity of PT, and SLP interventions (total hours per day) could influence motor function but not cognitive function (68). Zhu et al. indicated that more intensive rehabilitation in OT and PT (2 hours per day versus 1 hour per day) may speed-up recovery at 6 months post-discharge (69). A study on patients with TBI who were treated in US-IR facilities, demonstrated that discharge functional outcomes were influenced by receiving more time of complex activities in

OT, PT, and SLP sessions (minutes per RLoS /7 days) controlling for patients characteristics, clinical factors, and variety of rehabilitation centers (45). A recent systematic review on the effects of timing and intensity of neurorehabilitation on functional outcomes following TBI concluded that an earlier onset rehabilitation program and receiving more intensive rehabilitation (at least 20 hours per week) have positive effects on cognitive and motor outcomes (66).

1.3.2 Patient Involvement in the Process of Rehabilitation and Short-Term Functional Outcomes

In addition to the intensity of interventions, one of the important non-medical factors that needs to be considered in the process of rehabilitation, is patient's potential to participate in their process of care (1). While numerous researchers have focused on predisposing factors such as demographic and clinical features and outcomes from rehabilitation, capturing the process factors such as patients' engagement or participation that contribute to rehabilitation failure or success has been more challenging (70). Patients' involvement in the process of rehabilitation has been measured using overlapping concepts such as engagement, participation, motivation, and effort (71-73).

In the International Classification of Functioning, Disability and Health (ICF), activities and participation are considered as one of the main sub-domains of this framework. The ICF defines participation as "involvement in a life situation" or as "the lived experience" of people in the actual context in which they live, while the activity is defined as "the execution of a task or action by an individual" (74). The ICF is criticized widely due to the lack of considering subjective experience or satisfaction in defining "participation" (75, 76). Further, in the ICF, the activity and participation components are presented in a single list (74, 75). A systematic review on the concept of engagement in health care and rehabilitation considered engagement to be more than simply patient's participation (77). They defined engagement as an active commitment, enthusiasm, energy and effort (77) which is a process that starts from tolerating treatments to participating in therapeutic sessions (77). Patient's involvement in the process of rehabilitation of assessment, goal planning, and interventions is a core value of the client-centered approach (78) and this approach allows patients to actively participate in their own care (78). Interest in assessing such process variables has continued over time to identify elements that facilitate participation in rehabilitation. The advantage of patient's engagement in the rehabilitation process has been explored in more qualitative and experimental studies while considering patients' participation in the process of assessments and goal setting in different populations (71, 78-81). For example, a study that explored the effect of level of engagement of patients with neurological impairment on rehabilitation outcomes by using goal engagement, goal satisfaction, and goal attainment scaling showed that functional gains can be improved by a higher level of patient engagement in planning the goals of rehabilitation (80). A systematic review study revealed that a lack of motivation is a common problem that leads to disengagement from rehabilitation (78). Seel et al. found that PTA and agitated behavior are primary risk factors that substantially reduce patient effort in therapy sessions in patients with TBI by using the Rehabilitation Intensity of Therapy Scale (RITS) (71). However, fewer numbers of prognostic studies have investigated the independent effect of the level of effort on rehabilitation outcomes particularly in patients with TBI who were treated in Canadian centers. A recent attempt to examine the effect of the level of patient's effort in therapy sessions on functional outcomes showed that this variable was significantly associated with better cognitive and motor outcomes in patients who were treated in US facilities (45). This study also used the RITS to assess patients' involvement in the rehabilitation therapy session (45).

1.3.3 Research Gaps

The sequelae of TBI have been addressed with the multidisciplinary rehabilitation approach (82-85). However, the matrix of interventions/activities that occur within each rehabilitation discipline and their effects on functional outcomes at discharge from rehabilitation is elusive, particularly in a Canadian context. Most of the recently developed clinical guidelines for patients with TBI have been based on non-Canadian data (86-89), while it is recognized that the process of care can be affected by variety of health care practices in various jurisdictions (25).

Most of the existing evidence did not examine the independent contribution of treatments because of the complexity of some factors such as the degree of impairment and the scope of clinical practice (42, 62-65). Therefore, rehabilitation service provision for this population could not be compared between these studies. A recent systematic review of RCT studies on timing and intensity of rehabilitation demonstrated that intensive rehabilitation for at least 20 hours of therapy per week (4 to 5 therapy hours per day, weekends not included) improves outcomes in patients with TBI (66). However, they did not take into account the variation of RLoS in calculating intensity (66) as well as the content of rehabilitation activities that were provided by each discipline (66). Additionally, the impact of patients' involvement in the therapy session on functional outcomes in this population was not explored particularly for patients who were admitted to Canadian facilities.

Chapter 3 of this thesis bridges these knowledge gaps by (1) exploring the content of OT and PT activities considering their complexity, and influence of IR on cognitive and motor outcomes, and (2) investigating the predictive value of IR therapeutic factors (intensity of OT and PT activities and patient the level of effort) in explaining cognitive and motor function at IR discharge in patients with TBI who were treated in a Canadian facility.

1.4 Long-Term Functional Outcomes

1.4.1 Functional Recovery Following Traumatic Brain Injury

TBI presents a great challenge to the health care system with long-term devastating consequence and residual impairments. Previous literature demonstrates that the pattern of recovery has been studied widely in patients with moderate to severe TBI (90-96).

Several studies focused on the functional recovery in this population regardless of the influence of IR (90-93). However, other studies investigated the pathway of functional recovery on patients who received IR (94-96). Additionally, change in recovery was investigated at various time lines. Studies that focused on early recovery, considered a time period of approximately 3 to 12 months (36, 97-101), while others investigated the change of function over a longer course of time post-TBI (91, 92, 102-107). Of these studies, some of them took a general approach and focused on overall function (93, 95, 99, 102, 107-109) using the FIM, Glasgow Outcome Scale (GOS), and the Mayo Portland Adaptability Inventory (MPAI), DRS (106, 110), Functional Assessment Measure (FAM) (106, 110), and physical examination variable rating system (111). However, other studies explored more detailed information by considering the cognitive (94, 100, 112, 113) and motor (36, 49, 112, 114) components of function such as the neuropsychological battery, cognitive and motor components of the FIM (106, 108) and concrete measures of a single area of function such as the Activity of Daily Living (ADL) scale and driving (115).

For instance, an observational study that investigated the course of cognitive recovery using the cognitive components of the FIM and the Montreal Cognitive Assessment (MoCA) demonstrated that patients with acquired brain injury who received 3 weeks of IR had a significant improvement from admission to discharge on both measurements. At three months post-discharge, patients maintained their cognitive scores on the MoCA and their cognitive scores improved significantly as measured by the FIM (112).

Christensen et al. found that cognitive recovery in the first year is not consistent with more recovery occurring during 5 to 6 months post-injury and no significant variation over the latter part of the first year using neuropsychological assessments at 2, 5 and 12 months post-injury (100). Also, patterns of recovery were not uniform across cognitive domains with steeper recovery in memory, executive function, and verbal abstraction (100).

Another study by León- Carrión et al. showed that the course of cognitive recovery in 19 patients with TBI who received rehabilitation for 6 months (4 days a week for 4 hours) was not linear when comparing the sub-domains of cognition from admission to discharge. Results revealed that long-term memory, orientation and planning differed in terms of the amount of time that was needed to achieve recovery (101).

Very few studies focused on the course of motor recovery up to one-year post-injury considering the influence of IR (108, 111). These studies mostly focused on the overall functional recovery during a longer course of time (90, 102, 106, 115, 116). A study of patients with moderate to severe TBI who received 3 weeks of rehabilitation demonstrated significant motor recovery from IR admission to discharge but no significant variation was reported after discharge using the motor component of the FIM (108). Another study that focused on the sub-scale of physical function using the Traumatic Brain Injury Model System (TBIMS) physical examination variable rating system revealed that standing balance impairment was more common at IR admission and at 1-year follow-up compared to other physical skills impairment. While sitting balance impairments, muscle weakness and dysphagia mostly decreased by 1 year, impaired limbs were persistent for 1 year compared to coordination and tone, but was normal in the majority of the sample at 1 year (111).

Haller et al. conducted a comparison study on the course of disability between geriatric and non-geriatric patients with severe TBI at 3, 6, and 12 months post-injury using the Glasgow Coma

Scale-Extended (GCS-E). Findings showed that while the non-geriatric group's function improved from 3 to 6 months, the geriatric groups did not show significant improvement. However, the number in the samples were different at each time point, which may indicate that they did not look at the same population at various time intervals (117). Finally, a review study of motor recovery in patients with TBI indicated that motor impairments following TBI have a lower incidence and less severity with a better prognosis compared to cognitive deficits (114). They also concluded that very few studies explored the course of recovery of motor function (114). However, this systematic review did not compare studies by the outcome measures that they used to assess motor function.

1.4.2 Intensity of Rehabilitation and Long-term Functional Outcomes

The long-term prognosis of TBI has been studied widely, taking various factors into consideration. Literature indicates that studies on predictors of long-term outcomes after IR following TBI fall broadly in two major categories; pre-injury/demographic characteristics, and clinical features. Some studies have taken a more holistic approach to define outcome such as level of disability (118) or level of independence in function (56, 119-121). However, other studies have narrowed the focus of outcome by exploring predictors of cognitive function (36, 45, 49, 98), motor/physical ability (45, 49), psychosocial skills (122), behavioral and emotional changes and productivity or return to work (118).

The base line of long-term outcomes was defined differently in various studies. Less evidence focused on 5 to 12 months follow-up, and more literature investigated predictors of longer-term follow-up times from 2 to 30 years post-injury due to a higher rate of decreasing patient function long after injury (98, 102, 106). Studies that focused on cognitive outcomes 5 to 12 months post-injury, indicated that among demographic and clinical factors, age (36, 45, 49, 98), race (36), education (45, 56), public insurance (36), comorbid conditions (36, 56), time from injury to rehabilitation admission (36, 56), pre-injury psychiatric disorders (123), and PTA duration (113, 123) were associated with cognitive functional outcomes in patients with moderate to severe TBI.

Studies that explored predictors of motor function within the same timeframe, revealed that among demographic and clinical features, age (36, 45, 49), sex (male) (45), race (36), public insurance coverage (36, 45), comorbid conditions (36, 45), open head injury (36) and time from injury to rehabilitation admission (36, 45) were significantly associated with motor function. Studies that targeted outcome of total function between 6 to 12 months post-injury showed that age (118, 120), education (120), race (124), pre-injury employment status (48, 118), pre-injury substance abuse (118), PTA (48, 56, 120), functional status at admission to rehabilitation (48), functional status at discharge from rehabilitation (118), early admission to rehabilitation (119), fatigue (56), inter-cranial pathology (56), comorbid conditions (48), and geriatric consultation (121) were significant predictors of function. These studies mostly focus on patients who had follow-up data available and did not compare the drop-out and follow-up patients that may introduce the selection bias.

Most of the studies utilized RCT and experimental methodology to investigate the effect of early versus late rehabilitation admission or intensive versus non-intensive program on long-term functional outcomes. However, there is a paucity of research investigating the predictive value of rehabilitation treatments to explain the variation in post-discharge rehabilitation outcomes in patients who were treated in a Canadian rehabilitation context.

Zhu et al. compared patients who received intensive therapy (4 hours/day for 5 days) against non-intensive therapy (2 hours/day for 5 days) using RCT methodology (69). Their findings revealed that more intensive therapy resulted in better outcomes at 6 months post-discharge. However, patients in both groups did not show significant variation in recovery from 6 to 12 months post-injury. They suggested that this was due to the control group catching-up to the intervention group as opposed to a lack of effect in the intervention group (69). They concluded that intensive rehabilitation contributed to accelerating recovery rather than changing the eventual functional outcome (69). Andelic et al. found that early admission to rehabilitation (12 days after injury) and receiving continuous rehabilitation led to better functional outcomes at 12 months post-injury on DRS and GOSE measurements than late admission (39 days). Additionally, patients who were admitted early experienced a shorter RLoS (29 days shorter) (119).

Till et al. investigated the contribution of different factors on cognitive decline by comparing a declined versus non- declined patients in a Canadian facility. They reported a positive correlation of total hours of therapy at 5 months post-injury (including acute care, impatient and outpatient rehabilitation) in those with less cognitive decline from 1 to 5 years post-injury in this population (94). However, they did not use robust methodology to control for the effects of other covariates. Furthermore, the type of therapy that patients received during the 5 months post-discharge was not reported in their study. Additionally, no explanation was provided on patients who received outpatient rehabilitation that may introduce the selection bias.

Horn et al. evaluated the association of demographic and clinical factors as well as the intensity of rehabilitation with functional outcomes at nine months post-discharge in patients who were treated in nine US facilities (45). They demonstrated that the total therapy time per week for each specific discipline (OT, PT, SLP, psychological and recreational therapy) had a small amount of explanatory power (about 5%) beyond that found for demographic and clinical characteristics. However, adding the intensity of specific activities in each discipline, increased the contribution of the explanatory power significantly to about 11% compared with demographic and clinical features characteristic alone (45). As stated above, very few studies investigated the influence of intensity by considering RLoS on long-term functional outcomes.

1.4.3 Patient Involvement in the Process of Rehabilitation and Long-Term Functional Outcomes

While the benefit of patient engagement in the process of rehabilitation has been widely discussed, less attention has been given to the possible long-lasting effect of direct involvement of the patient in rehabilitation therapy. A study of the role of patient engagement in OT and PT sessions showed that level of motivation is a factor that helps them be actively involved in the process of care (125). Also, pain, anxiety and depression were found to be the main factors influencing the level of participation long-term after TBI (126). In another study, Seel et al. found that age, presence of comorbidities, days from injury to rehabilitation, agitated behavior, and severity of injury were associated with level of patient effort in process of IR (71). However, the long-lasting effect of active patient engagement in the process of rehabilitation has been less studied while controlling for basic and injury related factors.

Horn et al. in 2015 demonstrated that patient the level of effort during the therapy session was significantly associated with the FIM cognitive and motor scores at nine months post-discharge in patients who were treated in the American facilities (45). However, the variability of health system delivery, treatments protocol, and facility factors may affect patient's engagement differently. As stated above, comparing the health care system in Canada and US showed that the process of admission to IR differs between these two countries with respect to insurance policies and process of care (25, 127). Thus, investigating the association of process variables such as level of patient engagement with long-term outcomes in patients who are treated in the Canadian facilities is necessary.

1.4.4 Post-Discharge Situations and Long-Term Functional Outcomes

A large number of studies have focused on the long-term consequences of chronic conditions after TBI particularly with respect to cognitive impairments (128), physical and psychological comorbidities (129). Brandel et al. indicated that neuro-psychiatric sequelae of TBI are very common with patients having two or more comorbid psychiatric disorders in the first year post-injury (130). A systematic review by Fann et al. showed that depression is debilitating symptom that patients with TBI experienced in chronic phase of TBI (131). Another systematic review assessed the link between structural brain damage and chronic functional impairment in this population (132). This study considered the temporal progression of tissue damage with long-lasting pathological cascades as the main reason of chronic disability in this population (132).

Sleep disorders such as sleep apnea, insomnia, and fatigue are considered to be common chronic conditions after TBI (133). A recent study on patients with TBI showed that comorbid conditions are more common in older adults than patients who are younger or middle aged (134). While younger patients suffer mainly from multiple injuries and trauma, older patients are more likely to have mental health conditions, and nervous system disorders, circulatory, endocrine, nutritional, metabolic, and immune disorders (134).

Studies that focused on the epidemiology of different types of comorbidities identified demographic and clinical characteristics of these patients and the effect of comorbid conditions on the rate of mortality in this population (134, 135). Additionally, some studies examined the influence of comorbidities on outcomes in these patients over their course of recovery (136, 137). For instance, Haagsma et al. in 2015 investigated the influence of depression and post-traumatic stress disorder (PTSD) on outcome at 6- and 12-months post-injury in patients with mild TBI using Glasgow Outcome Scale (GOS). They concluded that severity of depression and PTSD were significantly associated with decreasing outcomes at both time periods (136). Another study by Gardizi et al. on patients with mild to severe TBI revealed that US patients with higher self-reported medical comorbidities were more likely to experience higher level of disabilities as measured by the DRS (137). However, there is a paucity of evidence that investigates the prolonged influence of post-IR discharge health issues on the motor and cognitive components of functional outcomes in the TBI population.

In addition to comorbidities, readmission to hospital and ED due to chronic disability and inadequate post-discharge care has been considered an increasing concern in North America. A recent estimate showed a readmission rate to acute care of about 17% -20% at 1 year in Canada for patients with TBI (138). While numerous studies focused on predictors of rehospitalization after acute care or rehabilitation by focusing on patients and injury characteristics (139-141), less attention has been given to the predictive value of readmission to ED to explain the variation in long-term cognitive and motor outcomes in patients with TBI. The frequency of readmission to hospital or ED can be a proxy of the amount of residual disability and insufficient treatment, or the lack of therapeutic consultation and education after discharge from IR. Therefore, more attention needs to be given to the influence of this factor on functional outcomes in this population.

Another important post-discharge factor is the level of support that patients receive from family and society. Following TBI, many patients experience changes in their social life, while dealing with long-term challenges of disability, and describe it as "a feeling of disconnected" from life (142). A prior study showed that living alone was associated with severity of depression and increasing the risk of suicide in this population (136). Also, prior studies showed that patients with TBI experience higher levels of familial distress, marital strain, and relationship dissatisfaction (143-145). However, fewer studies have focused on patient living situation after injury and level of support that patients received from family and community resources after discharge from rehabilitation. Investigating the association of patient living situation with long-term outcomes in this population will provide valuable information for patients, their families, and clinicians who provide therapy services in long-term institutions or community-based rehabilitation settings.

1.4.5 Research Gaps

The majority of studies on long-term recovery of cognitive and motor function over time typically considered two time points to assess the improvement of patients (90, 106-108). It has been noted that using only 2 time points makes the distinction of functional changes impossible during longer time (100, 146). Further, among the studies that targeted the influence of IR over time, they did not include patients with all data available from IR admission to time of follow-up that may introduce a selection/attrition bias (147).

Numerous studies have investigated the predictive value of pre-injury factors, demographic characteristics, and clinical features on long-term functional outcomes. However, few studies have investigated the predictive value of the intensity of activities in IR, patient tolerance/effort exerted during rehabilitation therapy sessions to explain the variation in cognitive and motor outcomes at about 1-year post-injury in patients with TBI who were treated in a Canadian facility.

Additionally, while more attention has been given to predictors of re-hospitalization after acute care or rehabilitation discharge as well as patient level of support following their rehabilitation plans, few studies have investigated the contribution of the number of readmissions to ED after discharge from rehabilitation and the level of support that patients received from family and community on long-term cognitive and motor outcomes after discharge.

Chapter 4 of this thesis will address these research gaps by: (1) exploring the influence of IR on temporal recovery of cognitive and motor focusing at 4 time points (admission, discharge, three- and nine-months post-discharge), and (2) investigating the contribution of therapeutic activity and post-discharge conditions to explain the variation in cognitive and motor function at nine months post-discharge from IR.

1.5 Main Research Objectives

While the sequelae of TBI are addressed using a rehabilitation approach, the content and process of IR and its' effects on short and long-term functional outcomes are elusive, particularly in patients who are treated in Canadian rehabilitation facilities. As such, the main goal of this thesis is to address this research gap to advance the knowledge on specific components of IR in a Canadian facility through these objectives:

1. Compare demographic characteristics, clinical features, treatments, and outcomes at discharge, three- and nine-months post- discharge using the TBI- PBE dataset between patients with TBI who were treated in one Canadian and nine US-IR facilities (Chapter 2, study I);

Based on previous studies, our first hypothesis was that both groups would be similar with respect to demographic characteristics based on prior population-based studies on TBI patients in North America. The second hypothesis was that Canadian patients may have fewer comorbidities and better function at admission to IR, given a longer duration of acute care in Canada. The third hypothesis was that patients in the Canadian facility may receive more therapy time from three main disciplines (OT, PT, and SLP) in total. However, US patients would receive more intensity of therapy from each discipline per week according to Medicare 3-hour rule per day. Finally, we hypothesized that Canadian patients would achieve better function at discharge and post-discharge, and most patients from both sides of the border would be discharged to home after IR.

2. Explore the content of OT and PT activities based on their complexity, and influence of IR on cognitive and motor outcomes in patients with TBI who were treated in a Canadian facility, and to investigate the predictive value of IR therapeutic factors (intensity of OT and PT activities and patients the level of effort) in explaining cognitive and motor function at IR discharge in this population (Chapter 3, study II).

   Based on previous research findings, our hypotheses were 1) IR would improve both cognitive and motor outcomes significantly; 2) level of effort and more complex activities would be associated significantly with better cognitive and motor scores at IR discharge after controlling for other factors.

3. Investigate the cognitive and motor recovery at 4 time points including admission, discharge, three and nine months post-discharge, and examine the predictive value of therapeutic factors and post-discharge conditions to explain the variation of cognitive and motor outcomes at nine months post-discharge, controlling for demographic and clinical characteristics in patients with TBI who were treated in a Canadian -IR facility (Chapter 4, study III).

   Based on previous research findings, our hypotheses were 1) IR gains would be maintained from discharge to three months post-IR discharge for both cognitive and motor scores but would not continue from three to nine months post-IR discharge, 2) while patterns of improvement may be similar for males and females, their functional recovery will be different following discharge from IR, and 3) more complex activities and fewer post-discharge conditions would be associated significantly with better cognitive and motor scores at nine months post-IR discharge after controlling for other factors.

1.6 Methodology

1.6.1 Data Source

For this thesis, data were obtained from the TBI- PBE dataset. These data were collected from 10 IR facilities from October 2008 to August 2011; one Canadian site from Toronto-Ontario and nine other facilities from the US that were located in various states (Table 1).

Table 1.1. Participating rehabilitation centers in the TBI-PBE study

Rehab centers	**Location**
Wexner Medical Center	Columbus, OH
Carolinas Rehabilitation, Carolinas Health Care System	Charlotte, NC
Mount Sinai Medical Center	New York, NY
National Rehabilitation Hospital	Washington, DC
Shepherd Center	Atlanta, GA
Intermountain Medical Center	Salt Lake City, UT
Rush University Medical Center	Chicago, IL
Brooks Rehabilitation Hospital	Jacksonville, FL
Loma Linda University Rehabilitation	Loma Linda, CA
Toronto Rehabilitation Institute	Toronto, ON, Canada

These data were gathered using the PBE methodology. The goal of this methodology is to "produce useful information on comparative effectiveness of treatments for specified types of patients and reduce un-certainty for clinician decision makers". The PBE studies are observational cohort studies that attempt to mitigate the gap of traditional observational studies by considering patients' characteristics to address confounders; using large samples to improve sample representativeness, power, external validity, and inclusion of clinicians in the design and application of studies to improve ecological validity (148).

The PBE project included data on patients' profile, clinical characteristics, interventions that patients were received in each session from rehabilitation disciplines; physical medicine and rehabilitation, nursing, PT, OT, SLP, recreational therapy (only in US sites), social work

(SW)/case management (CM), neuropsychology (only in US sites), and outcomes at discharge and three and nine months post-discharge (e.g., function, life satisfaction) (148).

For gathering these data, front-line clinicians developed a TBI auxiliary data module to capture detailed information on patients, process, and outcomes from patient's medical records. Also, they participated in an interactive process to elucidate components of care in each discipline (46). Data abstractors at each center were trained to gather these data using web-based software system. These staff attended specific practice training sessions for 4 days. After training, weekly conference calls were used to address any issues with respect to process of chart review. Reliability monitoring was conducted for abstractors after their first 4 charts were completed and again after 25 charts. Afterwards, reliability testing occurred periodically throughout the years when data were being collected by reliability staffs. A 95% agreement rate between the abstractor and the reliability staff was required for each reliability test. Re-training was performed in the case of lack of 95% agreement. Follow-up data were gathered through telephone call interview of patients or their substitute decision makers at three and nine months post-discharge by trained research and clinical staff (46).

1.6.2 Population

A total of 2120 patients who sustained TBI and were consecutively admitted to 10 rehabilitation centers, 1 in Canada (n=149) and 9 in US (n=1971) participated in the TBI-PBE study. A TBI in the PBE project was defined as damage to brain tissue caused by external force and evidenced by loss of consciousness, PTA, skull fracture, or objective neurological findings (46). In addition to the clinical diagnosis, patients with TBI in the PBE project were recognized by the International Classification of Diseases, Ninth Revision (ICD 9th), and Clinical Modification code consistent with the Centers for Disease Control and Prevention Guidelines for Surveillance of Central Nervous System Injury who received their first IR care in the designed adult brain injury unit (46) (please see Appendix A for ICD codes).

1.6.2.1 Population for Study (I)

For the purpose of the first study (chapter 2), patients were stratified into three sub-groups based on their admission FIM cognitive score; ≤15, 16-20 and ≥21. According to the previous articles on the methodology of the TBI-PBE project, admission FIM cognitive score was recognized as a reliable criteria to stratify patients (43). Because of the small sample size of the first (n=20) and second (n=26) cognitive sub-groups in the Canadian site, a comparison was only conducted between patients with a higher level of admission FIM cognitive score (≥21). The final sample for this study was 504 patients in total (Canada, n=103 and the US, n=401). Long-term post-discharge outcomes were reported on patients who had data available at nine months post-discharge (Canada, n=73, the US, n=285). The reliability and validity of functional assessment via telephone interviews for follow-up study has been established (149).

1.6.2.2 Population for Study (II)

In the second study (chapter II), only patients who were treated in the Canadian facility were included in the analyses (n=149).

1.6.2.3 Population for Study (III)

For the purpose of this study, only patients from the Canadian site who had data available from admission to nine months post-discharge were included in the final analysis (n=85) to reduce the selection bias.

1.6.3 Variables

This section lists all of the variables that were used in this thesis and were obtained from the TBI-PBE dataset. It should be noted that for categorical variables, missing data were reported as a separate category. Additionally, related categories for some variables were merged to provide more reasonable analyses.

1.6.3.1 Demographic and Pre-Injury Variables

Demographic characteristics that were used in this thesis included age, sex, race, marital status, educational status, employment status. Pre-injury features comprised of pre-injury driving ability, pre-injury independence status ,and pre-injury living situation.

1. *Age* was reported as a continuous varible for all three sudies in this thesis.
2. *Sex* was noted as a dichotomous variable in the sample of each study.

3. *Race/ethnicity* was categorized into four main groups based on availability of data; White/Caucasian, Black/African, Asians (Chinese, Filipino, Japanese, Korean, South Asian, South/ East Asian), and others (first Nations/Indigenous, Native Hawaiian/Pacific Islander, American Indian/Alaska Native, Arab/West Asian, Latino).
4. *Marital status* was reported in three main categories; Single (never married), married/ common-law, previously married (widowed, separated, divorced).
5. Educational status was categorized in two main categories: Bachelor's degree or higher education and college/associated degree or lower degree.
6. *Employment status* was reported in four groups; employed (full or part-time job), unempoloyed (no income), retired and sudent.
7. *Pre-injury driving* was reported using two categories "yes" and "no".
8. *Pre-injury independence* was reported with two main categories; activities of daily living and ambulation ability. Patients were identified as independent if they did not need any assistance to complete their daily routines or to walk.
9. *Pre-injury living situation* was categorized in two groups; home or apartment/private residence, and other (e.g., long-term care, SNFs, other institutes).

1.6.3.2 Clinical Variables

1. *Mechanism of injury* was categorized in four main groups; Motor Vehicle Collision (MVC), falls, violence, and miscellaneous/other.
2. *Days from injury to IR admission* is the number of days between acute care admission and IR admission. This variable was reported as a continuous variable.
3. *Rehabilitation LoS* was the number of days between IR admission and discharge which excluded days spent out of the rehabilitation facility for readmission to acute care.
4. *Severity of injury* was reported based on GCS score in three categories; severe (3-8), modrate (9-12), and mild (13-15).
5. *Severity of illness/comorbidities* was described using modified Comprehensive Severity Index (CSI®) that included brain and non-brain components (46). Severity in CSI was defined as both the physiologic and psychologic complexity (46, 150). The brain component was the amount of intracranial bleeding, amount of compression, hydrocephalus, and pupillary reaction (46). Any other symptoms were assumed to be

non-brain CSI (46) which has been validated extensively in IR and long-term care studies (43, 150, 151). In this thesis, the total CSI score was reported at admission (at the first 72 hours of admission), and discharge (72 hours before discharge). Higher scores represented a higher severity of injury.

6. *Pre/co-morbidities* in this dataset included medical and psychologic disorders that patients experienced before or at time of injury such as using alcohol and drugs, anxiety, depression, cornary artety disease, diabetes, hyper tension, renal failure, and previous brain injury.
7. *Insurance status* was reported in two main categories: primary and secondary insurance payers. A primary insurance payer is defined as public insurance that includes Medicare and Medicaid in US and centralized provincial government in Canada. *Secondary insurance* payers included any private or supplemental insurance such as worker's compensation, self-pay, no-fault auto, Managed Care Organization (MCO) (in the US only), and Health Management Organization (HMO) (in the US only).

1.6.3.3 Therapeutic Variables

1. *Rehabilitation discipline activities* included information on OT, PT, SLP, SW/CM, recreational therapy, and neuropsychological activities collected using point of care forms in the TBI-PBE project (43). It should be noted that no data were available on recreational and neuropsychological therapy in the Canadian site, as these services were not provided in a Canadian facility at the time of data collection. In the first study, this information was reported on OT, PT, SLP, and SW/CM activities that were categorized into smaller groups based on their function. For study II and III, activities were merged into basic and advanced groups based on their complexity and only reported for OT and PT activities. Data on SLP and SW/CM activities were not included in the second and third studies due to the lack of sufficient data to conduct regression analyses in particular. To calculate therapy intensity in each discipline by minute per week, total therapy minutes of activities were divided by (rehabilitation LoS/7 days). No distinction was made between services provided on weekends and week days. Activities in each discipline as well as basic and advanced activities were reported in the Appendix B and C, respectively.

2. *Medication data* were reported on medications that patients received during IR considering the viability of data. These medications included narcotic analgesics, non-narcotic analgesics, anti-cholinergics, anticoagulants, anti-convulsants, anti-depressants, trazodone, and ulcer drugs.

3. *Level of effort* was measured using the Rehabilitation Intensity of Therapy Scale (RITS). This measurement includes a single item that was ranked from 1 (absence of effort) to 7 (superior effort). This observable behavioral construct was rated weekly by trained clinicians during rehabilitation therapy sessions for each discipline (71). Effort is defined as "the use of physical or mental energy to do something" (71, 152). In the PBE project, effort is operationally defined as "being attentive and engaged in goal-directed activity, including initiating activity, incorporating therapist feedback, and persevering when therapies become challenging" (71). The reliability and validity of this scale is established in the rehabilitation setting (71, 152). For the purpose of this thesis, the average of the level of effort during OT and PT sessions was used in the second and third studies.

1.6.3.4 Post- Discharge Variables

All post-discharge information was gathered through telephone from patients or families.

1. *The* N*umber of referrals to ED* was reported in to two categories (≥ 2 times and ≤ 1 time) to inform the number of admissions to ED after discharge from rehabilitation.

2. *The Number of health issues post-discharge* was reported based on a list of 22 health issues in the PBE follow-up study that included both physical and mental health conditions in which patients received medical attention post-discharge (Appendix D). This variable was reported in two categories: ≥ 1 issue and no health issue.

3. *The Living situation* was reported in two groups: alone and not alone (living with spouse, parent(s), sibling, child ≥ 21/other relative, roommate/friend, significant other, other patients, other residents, personal care attendant, other or unknown).

1.6.3.5 Outcome Measures

Different outcome measures were used for the three studies that are presented in this thesis and based on the objectives:

1. The cognitive and motor components of the FIM scores at admission (II) and discharge (II), three months (study III) and nine months (and III) post-discharge. The FIM includes an 18-item rating scale that assesses patients' level of independence (27, 28). Scores for each item range from 1 (total assistance) to 7 (complete independence). FIM motor is the summation of 13 items (score range 13-91) and FIM cognition is the summation of 5 items (score range 5-35) (153, 154). To provide internal level metric for both cognitive and motor scores and to address measurement error associated with summing of ordinal-level scores, the FIM-Rasch score was used instead of the FIM raw score in all three studies which ranged from 0 to 100 points (43, 155, 156).

2. Participation Assessment with the Recombined Tools-Objective (PART-O) at nine months post-discharge was used to capture community participation outside the home. It includes a 24-item scale with scores ranging from 0 to 5. Higher scores represent better function at the societal level (46, 157) (study I).

3. Life satisfaction was assessed using the Satisfaction with Life Scale (SWLS) at nine months post-discharge in the PBE dataset. This measurement includes 5 items with the average score ranging from 5 to 35, and higher scores representing greater satisfaction with life (46, 158, 159) (study I).

It should be noted that due to the descriptive methodology, study I does not have any primary outcomes and FIM scores, PART-O and SWLS are reported to compare function, level of social participation, and life satisfaction, respectively between patients in Canadian and US facilities.

1.6.4 Financial Support

The TBI-PBE project was supported by the National Institutes of Health, National Center for Medical Rehabilitation Research (grant no. 1R01HD050439-01); National Institute on Disability and Rehabilitation Research (grant no. H133A080023); and Ontario Neuro-trauma Foundation (grant no. 2007-ABI-ISIS-525). Sareh Zarshenas was supported by a Toronto Rehabilitation Institute Scholarship for graduate students (2016/17, 2017/18) and University of Toronto Fellowship (2014-2018).

1.6.5 Statistical Analysis

Data were analyzed using SAS 9.4. For the first study, the *p*-value was adjusted based on Bonferroni correction method and for the second and third study, the *p*-value of <0.05 with 95% confidence interval (CI) was considered statistically significant.

1.6.5.1 Study I

For the first study, categorical variables were analyzed using the Fisher Exact test or Chi-Square test. Continuous variables with approximately normal distributions were examined by t-test (Pooled-Standard test or Welsh-Satterthwaite test considering the equality of variance). Where possible, missing data were reported as a separate category. To counteract the problem of multiple comparisons, the Bonferroni correction method was used for each category of variables. This value is calculated by "α/number of comparisons" for each category of varaibles. Considering this formula, for demographic (n=16) and pre-injury (n=15) characteristics, the value of significance would be $p \leq 0.003$, for clinical factors, it would be $p \leq 0.007$(n=7), for total therapy time, itwould be $p \leq 0.001$(n=31), for OT activities, it would be $p \leq 0.003$ (n=14), for PT activities, it would be $p \leq 0.004$(n=12), for SLP activities, it would be $p \leq 0.003$(n=16), for SW/CM activities, it would be $p \leq 0.01$ (n=3), and for funcational scores this value would be $p \leq 0.005$ (n=9).

1.6.5.2 Study II

For the second study, descriptive results were reported using mean and standard deviation (SD) or median and inter quartile range (IQR) for continuous variables and frequency of categorical variables. The paired-t test was used to explore the effectiveness of the IR program on cognitive and motor function. Univariate linear regression was performed to identify factors that had a significant association with outcome measures. Multivariable linear regression was used to examine the independent influence of therapeutic factors on functional outcomes. Demographic and clinical factors were entered into the model in the first step as the known variables and therapeutic factors as the target variables in the last step, regardless of their significance value. Confounding factors (demographic and clinical factors) were chosen based on availability of variables in the dataset, results of univariate regression, and results of previous studies (31, 42, 59, 61, 87, 160).

1.6.5.3 Study III

Descriptive statistics were performed to examine the mean and standard deviation (SD) or median and inter quartile range (IQR) for continuous variables and frequency of categorical variables. To investigate the trajectories of recovery at 4 time points, mean group differences over time were analyzed using repeated measure analysis of variance (RM-ANOVA) and Bonferroni follow-up test to distinguish the significant differences between time periods. Follow-up sex-based analysis also was conducted on the functional recovery.

Univariate linear regression was used to identify factors that had a significant association with outcome measures at nine months post-discharge. Multivariable linear regression was performed to examine the independent association of therapeutic and post-discharge factors with long-term functional outcomes. Demographic and clinical factors were entered in the first step as the known confounding variables and therapeutic factors and post-discharge variables were entered in the last step regardless of their significance value as the target variables. Confounding factors (demographic and clinical features) were chosen based on potential clinical relevance, availability of variables in the dataset, results of univariate regression, and results of previous studies.

Multicollinearity was examined using Variance Inflation Factor (VIF>10). In the case of multicollinearity, one of a pair of variables was removed from the regression (e.g., admission/discharge cognitive and motor FIM-Rasch score) or if it was possible, two variables were combined (e.g., activity intensity and RLoS combined as minutes per LoS/7 days). Where possible, missing data were reported in a separate category for categorical variables and the final sample size was reported for each model. Values of R^2 and adjusted R^2 were used to capture the variation in outcome measures that was accounted for by the predictors in a linear regression. Confounding factors (demographic and clinical factors) were chosen based on the availability of variables in the dataset, results of univariate regression and results of previous studies. Also, using SAS Macro Programs and Microsoft Excel, R^2 change, and F-change value were calculated to differentiate the contribution of adding demographic, clinical, therapeutic, and post-discharge variables to the model.

1.6.6 Research Ethics Statement

Research ethics approval was obtained from the Toronto Rehabilitation Institute, University Health Network (Appendix E).

Chapter 2
Cross-Border Comparison of Inpatient Rehabilitation

2 Inpatient Rehabilitation for Patients with Traumatic Brain Injury: A Comparison of one Canadian and nine American Facilities

2.1 Introduction and Background

Traumatic brain injury is a critical public health problem and a major cause of death and disability globally (1). Patients with TBI are projected to have the greatest number of individuals experiencing severe disabilities by the year 2020 (2, 3, 11). The economic burden of TBI on families and society is very significant and is estimated to increase substantially in CA and the US (3, 8, 97, 161). Inpatient rehabilitation is one of the main approaches to care for patients with TBI to improve their independence in various aspects of life (17). The process of IR is based on an interdisciplinary collaborative approach in a hospital environment where patients receive continuous interventions from OT, PT, SLP, and physicians following medical stabilization (21, 31).

A recent review of previous studies showed that more attention has been given to the international comparison of health care systems (41, 42, 162-164). The World Health Organization has considered “collecting internationally comparable data on disability and related services” as one of the main objectives of the global disability action plan of 2014 to 2021 (40). However, there is little published evidence to compare components of IR between various health care systems in patients with TBI. A cross-national comparison study between Denmark and the US showed that Danish facilities provide longer RLoS and more functional and emotional treatments during the first year after TBI. Although Danish patients experienced a greater level of functional impairment at admission, there was no significant difference between patients in these countries with respect to discharge functional and emotional outcomes after controlling for baseline factors (42).

Comparing health care system between Canada and the US continues to be of great interest in both countries. Although the two countries are relatively similar with respect to cultural values and client-centered approach, there are some differences between them with respect to system of health care delivery (127). Canadian patients have access to universal health care that provides basic health care services and rehabilitation to patients with TBI. In the US, patients with insurance coverage, including a private plan or governmental plan, may be admitted to rehabilitation facilities (17, 21, 165). Published information on patients with TBI showed that Canadian patients experience longer acute care and longer RLoS compared to patients in the US (17, 34, 35, 163, 166)

Horn et al. conducted a comprehensive study of patients with TBI who were treated in 10 IR facilities (1 from Canada and 9 from the US) using the TBI-PBE study methodology. Their aims were to provide comprehensive information on the profile of patients with TBI and the content of IR (46) in order to investigate factors associated with outcomes (45).They used admission FIM cognitive score to stratify patients (46). They showed that demographic and clinical factors had a stronger association with cognitive and motor scores at discharge and nine months post-discharge than therapeutic activities. Also, they found that the intensity of specific activities from each discipline added more power to the explanation of cognitive and motor function than just a total time of therapy (45). However, no attempt has been made to directly compare patients, components of rehabilitation, and IR improvements between patients treated in Canadian settings versus US facilities and provide detailed information on components of IR in Canada.

2.1.1 Research Objectives

The main goals of this study are to descriptively compare: 1) demographic and pre-injury characteristics, 2) clinical features and insurance coverage, 3) type and intensity of therapeutic activities in rehabilitation disciplines, and 4) functional scores at discharge and nine months post-discharge, social participation and quality of life at nine months post-discharge as well as discharge location between patients with TBI who were admitted to one Canadian setting and nine facilities in the US.

Based on previous studies, our first hypothesis was that both groups would be similar with respect to demographic characteristics based on prior population-based studies on TBI patients in North America. The second hypothesis was that Canadian patients may have fewer comorbidities and better function at admission to IR, given a longer duration of acute care in Canada. The third hypothesis was that patients in the Canadian facility may receive more therapy time from three main disciplines (OT, PT, SLP) in total due to longer RLoS. However, US patients may receive more intensity of therapy by minute per week from each discipline according to Medicare 3-hour rule per day. Finally, we hypothesized that Canadian patients may achieve better function at discharge and post-discharge, and most patients from both sides of the border may be discharged to home after IR.

2.2 Methodology

2.2.1 Design and Data Source

Data were obtained from the TBI-PBE dataset for this secondary analysis. This project was a multicenter, collaborative study at 10 IR facilities, one Canadian site from Toronto-Ontario and nine other facilities from US that were located in various states (46). For collecting these data, front-line clinicians developed a TBI auxiliary data module to capture detailed information on patients, processes, and outcomes from patient's medical records. Data abstractors at each center attended specific dyadic and practice training sessions for four days. After training, weekly conference calls were used to address any issues with respect to the process of chart review. Reliability monitoring was conducted for abstractors after their first four charts were completed and again after 25 charts. Afterwards, reliability testing by reliability staffs occurred periodically throughout the years when data were being collected. A 95% agreement rate between the abstractor and reliability staff was required for each reliability test. A complete explanation of the PBE methodology and data gathering was published in a supplemental article by Horn et al (46).

2.2.2 Population

Patients with TBI who were consecutively admitted to 10 IR facilities in Canada and the US between 2008 and 2011 were included in this study. In total, 2,120 patients were admitted to this study (Canada, n= 149 and the US, n= 1971) (46). Patients were stratified into three sub-groups based on their admission FIM cognitive score; ≤15, 16-20, and ≥21. According to the previous articles on the methodology of the TBI-PBE project, admission FIM cognitive score was recognized as a reliable criteria to stratify patients (45, 46). Because of the small sample size of the first (n=20) and second (n=26) cognitive sub-groups in the Canadian site, analyses was only conducted on patients with a higer level of admission FIM cognitive score (≥21). The final sample for this study was 504 patients in total (Canada, n= 103 and the US, n=401). Long-term post-discharge results were reported on patients who had data avaiable at nine months post-discharge (Canada, n=73, the US, n=285).

2.2.3 Variables

Demographics and pre-injury characteristics included age, sex, race/ethnicity, educational status, marital status, and pre-injury characteristics (occupational status, living location, independent status, and pre-morbid/co-morbid conditions). Other clinical features included mechanism of injury, days from injury to IR admission, and RLoS. Severity of illness or comorbidities at admission to and discharge from IR was measured by the CSI score (150). CSI defines severity of illness /comorbidities as the physiologic and psychologic complexity presented to medical personnel due to the extent and interactions of a patient's disease(s) and has been validated in rehabilitation related studies (46, 167). Payer systems were also reported based on type of insurance coverage. The frequency and intensity of rehabilitation activities from rehabilitation services including OT, PT, SLP, SW/CM were used to compare the content of rehabilitation treatments (46). For the purpose of this study, activities were categorized into sub-groups based on their function (31) (Appendix B). To compute the therapy intensity by minute per week, the total therapy minutes were divided by (RLoS/7 days). Non-rehabilitaion interventions such as medications were reported separately.

2.2.4 Functional Scores, Social Participation, and Quality of Life

Functional scores were measured by cognitive and motor components of the FIM at admission, discharge, and nine months post-discharge (153). To provide internal level metric for both cognitive and motor scores and to address measurement error associated with summing of ordinal-level scores, the Rasch-transformed FIM score was used for both cognitive and motor components (46, 155, 168). Community participation outside the home was captured by a 24-

item PART-O tool at nine months post-discharge (157). The average of item scores ranged from 0 to 5. Quality of life was measured by subjective well-being on the Satisfaction with Life Scale (SWLS) at nine months post-discharge (158). This measurement includes 5 items and the average score ranged from 5 to 35. For both measures, higher scores represent better functioning or satisfaction. Discharge location from IR was another measure in this study. Post-discharge follow-up data were collected by telephone interview in the PBE project.

2.2.5 Analysis

Categorical variables were analyzed using the Fisher exact test or Chi-Square test and continuous variables with approximately normal distributions were examined by t-test (Pooled-Standard test or Welsh-Satterthwaite test considering the equality of variance). Where possible missing data were reported as a separate category. To counteract the problem of type I error in multiple comparisons, the Bonferroni correction. This value was calculated by "α/number of comparisons" for each category of varaibles. The significant *p*-value for each category of variable was reported under each table. Data were analyzed using SAS 9.2. (SAS Institute, Inc., Cary, NC).

2.3 Results

2.3.1 Demographic and Pre-Injury Characteristics

There were significant differences between Canadian and US patients for race, pre-injury independent status, and premorbid and comorbidities conditions (Table 2.1). Although most patients with TBI were white in both groups, the percentage of Asians was significantly higher in Canadian patients. Patients in the US were diagnosed with a greater number of comorbidities (e.g., depression, anxiety, pre-injury drug use) than their Canadian counterparts who showed higher percentage of alcohol use at time of injury. However, no significant differences were found in the remaining demographic and pre-injury variables.

2.3.2 Clinical Characteristics and Insurance Status

Time from injury to IR admission and RLoS were significantly longer for Canadian patients. Patients on both sides had a similar variation in mechanism of injury (Table 2.1). The US patients showed a greater CSI score at admission to and discharge from rehabilitation indicating more comorbid conditions at this transitional point in time.

Comparing sources of insurance showed that while all the Canadian patients were covered by government funding as the primary source of insurance, US patients were covered by a combination of governmental insurance (37.6%) and private insurance (58.5%). The percentage of patients who had access to a secondary source of insurance was greater in the US (36.1 vs. 20.2%). However, as seen in Table 2.2, the percentage of un-insured patients was lower in Canadian facilities (outside of universal health care) than in US settings (12.6% vs. 43.1%).

2.3.3 Rehabilitation Treatments and Medications

Findings of this study revealed that US patients received a significantly higher intensity of treatments per week than Canadian patients from PTs, OTs, SLPs, and SWs/CMs) combined and from PTs, OTs, and SLPs separately (Table 3). However, Canadian patients received a greater total time of individual therapy combined and in each discipline during their stay significantly than US patients due to their longer RLoS (Table 2.3).

Patients in US settings received a significantly higher percentage of narcotic medications, anti-cholinergics, anti-convulsants, Trazodone, and ulcer medications compared with Canadian patients (Table 2.3).

2.3.4 Therapy Activities by Minute per Week

2.3.4.1 Occupational Therapy

OTs in the Canadian facility spent a greater proportion of time on cognitive-based activities and assessments per week, while therapists in US facilities spent more time on home IADL, physical impairment, education, advanced personal care, and initial evaluation/interview. Patients in both countries received similar intensity of the remaining activities (Table 2.4).

2.3.4.2 Physical Therapy

Patients in the Canadian facility received a greater intensity of therapeutic exercise and spent significantly more time on assessment, whereas patients in US facilities received a greater amount of gait, advanced gait, transitional movement, and preparation time (Table 4).

2.3.4.3 Speech Language Pathology

In US facility, SLPs provided a higher intensity of education, advanced problem-solving, advanced orientation/memory, community access, and swallowing for patients. Both groups received a similar amount of the remaining activities (Table 2.4).

2.3.4.4 Social Worker/Case Management

While Canadian SWs/CMs spent significant time on education, in the US, patients received a greater mean time of psychosocial assessment. Both countries were similar with respect to time spent on meeting and discharge planning (Table 2.4).

2.4 Functional Scores, Social Participation, and Quality of Life

As seen in table 2.5, Canadian patients were noted to have higher admission and discharge FIM motor scores than their US counterparts. At nine months post-discharge, the FIM motor scores were not significantly different between patients in Canadian and US settings, while US patients showed significantly better cognitive function than Canadian patients. Additionally, US patients were significantly more engaged in community activities post-discharge compared with their Canadian counterparts. The level of satisfaction with life using the SWLS was similar on both sides of the border. Also, almost all patients in both countries were discharged to home (Table 2.5).

2.5 Discussion

To the best of our knowledge, this is the first study to compare components and quantity of IR services between Canadian and US patients with TBI. Results of this study demonstrate that patients with high cognitive FIM scores at IR admission in both countries were similar in demographic characteristics. However, they had significant variations in many clinical features, interventions, and functional measures.

Canadian patients were admitted to IR with a lower CSI score (less severe) and better FIM motor score (less disability). This result supports our hypothesis. This might be explained by a lower percentage of pre-morbid conditions such as depression, anxiety, and pre-injury drug use in

Canadian patients. Prior studies showed that patients with more comorbidities were more likely to have a higher level of disability (6, 137). Variations in documentation of pre-morbid conditions in various health care systems as well as financial incentives in reporting more comorbidities should be noted in interpreting the results of pre-morbid/comorbid conditions as we were informed that documentation of psychological comorbidities in medical records was more limited by law in Canada than in the US (46). Although longer time from injury to IR admission may be considered as a proxy for higher severity of brain injury in Canadian patients, longer acute LoS may also contribute to a lower medical frailty, lower CSI score, and better admission FIM motor score in this population (34, 35).

As we hypothesized, patients in the Canadian facility received a greater total time of individual therapy during their RLoS, while US patients received more time of therapy per week. This may be explained by the longer RLoS in Canadian facility than US settings and variation in practice between Canadian and US. In the US, IR facilities are following Medicare policies as the principal payer of IR services (3 hours of therapy a day for at least 5 days a week) over a shorter RLoS, while in Canada, IR intensity was not governed by federal or provincial health care policy at the time of this study (37, 165, 169, 170) (20).

There is a growing body of evidence on patients with neurological disorders suggesting that activities during rehabilitation will become more advanced in patients with better function (31, 41, 170). However, results of this study showed that this pattern may not apply to all IR systems of care. Patients with similar admission cognitive scores in Canada and the US were provided different intensity and types of activities in IR. This might reflect the influence of variation in patterns of insurance coverage, CSI score, and duration of RLoS between Canada and US. This variability in type and intensity of activities indicates the lack of standard of care in IR for patients with similar cognitive functions within different health care systems.

The higher FIM motor score in Canadian patients at discharge may reflect the higher admission FIM motor scores in Canadian patients. Additionally, this may be explained by the considerable effects of clinical factors (lower CSI score, lower number of pre/co-morbid conditions, and longer acute care and RLoS) and influence of receiving greater intensity of specific physical activities (e.g., therapeutic exercise) and a greater total time of PT on motor function a few months post-injury (34, 171).

Greater cognitive score in Canadian patients at discharge may be explained by a lower admission CSI score and receiving a greater intensity of cognitive activities from OT. Thus, this finding provides support for the therapeutic approach that delivery of more intensity of specific activities such as cognitive activities from OT could improve cognitive recovery in patients with better cognitive function at admission (45). Contrary to our hypothesis, despite better discharge cognitive scores in Canadian patients, their cognitive functioning was lower than US patients at nine-month post-discharge. This result may be explained by the early admission in US patients. Previous studies on long-term cognitive recovery in adults with TBI revealed that patients who received more intensive therapy per week during the first 5 months post-injury showed better cognitive recovery long-term after injury controlling for demographic and other factors (45, 94).

Due to lack of information on the type and intensity of treatments and the large number of missing information about the insurance status of patients after discharge in the Canadian facility, it is difficult to discuss the possible reasons for a lower cognitive score in Canadian patients at nine months follow-up. Future studies are needed to focus on the predictive value of post-discharge treatments and insurance status for long-term outcomes, particularly in Canadian patients. Prior studies showed that it is important to consider the role of third party-payer insurance coverage (private insurance/automobile insurance coverage) in addition to governmental support in accessing home-based support and other rehabilitation facilities after discharge from IR, specifically in Canadian patients (94, 127, 172). The higher level of community participation at nine months post-discharge in US patients may reflect their higher cognitive function long-term after discharge, which is consistent with the findings of a previous study (173).

2.6 Limitations

This study has several limitations. Due to the large number of patients with missing data for the Glasgow Coma Score in US dataset and significant missing data on PTA in the Canadian dataset, these variables were not compared between patients, and samples were not stratified based on these clinical factors. Moreover, no data were available on number of clinicians and their clinical reasoning for choosing type and intensity of activities. Although it was hypothesized that the ceiling effect of the FIM cognitive component to be corrected by using the Rasch score in this study (46), using more precise measurements with a lower ceiling effect such as the

Neurobehavioral Functioning Inventory is suggested for future studies (106). Findings on follow-up data should be interpreted cautiously, given that the population who had data available at follow-up might not be the same for cognitive and motor FIM-Rasch scores (Table 6). The variety of economic, health, and IR facilities across Canada may preclude generalizability of this study to other provinces in Canada (21).

2.7 Conclusion

This study informs clinicians, researchers, and decision makers of the large variation in service provision in this population. The results of this study provide valuable information on the components of therapeutic activities in various disciplines for patients with TBI. This helps clinicians and researchers in Canada and the US to be aware of the frequency and intensity of activities in each discipline for patients with high admission cognitive scores considering the variation of clinical factors and functional scores between patients. Additionally, this study provides the foundation for future attempts to determine the independent contribution of type and intensity of activities to explain the variation in short and long-term functional scores in patients with TBI in different severity groups. An economic analysis is warranted to investigate the risks versus benefits of greater intensity of therapy per week as opposed to the longer RLoS.

2.8 Tables

Table 2.1. Demographic and pre-injury characteristics

Parameter	**Canada (n=103)**	**United States (n=401)**	***p- value***
Demographic characteristics			
Sex (male), n (%)	75 (72.82)	266 (66.33)	0.238
Age at admission, mean (SD)	46.26 (19.02)	46.89 (22.52)	0.774
Race/ethnicity, n (%)			
Asian	22 (21.36)	13 (3.24)	≤0.001*
Black	6 (5.83)	64 (15.96)	0.006
White	75 (72.82)	324 (80.8)	0.079
Education, n (%)			
Associate degree and less	63 (61.17)	227 (56.61)	0.435
Bachelor's degree and Higher	29 (28.16)	143 (35.66)	0.163
Unknown	11 (10.68)	31 (7.73)	0.323
Marital status, n (%)			
Single	41 (39.81)	165 (41.15)	0.823
Married	45 (43.69)	146 (36.41)	0.21
Previously married	14 (13.59)	72 (17.96)	0.378
Other	3 (2.91)	18 (4.49)	0.591
Employment status, n (%)			
Employed and student	66 (64.08)	252 (62.84)	0.909
Unemployed	13 (12.62)	39 (9.73)	0.369
Retired	24 (23.3)	109 (27.18)	0.455
Unknown	0 (0)	1 (0.25)	0.099
Preinjury characteristics			
Ability to drive before injury, n (%)	81 (78.64)	287 (71.57)	0.171
Pre-injury living location, n (%)			
Home	100 (97.09)	396 (98.75)	0.211
Pre-injury independence, n (%)			
ADL ability	100 (97.09)	371 (92.52)	0.118
Ambulation ability	98 (95.15)	351 (87.53)	0.032
Pre-morbid/comorbid conditions, n (%)			
Alcohol use pre-Injury	47 (45.63)	160 (39.9)	0.313
Alcohol use at time of injury	30 (29.13)	63 (15.71)	≤0.003*
Drug use pre-injury	1 (0.97)	85 (21.2)	≤0.001*
Drug use at time of injury	0 (0)	23 (5.74)	0.099
Anxiety	7 (6.8)	182 (45.39)	≤0.001*
Coronary artery disease	6 (5.83)	44 (10.97)	0.141
Depression	13 (12.62)	194 (48.38)	≤0.001*
Diabetes	8 (7.77)	57 (14.21)	0.099
Hypertension	32 (31.07)	169 (42.14)	0.043
Renal failure	6 (5.83)	38 (9.48)	0.327
Number of previous brain injury	9 (8.74)	36 (8.98)	0.099

ns: not significant, SD: Standard Deviation, ***:** *p*-value ≤0.003 was considered significant.
Pre-injury situation was reported by family.

Table 2.2. Clinical characteristics

Clinical features	Canada (n=103)	The US (n=401)	*p- value*
Mechanism of injury, n (%)			
Falls and sports	41 (39.81)	164 (40.9)	0.911
Vehicle collision accident	50 (48.54)	198 (49.3)	0.912
Violence and miscellaneous	12 (11.6)	39 (9.7)	0.583
Days from injury to rehab admission, mean (SD)	56.2 (41.4)	16.81 (19.6)	≤0.001*
Days from rehab discharge to 9-months post-discharge	297.3 (36.6)	323.2 (41.8)	≤0.001*
Rehabilitation LoS, mean (SD)	39.2 (19.4)	13.77 (7.56)	≤0.001*
IR admission CSI score mean (SD)			
BI-CSI	15.0 (8.2)	20.9 (10.08)	≤0.001*
Remain-CSI	4.5 (6.6)	14.1 (12.1)	≤0.001*
total CSI	19.6 (11.8)	35.1 (16.7)	≤0.001*
IR Discharge CSI score mean (SD)			
BI-CSI	7.02 (6.61)	12.5 (7.3)	≤0.001*
Remain-CSI	2.77 (4.65)	8.5 (9.1)	≤0.001*
Total CSI	9.79 (8.68)	21.1 (12.6)	<0.001*
Insurance status			
Primary payer, n (%)			≤.001*
Governmental-Medicare	0 (0.00)	112 (27.9)	
Governmental-Medicaid	0 (0.00)	39 (9.7)	
Private	0 (0.00)	90 (22.4)	
Governmental Universal Health Care	103 (100.0)	0 (0.00)	
Workers compensation	0 (0.00)	33 (8.2)	
Self- pay	0 (0.00)	7 (1.7)	
MCO/ HMO	0 (0.00)	62 (15.5)	
No-fault auto	0 (0.00)	29 (7.2)	
None	0 (0.00)	14 (3.5)	
Other/Unknown	0 (0.00)	15 (3.7)	
Secondary payer, n (%)			≤.001*
Medicare	0 (00.0)	7 (1.7)	
Medicaid	0 (00.0)	16 (4.0)	
Private	17 (16.5)	70 (17.5)	
Workers compensation	4 (3.9)	0 (0.00)	
Self- pay	0 (0.00)	13 (3.2)	
MCO/ HMO	0 (0.00)	12 (3.0)	
No-fault auto	6 (5.8)	27 (6.7)	
None	13 (12.6)	173 (43.1)	
Other/Unknown	63 (61.2)	83 (20.7)	

*IR: Inpatient Rehabilitation, LoS: Length of Stay, MCO: Managed Care Organization, HMO: Health Management Organizations, ns: not significant, SD: Standard Deviation, *: p-value ≤0.007 was considered significant.*

Table 2.3. Time of treatments, individual and group-therapy, and medications

Total time of activities by discipline	**Canada (n=103)**	**The US (n=401)**	***p- value***
All therapy combined			
Receiving any PT, OT, SLP, SW, n (%)	103 (100)	400 (99.75)	0.612
Total min/week, mean (SD)	648.93 (287.83)	994.33 (333.29)	≤0.001*
Individual therapies (combined)			
Receiving any PT, OT, SLP, n (%)	103 (100)	400 (99.75)	0.612
Total min, mean (SD)	3208.03 (2187.91)	1335.89 (898.6)	≤0.001*
Total min/week, mean (SD)	557.77 (231.42)	675.93 (231.71)	≤0.001*
Group therapies (combined)			
Receiving any PT, OT, SLP, n (%)	21 (20.39)	288 (71.82)	≤0.001*
Total min, mean (SD)	174.76 (149.02)	378.33 (429.05)	≤0.001*
Total min/week, mean (SD)	26.05 (22.06)	168.55 (138.08)	≤0.001*
Medications, n (%)			
Narcotic analgesics	37 (35.92)	309 (77.06)	≤0.001*
Non-narcotic analgesics	94 (91.26)	274 (68.33)	≤0.001*
Anticholinergic	51 (49.51)	303 (75.56)	≤0.001*
Anticoagulants	9 (8.74)	256 (63.84)	≤0.001*
Anticonvulsant	1 (0.97)	143 (35.66)	≤0.001*
Trazodone	19 (18.45)	169 (42.14)	≤0.001*
Ulcer drug	40 (38.83)	245 (61.1)	≤0.001*

*OT: Occupational Therapy, PT: Physical Therapy, SLP: Speech Language Pathology, SW: Social Work, CM: Case Management, Min: Minute, ns: not significant, SD: Standard Deviation, *: p-value ≤0.001 was considered significant.*

Table 2.4. Intensity of each activity by minute per week in rehabilitation disciplines

Mean (SD)	**Canada (n=103)**	**United States (n=401)**	***p*-value**
Occupational therapy activities*(n=504)*			
Cognitive impairment activities	103.17 (75.67)	63.54 (56.22)	≤0.001*
Education	11.57 (8.61)	19.73 (18.84)	≤0.001*
Home IADL	23.26 (19.35)	41.03 (27.87)	≤0.001*
Community IADL total	37.05 (38.05)	41.99 (48.58)	0.385
Physical impairment	36.8 (33.09)	83.02 (67.3)	≤0.001*
Basic personal care	22.66 (31.63)	41.64 (34.88)	0.025
Advanced personal care	9.68 (13.63)	22.03 (17.07)	0.007
Basic transfer	5.32 (9.55)	11.16 (11.68)	0.167
Advanced transfer	7.42 (7.21)	15.61 (13.57)	0.003*
Casting	6.21 (6.81)	8.13 (5.49)	0.522
Environmental adaptation	2.59 (1.21)	16.25 (23.55)	0.059
Wheelchair management	13.23 (17.22)	10.78 (10.15)	0.724
Evaluation/initial interview	8.27 (6.57)	26.37 (20.28)	≤0.001*
Assessment	73.94 (43.6)	49.99 (37.25)	≤0.001*
Physical therapy activities			
Therapeutic exercise	109.99 (59.83)	62.39 (42.6)	≤0.001*
Pre-gait/standing	30.98 (36.38)	32.33 (23.49)	0.812
Gait min/week	36.67 (36.86)	90.59 (83.18)	≤0.001*
Advanced gait/community mobility	19.39 (17.71)	32.86 (31.95)	≤0.001*
Pre-Functional activity min/week	10.9 (13.39)	16.18 (17.34)	0.082
Transitional Movement min/week	12.58 (13.79)	39.94 (39.89)	≤0.001*
Preparation time, min/week	5.15 (3.93)	10.65 (9.31)	≤0.001*
Equipment management	5.13 (4.23)	8.26 (8.57)	0.344
Wheelchair mobility	4.94 (8.99)	18.65 (20.05)	0.131
Home evaluation	10.36 (7.92)	52.5 (37.12)	0.131
Resting	4.85 (3.83)	27.4 (22.57)	≤0.001*
Assessment	51 (26.15)	39.98 (27.91)	≤0.001*
Speech language pathology activities			
Education	13.58 (11.7)	22.59 (17.48)	≤0.001*
Basic problem-solving	17.95 (19.35)	33.34 (25.3)	0.007
Basic expression	31.5 (34.52)	13.78 (12.14)	0.018
Basic auditory comprehension	10.67 (6.8)	8.34 (10.79)	0.718
Basic orientation	26.78 (24.01)	29.24 (28.4)	0.809
Basic reading/writing	37.49 (62.6)	7.54 (5.97)	0.345
Advanced problem-solving	9.38 (4.54)	29.64 (23.24)	≤0.001*
Advanced expression	30.5 (31.08)	18.72 (17.14)	0.031
Advanced auditory comprehension	17.62 (14.11)	13.97 (10.62)	0.187
Advanced orientation/memory	11.52 (8.96)	33.04 (24.57)	≤0.001*
Advanced reading/writing	28.5 (20.46)	14.5 (12.74)	0.007
Community access	17.41 (12.78)	44.65 (53.29)	≤0.001*
Computer applications	22.21 (7.23)	15.7 (10.08)	0.405
Motor speech	44.03 (36.94)	25.74 (23.08)	0.07
swallowing	7.34 (6.09)	36.37 (40.42)	≤0.001*
Assessment	49.15 (40.98)	54.54 (40.24)	0.301
Social work/case management activities			
Team meeting	10.47 (11.74)	10.97 (6.7)	0.727
Discharge planning	14.39 (19.2)	15.53 (16.4)	0.702
Education support	29.54 (20.58)	21.05 (20.33)	0.009*
Psychosocial assessment	12.26 (9.81)	19.07 (14.4)	≤0.001*

*IADL: Instrumental Activities of Dailey Living, ns: not significant, SD: Standard Deviation, Activities with 0% of frequency not reported in this table, *: p-value ≤0.003, ≤0.004, ≤0.003and ≤0.01 were considered significant for OT, PT, SLP, and SW/CM, respectively.*

Table 2.5. Functional scores, social participation, and quality of life

	Canada (n=103)	United States (n=401)	*p-value*
Admission FIM Rasch score, mean (SD) (n=504)			
Motor score	67.34 (15.71)	43.42 (10.45)	≤0.001*
Cognitive score	60.01 (6.01)	59.5 (8.05)	0.48
Discharge FIM Rasch score, mean (SD) (n=504)			
Motor score	83.41 (15.06)	59.51 (11.14)	≤0.001*
Cognitive score	71.28 (9.85)	67.59 (11.34)	≤0.003*
Nine months post-discharge FIM Rasch score, mean (SD)			
FIM RASCH motor (n=349)	84.14 (15.45)	85.66 (16.66)	0.49
FIM RASCH cognitive (n=358)	76.74 (13.72)	83.69 (14.47)	≤.001*
Nine months post-discharge PART-O total score mean (SD) (n=317)	1.5 (0.6)	1.9 (0.7)	≤.001*
Nine months post-discharge SWLS total score, mean (SD) (n=336)	21.27 (8.04)	22.75 (8.3)	0.182
Discharge location, n (%) (n=504)			
Home	100 (97.09)	366 (91.27)	0.057
Other institutions	3 (2.91)	33 (8.23)	0.083

*IR: Inpatient Rehabilitation, FIM: functional Independence Measure, CSI: Comprehensive Severity Index, BI: Brain Injury, PART-O: Participation Assessment with Recombined Tools Objective, SWLS: Subjective well-being measured by Satisfaction with Life Scale, ns: not significant, SD: Standard Deviation, *: p-value ≤0.005 was considered significant.*

Chapter 3

Inpatient Rehabilitation and Short-Term Outcomes

3 Association of Therapeutic Factors with Discharge Outcomes in Patients with Traumatic Brain Injury

3.1 Introduction and Background

Inpatient rehabilitation (IR) is one of the main components of the continuum of care for patients following a traumatic brain injury. During IR, an inter-professional team provides coordinated post-injury care for patients (17, 174). This team includes trained specialists in OT, PT, SLP, psychology, and physiatrists (17). Results of prior studies have shown that IR outcomes can be greatly influenced by patient characteristics, clinical features, and variation in rehabilitation facilities (50, 53, 59, 61, 160).

Results of studies assessing association of rehabilitation treatment intensity with outcomes are not consistent in these patients with intensity having various definitions. Studies that considered intensity as total time of rehabilitation concluded that patients who received more intensive therapy were more likely to have a greater level of function (47, 62-65). Nevertheless, Zhu et al. demonstrated that while early rehabilitation could improve functional outcomes, intensive rehabilitation (20 hours per week) may increase the pace of recovery (69). In another study, comparing the influence of rehabilitation intensity on functional outcomes in patients with severe TBI between patients in Danish and US facilities showed that a higher intensity of total treatments (total hours) was associated with better functional outcomes (42). However, they did not examine the independent contribution of treatments (42).

Intensity of rehabilitation in each rehabilitation discipline was investigated by a few studies. Heinemann et al. investigated the impact of intensity of OT, PT, SLP, and psychologic interventions by hour per day on cognitive and motor outcomes in population with TBI (67). They concluded that while intensity of psychology services may affect cognitive function, intensity of other disciplines did not influence cognitive and motor function after controlling demographic and clinical factors (67). In another study Cifu et al. indicated that lower intensity of PT, and SLP interventions by hours per day associated with better motor function but not cognitive function (68). However, none of these studies investigated the independent influence of specific type of activities in each discipline by their level of complexity and impact of the level of patients' tolerance on functional outcomes in patients with TBI.

In a recent study by Horn et al. the TBI-PBE methodology was used to investigate predictors of functional outcomes in US patients (45). They showed that better discharge functional outcomes were associated with receiving more time of complex activities in OT, PT, and SLP sessions by minutes per RLoS/7 days and a higher level of patients' effort during therapy session controlling for patients characteristics, clinical factors and variety of rehabilitation centers (45).

Recent efforts to provide standard care for patients with TBI have led to the development of practice guidelines for clinicians and care providers. Some of these guidelines provide specific information on duration or amount of treatments and patients' participation (86-89). The majority of these guidelines were based on evidence from US and European studies (42, 86). However, the content and duration of those therapies may be associated with local policies in various jurisdictions. Consequently, the specific content of IR and the independent influence of intensity of specific rehabilitation activities on cognitive and motor functional outcomes at discharge in a Canadian population with TBI have remained elusive.

3.1.1 Research Objectives

The main objectives of this study were to (1) investigate the content and influence of IR on cognitive and motor outcomes in patients with TBI who were treated in a Canadian facility, and (2) investigate the predictive value of IR therapeutic factors in explaining cognitive and motor function at discharge in this population.

Based on previous research findings, our hypotheses were 1) IR may improve both cognitive and motor outcomes significantly; 2) level of effort and more complex activities will be associated significantly with better cognitive and motor scores at IR discharge after controlling for other factors.

3.2 Methodology

3.2.1 Design and Data Source

This study was a secondary analysis of data that were obtained from the multicenter TBI-PBE dataset (46). The dataset contains information from 2120 patients with a primary diagnosis of TBI who were consecutively admitted to 10 IR facilities: 1 in Canada and 9 in the US between October 2008 and August 2011. For this study, only patients who were treated in the Canadian facility were included in the analyses (n=149) regardless of their admission cognitive scores. This study was approved by the Research Ethics Board of Toronto Rehabilitation Institute.

3.2.2 Variables

Demographic characteristics included age, sex (male and female), race/ethnicity, marital status (married/common-low, single, previously married, missing), educational status (bachelor and higher degree, associated and high school degree, missing), and employment status (employed, not employed/retired, student).

Clinical features included mechanism of injury, days from injury to rehabilitation admission, RLoS and admission FIM-Rasch cognitive and motor scores. Severity at the time of injury was defined by the GCS, and patient comorbidities and their severity of illness at IR admission were identified by the CSI that defines severity as both physiological and psychological complexity. CSI has been validated in various IR and long-term care studies (22-24).

Therapeutic factors included intensity of activities and patient total level of effort during OT, and PT sessions. In order to provide more concise results, in addition to total intensity of OT and PT services, activities in each discipline were stratified into basic and advanced, based on their function (Appendix C). To compute therapy intensity in each discipline by minutes per week, the total therapy minutes of basic and advanced activities in each discipline were divided by (RLoS/7 days). No distinction was made between services provided on weekends and week days. Because of significant amount of missing data in SLP and psychology activities, data from these two disciplines were removed from the analysis. The level of effort was measured using the Rehabilitation Intensity of Therapy Scale which includes 60 goal-directed activities and is scored weekly with a single-item, 7-point scale (71). Effort is defined as "physical and mental energy of patients within a therapy context including initiating activity, incorporating therapist feedback, and persevering when therapies become challenging"(71, 152).

3.2.3 Outcome Measures

The main outcome measures were the cognitive and motor components of the FIM at admission and discharge from an IR facility. FIM includes an 18 item rating scale that assesses patients' level of independence (153, 154). Scores for each item range from 1 (total assistance) to 7 (complete independence). FIM motor is the summation of 13 items (score range 13-91) and FIM cognition is the summation of 5 items (score range 5-35) (154). To provide internal level metric for both cognitive and motor scores and to address measurement error associated with summing of ordinal-level scores, the Rasch-transformed FIM score was used for both cognitive and motor components instead of FIM raw scores (31). The Rasch-transformed FIM ranged from 0 to 100 for each component.

3.2.4 Statistical Analysis

All analyses were performed using SAS 9.4. For the first objective, descriptive statistics were performed to examine mean and standard deviation (SD) or median and inter quartile range (IQR) for continuous variables and frequency of categorical variables. Also, the paired-t test was used to explore the effectiveness of the IR program on cognitive and motor function of patients. For the second objective, the initial analyses examined variables using univariate linear regression to identify factors that had a significant association with outcome measures. Multivariable linear regression was used to examine the independent influence of therapeutic related factors on functional outcomes. Demographic and clinical factors were entered first as the known variables. Therapeutic factors as the target variables were entered in the last step, regardless of their significant value. Confounding factors (demographic and clinical factors) were chosen based on availability of variables in the dataset, results of univariate regression and results of previous studies (31, 42, 59, 61, 69, 87, 160).

Multicollinearity was examined using Variance Inflation Factor (VIF>10). In the case of multicollinearity, one of a pair of variables were removed from the regression (e.g., admission cognitive and motor FIM-Rasch scores, OT and PT total intensity) or if it was possible, two variables were combined (e.g., activities intensity and RLoS combined as minutes per RLoS/7 days). The value of R^2 and adjusted R^2 were used to capture variation in outcome measures that was accounted for by the predictors. Also, using SAS Macro Programs, R^2 change and F-value were calculated to differentiate the contribution of adding demographic, clinical, and therapeutic variables to the model. Where possible, missing data were reported as a separate category for categorical variables and final sample size was reported for each model. A p-value of <0.05 with 95% confidence interval was considered statistically significant.

3.3 Results

3.3.1 Descriptive Results

Results of descriptive analysis on demographic, clinical, therapeutic factors and outcome measures are reported in Table 3.1. Males accounted for 72.5% of the population and with the mean age of 48 ± 18.7 years. About 53% of patients were intubated or had severe TBI at time of injury. Patients received a greater intensity of advanced activities during OT and PT sessions. All patients had provincial insurance coverage. Additionally, results of the paired t-test showed that there were significant differences between admission and discharge FIM-Rasch cognitive scores ($t=15.6$, $p<.0001$) and between admission and discharge FIM-Rasch motor scores ($t=16.7$, $p<.0001$) (Table 3.1).

3.3.2 Regression Results

As seen in Table 3.2, demographic and clinical characteristics together explained 44.2% and 42.7% of variation in cognitive and motor scores, respectively. While adding the level of effort to the cognitive model explained significant variation in cognitive scores (6.6%), this variable did not add significantly to variation of motor scores. With respect to intensity of OT and PT activities, while adding this factor explained small but significant additional variation in motor scores (7.2%), it did not make significant variation in cognitive scores.

Predictors of cognitive and motor scores are shown in Tables 3.3 and 3.4. After controlling for confounding factors, higher level of OT and PT's level of effort was the only significant predictor of cognitive score within the therapeutic factors. Among demographic and clinical factors; higher educational status, and a lower admission CSI score were associated with a greater cognitive score after controlling for other factors (Table 3.3). We also investigated the contribution of intensity of total PT and OT activities in the full model, which was significantly associated with discharge cognitive score in univariate regression. However, our results showed that adding the level of effort to the model made the intensity of activities effect non-significant (not shown in table).

As reported in Table 3.4, less intensity of simple OT and PT activities, and more intensity of complex OT activities by minute per week were significant and independent predictors of better motor score. However, complex PT activities were not associated with motor score. Additionally, younger age, less number of days from injury to rehabilitation admission, and a lower admission CSI score were significant confounding factors in a motor function model.

3.4 Discussion

This study focused on content of IR and influence of therapeutic factors on functional outcomes in patients with TBI. Exploring the content of IR in this population showed that while more than half of patients experienced severe injury or were intubated at time of injury, they were admitted to IR with relatively high admission FIM cognitive (≥21) and motor (>50) scores (Table 3.1). This may be attributable to longer acute care LoS in the Canadian health care system allowing more time for recovery from comorbidities and medical frailty and therefore better function at admission to IR. Findings of this study were congruent with results of previous evidence and supported our hypothesis with respect to the positive effect of IR on better cognitive and motor function at discharge (17, 49). Receiving a greater intensity of OT and PT complex activities may reflect patients' improved function to engage in more complex activities.

Results of this study indicate that by adding the level of effort and intensity of simple and complex OT and PT activities, the predictive values of the cognitive and motor models were increased, respectively. However, the power of the models was not as high as the TBI-PBE study on patients who were treated in US facilities (45). We note that the TBI-PBE dataset for Canadian site had a significant amount of missing data for SLP and no data for psychotherapy interventions or recreational activities. Thus, the contribution of intensity of activities was limited to OT and PT disciplines in this study. Secondly, because of the small sample size of the Canadian population (Canada, n=149 vs. the US, n=1971), this study could not investigate the contribution of each activity in the model. Thirdly, while adding the admission FIM-Rasch score could increase the explanation power of the final model significantly, this variable was removed from final analysis because of high collinearity with CSI score.

This study showed that while a higher level of effort during OT and PT was a significant predictor of better cognitive function in patients with TBI, a greater intensity of complex OT activities and a lower intensity of basic PT and OT activities were significantly associated with motor function, controlling for other factors. These findings were consistent with previous evidence about the importance of patient engagement in the process of therapeutic activity (45, 71). These results highlight the specific types of activities that correlated with better functional outcomes. These findings also confirm the necessity of integrating methods of promoting patient's active contribution during IR into the process of goal setting to improve cognitive function (70, 71, 77).

Results of the current study reveal that the level of effort was not significantly associated with discharge motor function and did not support our hypothesis. This may be related to a different level of motivation and tolerance that patients need to engage in cognitive activities versus physical activities with respect to their clinical characteristics. Horn et al. showed that a higher level of effort was the only significant predictor of motor function in patients who were admitted to IR facilities with a lower admission FIM cognitive score (<20), while the level of effort was not associated with better motor function in patients with a higher admission FIM cognitive score (≥21). However, their results were consistent between lower and higher admission cognitive groups with respect to the positive association of patients level of effort with a better discharge cognitive score (45).

A primary comparison of clinical characteristics between patients who were treated in the Canadian and US facilities using the TBI-PBE methodology showed that the majority of patients in the Canadian facility were admitted to IR with a FIM cognitive score ≥21(33). This may explain the significant association of the level of effort with cognitive function and lack of significant association of motor function with the level of effort for Canadian patients with TBI.

Additionally, our results showed that although intensity of total OT and PT was significantly associated with discharge cognitive score, by adding the level of effort to the model it became non-significant in the final model. This might be explained by the correlation of intensity of activity with patients' tolerance (78). Further investigations are needed to examine the mediator effect of patients' effort on therapy intensity in future studies. Also, it is very important to consider the influence of other factors such as mental health issues, age, and severity of injury on patients' tolerance and participation in therapeutic activities (79). Prior studies showed that younger patients with lower levels of agitated behavior, lower severity scores and lower number of comorbidities were more willing to participate in interventions (71).

Findings of this study on association of intensity of less basic and more advanced activities with better motor function were consistent with results of Horn et al. on US population confirmed our hypothesis. The high admission function of Canadian patients due to receiving a longer acute care and hence having more time for spontaneous recovery in earlier phase of TBI recovery may have allowed them to participate in more challenging activities (Table 3.1). However, the smaller sample size and the strong effect of clinical factors and the level of effort on cognitive outcome may underestimate the influence of activities on cognitive function in our study, making the results vary somewhat from the Horn et al. study (45).

Heinemann et al. reported that therapy time was not associated with motor function, while our study showed specific types of activities were positively associated with motor outcome (71). This may reflect the importance of considering intensity of specific type of activities on motor outcome rather than simply total time of therapy. Results of the current study were consistent with the study of Cifu et al. with respect to the lack of influence of intensity on cognitive function. Our results were also congruent with their findings with respect to the association of treatment intensity with motor function (68). Previous evidence showed that the majority of studies investigated the total intensity of treatments by discipline, regardless of the type of activities. Horn et al. showed that the total time in therapy was not as strongly associated with outcome as time spent in specific types of activities (45).

The other factor that needs to be considered with respect to the influence of therapy intensity on functional outcomes is the definition of intensity. While some studies used total minute or hours of therapy in their study as a proxy of intensity, others used minutes or hours per week or per day in the model. Considering the variety of practices in different health care systems in providing IR and RLoS between countries, it is important to consider RLoS in calculating the intensity of therapy to be able to make a more rigorous comparison between different studies.

Demographic and clinical factors were controlled in this study to provide more precise results on the independent influence of intensity of activities and patients' contribution to functional outcomes. Among all the confounding factors, age and admission CSI score were the most consistent confounding factors in both cognitive and motor function models. Results of this study on the association of age and admission CSI score with FIM cognitive and motor scores at discharge were consistent with previous studies (45, 53).

3.5 Limitations

This study had some limitations. Small sample size of study prevented us from investigating the predictive value of each activity to explain variation of motor and cognitive outcomes. Additionally, because of lack of data on clinicians' level of experience, clinical reasoning in choosing activities, psychological activities, and missing data on SLP activities, these variables were not investigated accordingly. Also, FIM cognitive score may not fully capture the magnitude of improvement specifically in cognitive abilities. Further studies are needed to assess cognitive recovery using more specified cognitive measurements. This study was conducted on a single center in Ontario and does not necessarily reflect all sites in CA. Thus, more studies are needed to examine the generalizability of these results to a multicenter dataset in Ontario. Also, it is important to use a dyadic measurement to assess patient engagement in the process of therapy.

3.6 Conclusion

To the best of our knowledge, this is the first study to explore content and influence of common therapeutic activities during IR on discharge cognitive and motor function in patients with TBI in the Canadian publicly insured population. This study provides evidence for making available the complex treatments for patients with TBI. Findings showed that while a greater level of effort was associated with higher cognitive score, more time spent on complex activities was a significant predictor of better discharge motor score. Results of this study may assist health care providers to consider patient tolerance and motivation as well as the level of complexity of activities in the process of goal setting.

3.7 Tables

Table 3.1. Descriptive characteristics of patients, injury, and content of rehabilitation

Characteristics (n=149)	**Mean (SD), n (%)**
Demographic characteristics	
Age at admission	48.1 (18.7)
Sex (Males), n (%)	108 (72.4)
Race, n (%)	
White	105 (70.4)
Black	9 (6.0)
Asian/Other	35 (23.4)
Marital status, n (%)	
Married /common in low	66 (44.3)
Single	50 (33.5)
previously married	24 (16.1)
Unknown	9(6.0)
Education, n (%)	
Bachelor and higher degree	29 (19.4)
Associate and lower degree	100 (67.1)
Unknown	20 (13.4)
Employment status, n (%)	
Employed	80(53.6)
Not employed/ retired	58(38.9)
Student	11(7.3)
Clinical features,	
Cause of Injury, n (%)	
MVC	68(45.6)
Fall	62(41.6)
Other	19(12.7)
GCS category, n (%)	
Intubated/severe	79 (53.0)
Moderate	25 (16.7)
Mild	31 (20.8)
Unknown	14 (9.4)
Days from injury to admission to IR, Mean (SD)	64.8 (47.4)
Rehabilitation length of stay (RLoS), Mean (SD)	46.1 (22.8)
Admission CSI score, Mean (SD)	24.66 (14.1)
Therapeutic factors, Mean (SD)	
Average of OT and PT level of effort (n=147)	4.7(1.1)
OT and PT total min/wk	477.8(198.4)
OT and PT total assessment min/wk	107.6(57.8)
OT basic activities min/wk	27.4(37.2)
OT complex activities total min/wk	157.5(92.1)
PT basic activities min/wk	19.8(33.6)
PT complex activities total min/wk	162.7(99.1)
Primary insurance payer	
Ontario Health Insurance Plan	149 (100)
Functional outcomes, Mean (SD)	
Admission FIM cognitive score	22.2 (5.7)
Discharge FIM cognitive score	26.9 (5.9)
Admission FIM motor score	69.7 (19.4)
Discharge FIM motor score	81.7 (14.7)
Admission FIM total Score	91.9 (22.9)
Discharge FIM total Score	108.7 (19.1)
Admission FIM-Rasch cognitive score	54.3 (11.3)
Discharge FIM-Rasch cognitive score	65.1 (14.5)
Admission FIM-Rasch motor score	62.8 (16.7)
Discharge FIM-Rasch motor score	78.5 (18.3)

Table 3.2. Contribution of blocks of variables to the model

Blocks of variables	Cognitive outcome			Motor outcome		
	R^2	R^2 change	F-change *P*-value	R^2	R^2 change	F-change *P*-value
Demographics + clinical	0.442	0.442	<.001	0.427	0.427	<.001
Demographics + clinical + level of effort	0.508	0.066	<.001	0.437	0.010	ns
Demographics + clinical+ the level of effort + intensity	0.532	0.024	ns	0.509	0.072	.003

ns; not significant, Intensity; intensity of basic and advanced activities in OT and PT

Table 3.3. Predictors of discharge FIM-Rasch cognitive score

n=142, $R^2 = 0.532$, Adjusted $R^2 = 0.492$, *p* <.0001	Unadjusted Parameter estimate(β) 95% CI	Adjusted Parameter estimate(β) 95% CI
Age at admission (yrs.)	-0.2 (-0.3, -0.1) **	-0.07(-.2, -.01) *
Sex (males) vs. females	ns	
Marital status (married) vs. others	-5.1(-9.8, -0.5) *	ns
Education (bachelor and above) vs. others	7.3 (1.4, 13.1) *	5.6(1.1, 10.1) *
Employment status (employed) vs. others	7.05 (2.4, 1.6) *	ns
Days from injury to IR admission	-0.09 (-0.1, -0.05) **	ns
Rehabilitation LoS	-0.2 (-0.3, -0.1) **	
Intubated/severe vs. other	ns	
Admission CSI score	-0.5 (-0.7, -0.4) **	-0.4(-0.5, -0.2) *
Cause of injury (MVC) vs. others	ns	
Admission FIM-Rasch cognitive score	ns	
Admission FIM-Rasch motor score	ns	
Average OT & PT level of effort over stay	6.3(4.4, 8.2) *	3.3(1.4, 5.1) **
OT and PT total min/wk	0.01(0.002, 0.02) *	
OT Basic activities min/wk	ns	ns
OT complex activities min/wk	ns	ns
PT basic activities min/wk	ns	ns
PT complex activities min/wk	0.03 (0.008, 0.05) *	ns

*CSI: Comprehensive Severity Index, MVC: Motor Vehicle Collision, LoS: Length of stay, *p<.05, **P<.001.*
Rehabilitation LoS and OT & PT total time, admission FIM-Rasch cognitive score, and admission FIM-Rasch motor score were not added to the final model because of multicollinearity.
Sex, GCS score Cause of injury were not added to the final model due to lack of significant value in an unadjusted model.
Only significant confounders and target variables were added to the final adjusted model.
R^2 and adjusted R^2 were reported for the final adjusted model.

Table 3.4. Predictors of FIM-Rasch motor score

n=142, $R^2 = 0.499$, Adjusted $R^2 = 0.461$, *p* <.0001	Unadjusted Parameter estimate(β) 95% CI	Adjusted Parameter estimate(β) 95% CI
Age at admission (yrs.)	-0.32(-0.47, -0.17) **	-0.14 (-0.27, -0.01) *
Sex (males) vs females	ns	
Marital status (married) vs. others	ns	
Education (bachelor and above) vs. others	ns	
Employment status (employed) vs. others	9.22 (3.46, 14.97) *	ns
Days from injury to IR admission	-0.15 (-0.20, -0.09) **	-0.09 (-0.15, -0.040) *
Rehabilitation LoS	-0.27(-0.40, -0.15) **	
Intubated/severe vs. other	ns	
Admission CSI score	-0.68 (-0.86, -0.50) **	-0.40 (-0.58, -0.22) **
Cause of injury (MVC) vs. others	ns	
Admission FIM Rasch cognitive score	0.80 (0.57, 1.03) **	
Admission FIM Rasch motor score	0.86 (0.75, 0.97) **	
Average OT PT level of effort over stay	0.10 (3.30, 8.35) **	ns
OT and PT total min/wk	ns	
OT Basic activities min/wk	-0.18 (-0.26, -0.11) **	-0.07(-0.15 -0.004) *
OT complex activities min/wk	ns	0.02 (0.0007, 0.059) *
PT basic activities min/wk	-0.19 (-0.27, -0.10) **	-0.08 (-0.169, -0.003) *
PT complex activities min/wk	ns	ns

*CSI: Comprehensive Severity Index, MVC: Motor Vehicle Collision, LoS: Length of stay, ns: not significant *p<.05, **P<.001, Rehabilitation LoS and OT & PT total time, admission FIM-Rasch cognitive score, and admission FIM-Rasch motor score were not added to the final model because of multicollinearity.*
Sex, marital status, education, and cause *of injury were not added to the final model due to lack of significant value in ad unadjusted model.*
Only significant confounders and target variables were added to the final adjusted model.
R^2 and adjusted R^2 were reported for the final adjusted model.

Chapter 4
Inpatient Rehabilitation and long-Term Outcomes

4 Functional Recovery and Predictors of Long-Term Outcomes in Patients with Traumatic Brain Injury

4.1 Introduction and Background

Traumatic brain injury is a critical public health problem globally and is projected to remain the major cause of disability from neurological disorders until 2031(1). In Ontario, the cost of inpatient rehabilitation (IR) for this population is about $93,340 per patient compared with those who do not receive IR ($25,394)(8). With advances in medical care, the rate of survival has been improved meaningfully following TBI (175). However, long lasting disability continues to be challenging for patients, families, and clinicians (90, 175) and imposes significant financial burden on health care systems (8, 97).

The course of functional recovery has been studied in patients with moderate to severe TBI. While few studies focused on early recovery (36, 45, 49, 96, 98, 100, 102, 108, 112, 119), others investigated change of function over a longer period post-TBI (91, 92, 102-107, 176-179). Studies that focused on the first year post-injury revealed that most cognitive and functional recovery was reached in the initial 5 to 6 months post-injury, but patients did not show significant functional improvement over the latter part of the first year (100, 108, 112, 114, 120, 180). Furthermore, some studies indicated that a plateau in cognitive function was reached with a decline noted specifically after one-year post-injury (94, 104, 177, 181). Few studies have examined the cognitive and motor recovery when the influence of IR is considered. For the most part, they explored patient recovery paths at 2 time points within a year post-injury (96, 108). This made differentiation of changes impossible between various time points during longer periods (100, 146). Moreover, databases examined have not included patients with data available from IR admission to follow-up; this fact may introduce selection/attrition bias (147). Thus, knowledge of temporal recovery and differences of functional scores between 4 time points from admission to about one-year post-IR injury will be particularly useful for practitioners to provide appropriate treatments at the right time and offer “just right challenge”.

It is also important to consider factors that may influence cognitive and motor function after rehabilitation discharge. Studies on predictors of cognitive and motor function up to 1 year post-injury mostly focused on demographic and clinical factors. These findings showed that younger age (45, 49), higher education (45), white race (36), PTA (36, 56), having insurance coverage (36, 94), fewer number of comorbidities (36, 45), and fewer number of days from injury to IR admission (36, 45) were associated with better cognitive function. With respect to better motor function these determinants included younger age (36, 49, 182), sex (males) (45, 107), white race (36), having insurance coverage (36, 45), fewer number of comorbidities (45, 107), open head injury (36), shorter time from injury to IR admission (36, 45, 107), and accessing home support services/home modification (107).

There is paucity of evidence in a Canadian-IR setting that investigates the association of intensity of therapeutic activities by complexity and level of patient involvement in process of care with long-term outcomes following IR. Results of a study on US patients showed that therapy intensity and patient level of effort explained significant variation in cognitive (22% and 42%) and motor (53% and 46%) scores at nine months post-IR, respectively than simply considering effect of demographic and clinical factors together on cognitive (20%) and motor (37%) scores (45). Comparing the effect of intensive versus non-intensive therapy by Zhu et al. showed no significant variation from 6 to 12 months post-injury between two groups (69).

Reviewing existing data from various jurisdictions showed that patterns of health care delivery are varied between different health care systems (i.e., Medicare 3-hour rule in the US for IR) (24, 25), which may reflect the necessity of studies of contribution of therapeutic factors and patient engagement to variation of outcomes in a Canadian populations with TBI (66). Providing more precise information about level of complexity of activities will help the care team in the process of clinical reasoning and planning treatment goals. Patient participation in therapy sessions also was found to be another important factor in successful rehabilitation (78, 80). However, fewer studies explored the association of this factor with long-term outcomes.

While impact of comorbidities at time of injury (130, 131, 134) and pre-injury living status (143, 144) have been studied broadly on long-term outcomes following TBI, fewer studies examine association of post-discharge chronic conditions and patients living situation with long-term functional outcomes in this population. Evidence showed that the prevalence of long-term mental and physical deficits is very high following TBI and these factors may contribute to difficulties in community reintegration and lower quality of life in this population (183-185). Also, given the physiologic and hormonal differences between males and females, patterns of functional changes over time in each sex group will provide valuable information for the care team. Results of prior studies are not consistent with respect to performance of patients by sex long-term after injury. A study by Chen et al. revealed that sex was not a predictor of outcome in patients with TBI. However, comparing predictors in each group, showed that associated factors with outcomes were different between males and females (160). Also, a recent study on functional recovery after 3 to 6 months IR post-discharge revealed that females were more likely to have a better cognitive improvement than males (36).

4.1.1 Research Objectives

The main goals of this study are to: 1) explore the cognitive and motor score changes between 4 time points including admission, discharge, three, and nine months post-discharge, 2) explore the cognitive and motor score changes between 4 time points in each sex group, and 3) investigate the predictive value of therapeutic factors and post-discharge conditions in explanation of cognitive and motor outcomes variation at nine months post-discharge while controlling for demographic and clinical characteristics in patients with TBI who were treated in a Canadian -IR facility.

Based on previous research findings, our hypotheses were 1) IR gains may be maintained from discharge to three months post-IR discharge for both cognitive and motor scores but may not continue from three to nine months post-IR discharge, 2) while patterns of improvement may be similar for males and females, their functional recovery will be different following IR discharge, and 3) more complex activities and fewer post-discharge conditions will be associated significantly with better cognitive and motor scores at nine months post-IR discharge after controlling for other factors.

4.2 Methodology

4.2.1 Design, Data source and Population

This study is a secondary analysis of the TBI-PBE multicenter dataset (46) with a total sample of 2120 patients with a primary diagnosis of TBI who were consecutively admitted to 10 IR facilities; 1 in CA (n=149) and 9 in the US (n=1971) between 2008 to 2011. Follow-up data were gathered through telephone interviews from patients or their substitute decision maker at three- and nine-months post-discharge by trained staff. Evidence of valid use of the post-discharge instrument via telephone interview has been reported for patients with neurological disorders in IR (149). For this study, patients who were treated in the Canadian-IR facility and had data available at all 4 time points of admission, discharge, three, and nine months post-discharge were included in the analyses (n=85) to reduce the selection bias. This study was approved by the Research Ethics Board of the Toronto Rehabilitation Institute.

Among 149 Canadian patients, 65.7% (n=98) and 63.7% (n=95) participated in a follow-up Interview at three- and nine-months post-discharge, respectively. Comparing base-line characteristics of participating and drop-out patients at two points of follow-up showed that participating patients were significantly more likely to be younger at three (44.3 ±17.9 vs. 55.3± 17.9, p=0.006) and nine (44.9±18.3 vs. 53.6±18.1, p=0.006) months post-discharge, respectively. Also, patients with higher admission and discharge cognitive scores were more likely to participate in follow-up interviews at three (56.1 ±9.5 vs. 50.8±13.5, 68.0 ±12.1 vs. 59.5±16.9, p=0.01) and nine (55.9± 9.4 vs. 51.4± 13.6, 67.6 ±11.9 vs. 60.6 ±17.4, p=0.03) months post-discharge than drop-out patients.

4.2.2 Variables

Demographic characteristics included age, sex, educational, and employment status. Clinical features included mechanism of injury, days from injury to rehabilitation admission, and RLoS. Injury Severity at the time of injury was measured by the GCS. Comorbidities and severity of illness at IR admission were measured by the CSI©, which defines severity as both physiologic and psychologic complexity. CSI has been validated in various IR and long-term care studies (49, 150). Additionally, availability of a secondary payer system was reported as a proxy of accessibility to outpatient rehabilitation based on type of insurance coverage (e.g., private, work related compensation) out of universal care. Post-discharge clinical features included a list of 22 health issues for both physical and mental health conditions in which patients received medical attention post-discharge (Appendix D), number of referrals to ED, and patient's living situation (living alone versus not alone) after IR discharge.

Therapeutic factors in IR included intensity of activities and average of level of effort during OT and PT sessions. In addition to total intensity of OT and PT, activities in each discipline were stratified into basic and advanced groups based on their function (Appendix C). To calculate therapy intensity in each discipline by minutes per week, total minutes of therapy activities were divided by (RLoS/7 days). No distinction was made between services provided on weekends and week days. Due to significant amount of missing data in SLP and psychology activities, data from these two disciplines were not included in analysis. The level of effort was measured using the Rehabilitation Intensity of Therapy Scale, which included 60 goal-directed activities scored weekly with a single-item, 7-point scale (49). Effort is defined as "the physical and mental energy of patients within therapy context including initiating activity, incorporating therapist feedback, and persevering when therapies become challenging" (71, 152).

4.2.3 Outcome Measures

Main outcome measures were Rasch-adjusted cognitive and motor components of the FIM^{TM} at admission, discharge, three, and nine months post-discharge from the IR facility (154). The FIM-Rasch ranged from 0 to 100 points to provide internal level metric for both cognitive and motor scores and to address measurement error associated with summing of ordinal-level scores (46, 168).

4.2.4 Statistical Analysis

All analyses were performed using SAS 9.4. To investigate functional score changes between 4 time points, multiple comparisons were performed between 4 time points using repeated measures analysis of variance (RM-ANOVA). In the case of significant ANOVA results, Bonferroni post-hoc test was used for pairwise multiple comparisons of means to determine significant differences of FIM-Rasch scores between each pair of time points. Follow-up sex-based analysis was done on functional score changes.

Initial analysis of the second objective examined variables using univariate linear regression to identify factors that had a significant association with outcome measures at nine months post-discharge. Multivariable linear regression was used to examine the independent association of therapeutic and post-discharge factors with long-term functional outcomes. Demographic and clinical factors were entered first as the known confounding variables to the model and therapeutic factors and post-discharge variables were entered in the last step regardless of their significance value as target variables. Confounding factors (demographic and clinical features) were chosen based on potential clinical relevance, availability of variables in the dataset, results of univariate regression, and results of previous studies (118, 123, 186, 187).

Multicollinearity was examined using Variance Inflation Factor (VIF>10). In the case of multicollinearity, one of a pair of variables was removed from the regression (e.g., admission /discharge cognitive and motor FIM-Rasch scores) or if possible, two variables were combined (e.g., time spent in activities and RLoS combined as minutes per RLoS/7 days). Where possible, missing data were reported as a separate category for categorical variables and the final sample size was reported for each model. Values of R^2 and adjusted R^2 were used to capture variation in outcome measures that was accounted for by the predictors in a linear regression. Also, R^2 change and F-change were calculated to differentiate the contribution of adding demographic, clinical, therapeutic, and post-discharge variables to the model. A *p*-value of <0.05 with 95% confidence intervals was considered statistically significant.

4.3 Results

4.3.1 Functional Recovery

Descriptive analysis results on all variables are reported in Table 4.1. Results of repeated-measures ANOVA and Bonferroni test showed that cognitive and motor scores improved significantly from admission to discharge. As seen in Table 4.2, patients showed significantly more cognitive and motor improvements from admission to discharge. From discharge to three months post-discharge, cognitive recovery continued significantly. From three to nine months post-discharge, cognitive and motor scores decreased by 2.2 and 0.5 points, respectively, but not significantly. As shown in Table 4.3, the pattern of motor recovery was similar in males and females with significant improvement from admission to discharge and maintaining motor score from discharge to three- and nine-months post-discharge. Females and males both showed a decline in cognitive scores (5.1 females vs. 1.1 males) from three to nine months post-discharge, respectively, but not significantly.

4.3.2 Predictors of Cognitive and Motor Function at Nine Months Post-Discharge

Demographic and clinical characteristics alone explained 16.5% and 23.5% of the variation in cognitive and motor scores at nine months post-discharge, respectively (Table 4.4). Adding the level of effort did not make a significant contribution in the amount of variation explained in cognitive and motor function. The intensity of time spent in basic and advanced activities explained 14.3% of the variation in motor scores but did not make a significant difference in cognitive scores. Adding post-discharge conditions to the model explained a small but significant variation in cognitive (9.9%) and motor (7.2%) scores.

Multivariate regression results showed that none of the therapeutic factors were significantly associated with cognitive function at follow-up after controlling for confounding factors. Among the post-discharge factors, number of health conditions significantly predicted cognitive function. None of the clinical and demographic factors were associated significantly with long-term cognitive function (Table 4.5).

A greater intensity of time spent in complex OT activities such as cognitive tasks, instrumental activity of daily living, community reintegration, and pre-vocational activities and fewer post-discharge health issues were significantly associated with better motor function at follow-up while controlling for remaining factors. Fewer numbers of days from injury to IR admission was significantly associated with better follow-up motor function. None of the demographic factors were significantly associated with motor function at nine months post-discharge (Table 4.6).

4.4 Discussion

To the best of our knowledge, this is the first study in Canadian patients with TBI to provide estimates of cognitive and motor function at 4 time points from IR admission to nine months post-discharge and to investigate the association of therapeutic factors and post-discharges conditions with long-term functional outcomes. Results of this study provide novel information for clinicians and patients in IR settings in Ontario particularly. While health care systems in

Canada operate within a national legislative framework, given differences of tax revenue among provinces, access to health care facilities is varied (19). Thus, generalizing the results of this study to other provinces or countries with different health care systems should be applied cautiously. Results of this study are consistent with previous studies in that patients with moderate to severe TBI experienced a greater cognitive recovery from IR admission to discharge compared to post-discharge (49, 100, 102, 120) and support our hypothesis. Although declining cognitive FIM-Rasch scores by 2.2 from three to nine months post-discharge were not statistically significant, this might be the start of more cognitive decline in these patients (105, 188). Till et al. and Ruff et al. emphasized that cognitive decline may begin earlier than 12 months post-injury in this population (94, 189). This might be due to the presence of post-discharge health issues and the association of a greater number of post-discharge mental and physical health issues with lower cognitive scores. Comparing functional recovery in each sex group showed that while females improved significantly from discharge to three- and nine-month post-discharge, females did not show significant development in same time frame. This may suggest the importance of considering sex in providing rehabilitation and necessity of providing continuous care for these patients.

Results of this study demonstrated that better post-discharge cognitive outcome was associated with fewer post-discharge mental and physical health related issues which confirmed our hypothesis. Prior literature has shown that most studies investigated an association of existing comorbidities at time of injury with long-term outcomes rather than chronic health issues after discharge from IR (36, 45, 90, 120). A study by Terpstra et al. showed that patients who experienced a higher level of anxiety at 5 and 12 months post-injury had more hippocampus dystrophy in the long-term, which mediates cognitive dysfunction in patients with TBI (129). Although our study was limited by a small number of patients with secondary insurance, prior studies concluded that patients, who had less access to insurance after discharge from IR, are at higher risk of psychosocial problems and cognitive decline (90, 94).

Contrary to our hypothesis, the results of the current study showed that therapy intensity and patient level of effort were not associated with cognitive function at nine months follow-up when controlling for remaining factors. Till et al. found that total therapy hours a week that patients received for 5 months post-injury was significantly associated with better cognitive scores at 1 to 3 years post-injury (94). However, they focused on total therapy times that patients received from various treatment programs. Additionally, they neither used regression analysis nor controlled the contribution of baseline and post-discharge health issues. Furthermore, differences of reference time for follow-up might be another reason for this inconsistency.

Findings of current study were not consistent with a previous study on US patients using the same methodology (PBE) with respect to contribution of the level of effort and intensity of therapy time spent in variation of cognitive scores and not congruent with our hypothesis (45). This may reflect differences in RLoS and timing of receiving therapy intensity in various health care systems or the small sample size in this analysis. For example, US patients received a greater intensity of therapy due to the Medicare 3-hour rule per day, admitted to IR earlier, and experienced a shorter RLoS (45). Also, the US study did not include post-discharge determinants in the predictive model of long-term cognitive function that may make the predictive value of therapy intensity per week and the level of effort significant contrary to current study (45).

This study revealed that Canadian patients showed more motor improvement from admission to discharge and they maintained their motor gains to three- and nine-months post- discharge. Very few studies have focused on the motor recovery from IR admission to up to one year post-discharge and their results confirmed the long-term positive effect of IR on motor function(108, 180). A prior study on motor recovery following TBI indicated that motor improvement could be retained during a longer time when compared with cognitive recovery and the rate of recovery may be dependent on type of injury (e.g., diffuse axonal injury versus focal cortical contusion) and upper or lower extremity weakness (114).

Analysis of predictors of motor function at follow-up showed that increased intensity of complex OT activities during IR and post-injury health issues contributed significantly to the model for long-term functional outcomes. These results were consistent with a prior study on the US population with respect to effect of complex activities with better long-term motor function (45) and may show the advantage of using more intensive complex OT activities including cognitive tasks (e.g., executive function, problem solving and time management), instrumental activities of daily living (e.g., home management, money management), community reintegration (e.g., shopping, banking, using community resources), and pre-vocational (e.g., prepare patients to perform either paid or volunteer work) activities for patients to maintain their motor function improvements long-term after discharge.

Lack of association between patient's level of effort with motor scores may refer to the admission FIM cognitive score (≥21). As shown in US study, the level of effort is not associated with post-discharge motor function in patients who were admitted to IR with relatively high admission cognitive scores and it added little to the model (45). It should be noted that the mean of admission FIM score was relatively high (≥21) that may make it possible for therapists to use more complex activities (Table 1).

Association of greater numbers of post-discharge health issues with lower motor scores at nine months post-discharge suggests the need to provide post-discharge services/counselling for patients and caregivers based on their needs and goals to decrease the risk of post-discharge health issues in this population. This result is consistent with a recent study that showed late functional changes are mainly associated with post-discharge depression and anxiety in this population (185). The results of our study did not find a significant association between age and cognitive and motor scores contrary to previous studies (45, 49). This may be explained by less variation of age in this population due to limited participation of older adults in follow-up interviews. The number of ED admissions after discharge and living situation did not significantly add to explained variation of long-term cognitive and motor scores; this may reflect a small percentage of patients who were admitted to ED or living alone after discharge in this dataset.

4.5 Limitations

Missing data on secondary insurance payers and therapeutic factors from SLP and psychology prevented us from exploring the influence of these factors on post-discharge functional recovery. The majority of non-participants in the follow-up study were older adults, which resulted in a limitation in variability of samples by age. This study was conducted on a single center in Ontario and does not necessarily reflect all sites in Canada. Also, the small sample size of Canadian patients studied here limited our ability to include more predictors in the model.

4.6 Conclusion

This study provides valuable information on patterns of cognitive and motor recovery at 4 time points from admission to nine months post-IR discharge and informs clinicians about critical periods of rehabilitation. The results of this study highlight the necessity of providing consultation on mental and physical health conditions in the process of discharge planning and access to community-based/outpatient rehabilitation programs as well as interval care based on patient's needs following discharge from IR. Additionally, these findings reveal the longitudinal effect of a higher intensity of complex OT activities on maintaining motor gains long-term after discharge that may help clinicians in the process of clinical reasoning and selecting appropriate activities. Further studies are needed to shed light on the association of receiving outpatient and community-based rehabilitation after IR discharge with chronic health conditions and residual disability rather than traditional factors.

4.7 Tables

Table 4.1. Demographic and clinical characteristics of patients at follow-up in a Canadian Facility

N=85	**Mean (SD), n (%)**
Age at admission, Mean (SD)	44.2 (18.3)
Sex (Males), n (%)	62 (72.9)
Education, n (%)	
Bachelor and higher degree	20 (23.5)
Associate and lower degree	64 (75.3)
Unknown	1 (1.2)
Employment status, n (%)	
Employed	51 (60.0)
Not employed/ retired	28 (32.9)
Student	6 (7.1)
Clinical features,	
Cause of Injury, n (%)	
MVC	45 (52.9)
Fall	31 (36.5)
Other	9 (10.6)
GCS category, n (%)	
Intubated/severe	47 (55.3)
Moderate	17 (20.0)
Mild	15 (17.6)
Unknown	6 (7.1)
Days from injury to admission to IR, Mean (SD)	61.1 (46.7)
Rehabilitation length of stay, Mean (SD)	43.6 (19.9)
Admission Comprehensive Severity Index, Mean (SD)	22.9 (13.6)
Secondary insurance payer, n (%)	
private, work compensate or no-fault Auto	23 (27.1)
None	11 (12.9)
Unknown	51 (60.0)
Therapeutic variables, Mean (SD)	
OT & PT Level of effort	4.6 (1.1)
OT and PT total min/wk	506.6 (202.6)
OT basic activity total min/wk	22.1 (26.6)
OT advanced activity total min/wk	174.5 (105.0)
PT basic activity total min/wk	17.5 (29.8)
PT advanced activity total min/wk	176.1 (104.6)
Post-discharge conditions	
Number of health issue post-discharge (≥1 issue)	41 (48.2)
Living situation post-discharge (not alone)	40 (47.5)
Number of referrals to ED (≥2 times)	14 (16.5)
Outcomes, Mean (SD)	
Admission FIM cognitive score	23.1 (5.0)
Admission FIM-Rasch cognitive score	56.2 (9.6)
Admission FIM-Rasch motor score	63.3 (15.4)
Discharge FIM-Rasch cognitive score	68.7 (11.7)
Discharge FIM-Rasch motor score	81.5 (16.3)
FIM-Rasch cognitive score 3-months post-discharge	75.6 (15.4)
FIM-Rasch motor score 3-months post-discharge	83.7 (16.0)
FIM-Rasch cognitive score 9-months post-discharge	73.4 (14.5)
FIM-Rasch motor score 9-months post-discharge	83.1 (16.0)

OT: Occupational Therapy, PT: Physical Therapy, ED: Emergency Department

Table 4.2. Pairwise comparison of the mean differences of FIM-Rasch cognitive and motor scores between 4 time intervals using RM- ANOVA

(n=85)	Mean differences	Bonferroni follow-up test (95% CI)
Cognitive score		
Admission to discharge	12.4	8.5, 16.4*
Admission to 3 months post- discharge	19.4	15.4, 23.3*
Admission to 9 months post-discharge	17.1	13.1, 21.0*
Discharge to 3 months post-discharge	6.9	2.9, 10.8*
Discharge to 9 months post-discharge	4.6	0.7, 8.6*
3 to 9 months post-discharge	-2.2	-6.2, 1.6
Motor score		
Admission to discharge	18.1	13.3, 23.0*
Admission to 3 months post-discharge	20.3	15.5, 25.2*
Admission to 9 months post-discharge	19.8	14.9, 24.6*
Discharge to 3 months post-discharge	2.2	-2.6, 7.0
Discharge to 9 months post-discharge	1.6	-3.2, 6.4
3 to 9 months post-discharge	-0.5	-5.4, 4.2

** Significant with $p < .0001$*

Table 4.3. FIM-Rasch cognitive and motor scores in 4 time points in each sex group

Male (n=62) **Female (n=23)**	**Admission** **Mean (SD)** **A**	**Discharge** **Mean (SD)** **B**	**3 months post- discharge** **Mean (SD)** **C**	**9 months post- discharge** **Mean (SD)** **D**	**Bonferroni follow-up test** **Pairwise comparison** **Significant *p*-value**
Cognitive score					
Male	55.6 (10.2)	67.6 (12.0)	75.1(15.8)	73.9(15.2)	*A-B, *A-C, *A-D, *B-C, *B-D
Female	58.0 (7.9)	71.7 (10.9)	77.2(14.7)	72.0 (13.2)	*A-B, *A-C, *A-D
Motor score					
Male	64.9 (15.6)	83.0 (15.7)	85.7(15.4)	84.8 (15.8)	*A-B, *A-C, *A-D
Female	59.1 (14.7)	77.5 (17.9)	78.3 (16.7)	78.5 (16.2)	*A-B, *A-C, *A-D

*$p<.0001$

Table 4.4. Contribution of blocks of variables to the model

Blocks of variables	Cognitive outcome at 9 months post-discharge			Motor outcome at 9 months post-discharge		
	R^2	R^2 change	F-change *P*-value	R^2	R^2 change	F-change *p*-value
Demographics + clinical	0.165	0.165	0.01	0.235	0.235	<0.0001
Demographics + clinical + level of effort	0.176	0.011	ns	0.261	.026	ns
Demographics + clinical+ level of effort + intensity	0.203	0.027	ns	0.404	0.143	0.004
Demographics + clinical+ level of effort + intensity+ post-discharge conditions	0.302	0.099	0.01	0.476	.072	0.03

ns, not significant; Intensity, intensity of basic and advanced activities in OT and PT

Table 4.5 Predictors of FIM-Rasch cognitive score at 9-months post-discharge

n=80, R^2 =.284, Adjusted R^2 =.157, p <.0001	**Unadjusted**	**Adjusted**
	Parameter estimate(β) 95% CI	**Parameter estimate(β) 95% CI**
Age at admission (yrs.)	-.1 (-.2, .06)	
Sex (males) vs. females	1.8 (-5.2, 8.9)	
Education (bachelor and above) vs. others	8.6 (1.4, 15.9)	ns
Employment status (employed) vs. others	2.2(-4.2, 8.6)	
Cause of injury (MVC) vs. others	-4.3 (-10.6, 1.8)	
Days from injury to IR admission	-.02 (-.09, .04)	
Rehabilitation LoS	-.2 (-.4, -.1)	
Intubated/severe vs. other	-6.1(-12.4, .05)	
Admission CSI score	-.4 (-.6, -.2)	ns
Admission FIM-Rasch cognitive score	.6 (.3, .9)	
Admission FIM-Rasch motor score	.2 (.09, .4)	
Discharge FIM-Rasch cognitive score	.5 (.2, .7)	
Discharge FIM-Rasch motor score	.3 (.1, .4)	
Average OT and PT level of effort over stay	2.2(-.4, 4.9)	ns
OT & PT total min/wk	.009 (-.007, .02)	
OT basic activities min/wk	-.1 (-.2, .01)	ns
OT complex activities min/wk	-.007(-.03, .02)	ns
PT basic activities min/wk	-.06 (-.1, .04)	ns
PT complex activities min/wk	.01(-.02, .04)	ns
Health issue post-discharge (≥1 issue vs. none)	-7.5 (-13.6, -1.3)	-7.4 (-13.06, -1.2)
Referral to ED post-discharge (≥2 times vs. 1 time)	-5.2 (-12.6, 2.08)	ns
Living situation post-discharge (not alone vs. alone)	-1.7 (-10.8, 7.3)	ns

CSI: Comprehensive Severity Index; MVC: Motor Vehicle Collision; LoS: Length of Stay; ED: Emergency Department; ns: not significant,
These variables were not entered in to final model because of lack of significant association with outcome in unadjusted model or multicollinearity with other variables: age, sex, employment status, cause of injury, days from injury to rehabilitation, rehab LoS, Glasgow Coma Score, admission and discharge motor and cognitive FIM scores, and OT& PT total min/wk. R^2 and adjusted R^2 were reported for the final adjusted model.

Table 4.6. Predictors of FIM-Rasch motor score at 9-months post-discharge

n=80, R^2 =.481, Adjusted R^2 =.388, p <.0001	**Unadjusted**	**Adjusted**
	Parameter estimate(β), 95% CI	**Parameter estimate(β), 95% CI**
Age at admission (yrs.)	-.3 (-.4, -.1)	ns
Sex (males) vs. females	6.3 (-1.4, 14.0)	
Education (bachelor and above) vs. others	-.3 (-8.5, 7.8)	
Employment status (employed) vs. others	4.0 (-2.9, 11.1)	
Cause of injury (MVC) vs. others	-.8 (-7.8, 6.1)	
Days from injury to IR admission	-.1 (-.1, -.04)	-.081 (-.14, -.01)
Rehabilitation LoS	-.2 (-.3, -.04)	
Intubated/severe vs. other	-4.4 (-11.3, 2.5)	
Admission CSI score	-.4 (-.6, -.1)	ns
Admission FIM-Rasch cognitive score	.2 (-.06, .6)	
Admission FIM-Rasch motor score	.5 (.3, .7)	
Discharge FIM-Rasch cognitive score	.4 (.1, .6)	
Discharge FIM-Rasch motor score	.6 (.4, .8)	
Average OT and PT level of effort over stay	.1 (-2.7, 3.1)	ns
OT & PT total min/wk	.01 (-.003, .03)	
OT basic activities min/wk	-.2 (-.3, -.09)	-.22 (-.34, -.09)
OT complex activities min/wk	.02 (-.01, .05)	.05 (.02, .09)
PT basic activities min/wk	-.1 (-.2, .01)	ns
PT complex activities min/wk	.01 (-.01, .04)	ns
Health issue post-discharge (≥ 1 issue vs. none)	-6.7 (-13.5, .07)	-7.85 (-19.5, -3.8)
Referral to ED post-discharge (≥2 times vs. 1 time)	-3.7 (-11.9, 4.4)	ns
Living situation at 9-months post-discharge (not alone vs. alone)	-8.6 (-18.5,1.1)	ns

CSI: Comprehensive Severity Index, MVC: Motor Vehicle Collision, LoS: Length of stay, ED: Emergency Department, ns: not significant.
These variables were not entered to the final model because of lack of significant association with outcome in unadjusted model or multicollinearity with other variables: sex, education status, employment status, cause of injury, rehab LoS, Glasgow Coma Score, admission and discharge motor and cognitive FIM scores, and OT& PT total min/wk.
R^2 and adjusted R^2 were reported for the final adjusted model.

Chapter 5
Discussion

5 Discussion

This study characterized the content and process of IR and the functional recovery in patients with TBI from admission to nine months post-discharge from IR. It also identified the predictive value of therapeutic factors to explain the variation in short and long-term cognitive and motor outcomes in this population. IR has been studied widely as an important part of the continuum of care with comparisons being made between those who received early versus late treatments, or between those who received intensive versus routine or less intensive rehabilitation programs (65, 67, 68). Recent attempts to open the undifferentiated “black box” of IR has provided comprehensive information on the components of IR for patients who were treated mainly in US facilities (45, 46). However, the elements and mechanism of the effects of IR are elusive, particularly in the Canadian clinical context. This thesis bridges these gaps of knowledge by providing information on rehabilitation interventions from different professionals and understanding which therapeutic factors lead to better outcomes at discharge and long-term recovery post-discharge. This thesis will be helpful in developing more operational rehabilitation programs for patients with TBI.

5.1 Discussing the Main Findings

5.1.1 Differences and Similarities in the components of IR for Patients with TBI between one Canadian and nine American Facilities

Findings from the first study of this thesis showed that patients who were admitted to Canadian and US facilities with higher admission FIM cognitive scores (≥21) were similar with respect to demographic characteristics. However, clinical features, components of interventions that patients received from rehabilitation disciplines, as well as outcomes were significantly different between patients in Canadian and US rehabilitation settings.

Comparing the pre-injury and clinical characteristics revealed that Canadian patients demonstrated fewer pre-morbid conditions such as depression, and pre-injury drug use. They experienced longer days from injury to rehabilitation admission, and were admitted to IR with fewer comorbidities on CSI while staying longer in IR. Comparing the primary and secondary insurance payers on both sides of the border showed that while Canadian patients had access to public insurance in Ontario (the Ontario Health Insurance Plan), only about 38% of patients in the US were covered by governmental insurance (Medicare and Medicaid) and were mostly covered by various types of private and supplemental insurance. The large number of missing data in the secondary payer system prevented from concluding precisely how many patients were covered by supplemental insurance. However, a preliminary comparison demonstrated that supplemental insurance was available to more US patients and may have influenced their accessibility to post-discharge care and facilities.

A comparison of the content of IR showed that while Canadian patients received more hours of therapy in total from all disciplines over a longer RLoS, they received less intensity of therapy per week. The format of therapy sessions of group vs. individual-based sessions revealed that in Canada, therapists spent more time providing individual therapy sessions, while in the US, patients received more group therapy sessions. A more detailed comparison of the therapeutic activities in each discipline demonstrated that although OTs in the Canadian facility spent significantly more time on cognitive activities and assessments per week, US patients received a greater intensity of physical impairment related activities, basic and advanced personal care, and transfer skills.

In PT, patients received a greater intensity of therapeutic exercise in Canada, while US patients were provided more intense gait and transitional related activities at basic or advanced levels. For SLP activities, patients on both sides of the border received similar amount of basic activities. However, US patients received more advanced activities. A comparison of the content of SW/CM sessions showed that patients in CA received more educational support while US patients were more likely to receive psychosocial assessments.

Patients with high admission cognitive scores were compared using FIM-Rasch measure, which revealed that Canadian patients had better scores on both cognitive and motor components at discharge than their US counterparts. At nine months post-discharge, comparison analysis showed that US patients achieved significantly greater cognitive scores than their Canadian counterparts. However, motor scores were not significantly varied between these two groups of patients.

Fewer pre -morbid/comorbid conditions and higher FIM-Rasch motor scores in Canadian patients at admission may attribute to receiving more acute care treatment and possible spontaneous recovery in the early phase of TBI due to a longer acute care LoS. It should be noted that differences in the number of pre-morbid/comorbid conditions between Canadian and US patients may also reflect the variation of documentation of this feature between Canadian and US facilities.

A longer time from injury to rehabilitation admission has been considered a proxy of greater severity of injury and associated with longer RLoS and lower discharge function in previous studies (45, 190). However, findings of the current study showed that prolonged time from injury to rehabilitation admission may represent more than just a measure of the severity of injury but may also indicate a lack of accessibility to post-acute facilities (191, 192) and longer alternate level of care (ALC) days in Canadian patients (166). According to the Ontario Ministry of Health and Long-Term Care, ALC is defined as “occupying a hospital bed by a patient while there is no requirement for the intensity of resources/services provided in this care setting in Canada” (193).

The protocol for the delivery of interventions was different between the two countries with respect to the type and intensity of activities in each rehabilitation discipline. One of the main reasons for providing a higher intensity of intervention for patients in the US-IR facilities may be the 3-hour mandatory rule by the Centers for Medicare & Medicaid Services (37). In these organizations, therapists need to provide at least 3 hours per day of IR therapy for patients with TBI (37). However, in Canada there is no specific organizational health care policy for providing a specific intensity to therapy for patients in an IR program. The differences in the intensity of time spent in individual and group-based activities between patients in Canadian and US facilities may reflect variety in clinical reasoning, patient or therapist preference and the effect of mental and behavioral symptoms on the therapy session format.

Previous studies demonstrated that elements such as personal values, clinical experience, knowledge of local cultures, leadership, patient expectations, environmental factors, and the use of specific frameworks (i.e., the International Classification of Functioning, Disability and

Health) are substantial factors in formulating and implementing the process of clinical reasoning and professional decision making in rehabilitation settings (194, 195). Nevertheless, clinical reasoning for selecting type and intensity of specific activities in the process of IR is elusive and needs to receive more attention in future studies.

Canadian patients acquired higher discharge cognitive FIM-Rasch scores that may reflect their lower CSI score, a lower number of pre-morbid conditions, a longer RLoS, and receiving a greater intensity of cognitive activities with OTs. Also, higher discharge FIM-Rasch motor scores in Canadian patients might be explained by higher admission FIM-Rasch motor sores in these patients. Earlier studies showed that the admission motor function was strongly associated with the discharge motor function in this population (45, 53). Additionally, higher FIM-Rasch motor scores in Canadian patients may also reflect fewer comorbidities and greater pre-injury independent ambulation in these patients.

The US patients' higher FIM-Rasch cognitive scores at nine months post-discharge may be attributed to the availability of post-discharge rehabilitation given the higher rate of accessing supplemental insurance. Another explanation might be that US patients received a greater intensity of total treatments per week which may have provided greater sustainability of the effects of the interventions longer after discharge (45). This result also might be attributed to the consumption of prescribed medicines. Prior study showed that using non-narcotic medications associated significantly with negative long-term cognitive scores (45). Hence, more studies need to investigate the impact of dosage of medications in addition to frequency of using medicines during IR.

Due to the lack of data at three months post-discharge in the US dataset, no comparison has been made between Canada and the US on the post-discharge recovery for more than one time point. However, the results of the third study of this thesis revealed that recovery in the Canadian patients was not linear from admission to nine months post-discharge at 4 time points and that they experienced cognitive decline between three to nine months post-discharge. This may explain the lower FIM-Rasch cognitive scores in Canadian patients compared to their US counterparts at nine months post-discharge.

5.1.2 Association of Therapeutic Factors with Functional Outcomes

Results of the second study on Canadian patients revealed that they achieved significant improvement from admission to discharge on cognitive and motor FIM-Rasch scores. These results are consistent with previous studies showing the positive association of IR with patients' functional improvement (45, 53). While 53% of patients categorized as intubated/severe on GCS at the time of injury, they were admitted to IR with relatively high cognitive scores (≥21). This may reflect the longer acute care LoS, receiving more therapy in acute care, and the spontaneous recovery in the earlier phase of TBI recovery that led to lower frailty and comorbidities. When the intensity of activities that patients received from OTs and PTs were compared, data showed that patients received a higher intensity of advanced activities from both disciplines when complexity was factored in to the analysis. This may be due to the relatively high admission FIM scores in these patients that made it possible for therapists to use more complex activities. However, this finding may challenge the prior concepts of using less complex activities for patients with a higher severity of injury at time of the trauma. Additionally, this result raises a question about the clinical reasoning for selecting more advanced versus basic activities; whether therapists rely on GCS score (severity of injury at time of injury) or admission FIM scores (admission IR function) to make decisions about the complexity of activities.

In the second objective, the effect of therapeutic factors comprising level of effort during OT and PT sessions, intensity of complex, and simple activities on discharge cognitive and motor FIM-Rasch scores were investigated. Findings of this study revealed that after controlling for demographic and clinical factors, level of effort was a significant predictor of the FIM-Rasch cognitive scores but was not associated with the FIM-Rasch motor scores. This may be related to a different level of motivation and tolerance that patients need to be able to engage effectively in cognitive activities versus physical activities with respect to their clinical characteristics. Horn et al. showed that a higher level of effort was a significant predictor of motor function in patients who were admitted to IR facilities with lower admission FIM cognitive scores (20≤) (45). However, the level of effort was not associated with better motor function in patients with higher admission FIM cognitive scores (≥21) (45). In the current study, patients in the Canadian setting were admitted to IR with relatively higher admission FIM cognitive score (≥21) which may have resulted in a lack of association of level of effort with the FIM-Rasch motor scores. Findings of this study were consistent with the results of Horn et al. with respect to the association of the level of effort with FIM-Rasch cognitive scores. As shown by Horn et al. level of effort was positively associated with the FIM-Rasch cognitive outcomes regardless of variation in the patients' admission FIM cognitive scores (45).

In the TBI-PBE dataset, patient level of effort was assessed using the RITS which is based on only the therapist's observation (45). A systematic review on the measurements of patient participation in health care revealed that the core requirements for patient participation include "shared decision-making, acknowledging the patient as having critical knowledge regarding their own health/needs, and promoting self-care/autonomy" (196). These components were considered as key factors to the measurement of patient participation. Additionally, although ICF is a well-known model for therapists to use for measuring and interpreting patient's participation in process of care, it is criticized due to considering activity and participation under a same category. Lequerica et al, introduced a model of "Therapeutic Engagement in Rehabilitation" that included elements that lead to the willingness of patients to engage in treatment as well as energy that patient needs to be able to prepare for process of goal setting and treatment planning, and finally engage in process of rehabilitation actively (70). According to this model, level of effort can assume as the energy that patient requires initiating the participation. Thus, further studies are required using dyadic measurements (such as the dyadic-OPTION measurement) to investigate the patient participation and its effect on functional outcomes (196).

While the intensity of complex activities was significantly associated with better FIM-Rasch motor outcomes, the result was not similar for the FIM-Rasch cognitive outcomes at discharge. This may reflect the strong association between the level of effort and clinical factors with the FIM-Rasch cognitive scores that made the influence of intensity of activities non-significant. This was confirmed by our analysis as well. Another explanation might be the lack of information on psychological interventions that mainly focused on cognitive skills in the TBI-PBE dataset for Canadian population. A prior study with the similar methodology on US population showed that intensity of psychological activities were significantly associated with FIM-Rasch cognitive scores (45). The association of more intensive complex OT and less basic OT and PT activities with better motor scores at discharge may be attributed to relatively high admission FIM motor scores in these patients that made them able to participate in more challenging activities controlling for other factors.

5.1.3 Functional Recovery and Association of Therapeutic Factors and Post-Discharge Conditions with Nine Months Post-Discharge Function

The third study of this thesis quantified the time course and magnitude of cognitive and motor recovery from IR admission to nine months post-discharge in patients with mild to severe TBI. Findings of the third study showed that patients' recovery path is not linear specifically for FIM-Rasch cognitive scores. While patients showed more recovery from admission to discharge for both FIM-Rasch cognitive and motor scores, the pattern of recovery was different for these two metrics at post-discharge specifically from three to nine months follow-up. For motor scores, the recovery plateaued from discharge to three months post-discharge and from three to nine months post-discharge. For cognitive recovery, patients continued their improvement to three months post-discharge. However, their scores decreased by about 2.30 points from three to nine months post- discharge on the cognitive FIM-Rasch component. Although, this amount of deterioration was not statistically significant, it should receive more attention. Previous studies by Hammond et al. and Kolakowsky-Hayner et al. showed that a decrease of more than 1 point on the FIM may be assumed to be a decline in function, considering the low sensitivity of the cognitive component of the FIM in capturing functional changes (188, 197).

Earlier studies have shown that focusing on more than two time points in patients' recovery paths may provide more specific information on non-linear functional changes (100, 146). The results of this study are consistent with previous literature that the majority of improvement occurred from admission to discharge from rehabilitation (180). However, the trajectory of recovery is varied long-term following TBI. While some studies resulted in no significant changes from 3 to 12 or 24 months after injury for motor and cognitive scores (180), others found a different pattern of recovery that ranged from deterioration in function to stable and good recovery particularly for cognitive scores (94, 98, 147, 198).

The variety of cognitive recovery pattern may be related to the use of the FIM as the measurement tool to assess functional changes. A large number of studies have challenged the utility of the cognitive component of the FIM to capture the functional changes after discharge due to the ceiling effects (106, 199). However, this measurement is of great interest to the stakeholders in Canada and many developed countries and is used widely by clinicians in acute and IR settings (200). Although we utilized FIM-Rasch scores to address this concern, employing specific validated measurements for assessing domains of cognition is suggested. For instance, Till et al. used neuropsychological assessments to assess recovery patterns in patients from 1 to 5 years post-discharge in patients with moderate to severe TBI (94). They found a significant cognitive decline specifically in verbal fluency and verbal learning.

Studies that focused on cognitive function in older adults with a history of TBI, found that the risk of cognitive decline is higher in these patients in addition to the normal process of ageing (201). However, our analysis showed that the target population of the third study of this thesis did not include older adults. Therefore, a possible explanation for this result may be related to factors beyond aging. For example, the lack of availability of treatments after discharge from IR for these patients may be a possible explanation. It is relatively uncommon for patients to access post-IR unless they sustained their TBI due to an MVC in Canada (94, 180). Missing data on secondary source of insurance as a proxy of receiving post-discharge treatments prevented us to conclude a clear result with respect to association of secondary insurance with post-discharge outcomes. However, Till et al. concluded that cognitive decline is negatively associated with total hours of therapy per week that patients received during the first 5 months post- injury due to accessing to out-patients or community rehabilitation (94). Additionally, earlier studies concluded that patients, who had less access to insurance after discharge from IR, are at higher risk of psychosocial problems and cognitive decline (90, 94). This result also confirmed by our study that post-discharge health issues significantly associated with lower post-discharge cognitive function. Another study that stratified patients by their cognitive trajectory revealed that patients with lower cognitive trajectories were younger, in minority race/ethnicity with more comorbidities, and experienced a longer time from injury to rehabilitation admission (36).

Further sex-based analysis of the pattern of recovery revealed that pattern of cognitive and motor recovery was similar between males and females from admission to discharge. Motor recovery has plateaued after discharge for both males and females. While males showed significant cognitive improvement from discharge to three- and nine-months post-discharge, this amount was not significant for females during the similar course of time. Also, males and females showed non-significant cognitive score decline between three- and nine-months post-discharge which was greater in females.

Findings of previous studies were varied with respect to the pattern of recovery by sex. For instance, a study on patients with concussion showed that there were no differences in the slope of recovery between male and female athletes (202). However, they indicated that females experienced higher baseline neuro-psychological symptoms (202). A review of the effects of static and dynamic factors on resilience following TBI showed that females had more recovery than males (203). Inconsistency between the findings of these studies may be a result of the variation in time course of recovery assessment as well as variation in age and severity of injury across study samples (204). A recent study on the interaction of sex and age and their effects on long-term cognitive recovery revealed that while younger males showed poorer verbal skills, middle aged females had poorer processing speed. Also, females who were in their 60s with either a mild or moderate TBI showed a slower reaction time and more memory deficits than males in a same age group (204).

This study revealed that Canadian patients showed more motor recovery from admission to discharge and they maintained the motor gains to three- and nine-months post-discharge. Very few studies have focused on the trajectory of motor recovery from IR admission to up to one year post-discharge (108, 180). A previous systematic review on motor recovery following TBI reported that motor improvement could be maintained for a longer period of time when compared to cognitive recovery and the rate of recovery might be varied by the type of injury (e.g., diffuse axonal injury versus focal cortical contusion) and upper or lower extremity weakness (114). They also emphasized the limitation of studies on the trajectory of motor recovery (114).

In the second objective of the third study, the predictive value of therapeutic factors and post-discharge conditions in explaining the variation of FIM-Rasch cognitive and motor scores at nine months post-discharge were investigated. Among therapeutic factors, more time spent in complex OT activities was significantly associated with better motor recovery, but there was no significant association of these factors with cognitive scores at nine months post-discharge. Very few studies have investigated the long-term effects of IR therapeutic factors on long-term functional outcomes (45, 94, 180). A recent systematic review and meta-analysis on the effects of intensive rehabilitation on functional outcomes only focused on RCT studies (66). They concluded that more intensive neuro-rehabilitation for 4-5 therapy hours per day for 4-5 days per week would have a positive effect on functional outcomes (66). They noted knowledge gaps on the effect of therapy intensity on long-term outcomes. It should be noted that none of the studies included in this systematic review were conducted on patients who were treated in Canadian settings.

The findings of current study were not consistent with a prior study on US patients using the same methodology (PBE) with respect to the contribution of the level of effort and the intensity of therapy in the variation of cognitive scores at nine months post-discharge (45). The level of effort and intensity of activity did not show significant association with long-term cognitive scores in Canadian patients. The above noted findings may reflect differences in RLoS and timing of receiving therapy and intensity in different health care systems. For example, US patients received a greater intensity of therapy, were admitted to IR earlier, and experienced a shorter RLoS (45). Additionally, the US study did not control for the influence of post-discharge conditions on long-term FIM-Rasch cognitive scores which may contribute to the significant effect of therapy intensity and the level of effort (45). Another explanation may be the psychological interventions in US patients with focusing on cognitive skills that associated with better cognitive scores at nine months post-discharge. However, in this study we did not have access to psychologic data for Canadian patients to investigate its influence on their short and long-term outcomes. Comparing the short and long-term effect of the level of effort on cognitive scores (second and third studies) revealed that the level of effort did not remain significant predictor of post-discharge cognitive function. This may reflect the strong effect of chronic health issues which may have undermined the long-term effect of the level of effort on cognitive outcomes at nine months post-discharge.

The negative effect of the number of post-discharge health issues on FIM-Rasch cognitive scores at nine months post-discharge may be attributed to possible changes in brain structure such as hippocampus dystrophy and whole brain atrophy in the chronic stage of TBI which is often evidenced by anxiety and behavioral changes (129, 205). The alternative explanation for this result may be related to the lack of continuous rehabilitation due to the inappropriate insurance coverage after discharge from IR in Canadian patients. Prior studies showed that patients who had less access to supplemental insurance coverage for rehabilitation after discharge from IR are at a higher risk of psychosocial problems and cognitive decline (90, 94).

An analysis of the predictors of motor function at follow-up showed that the intensity of OT activities during IR and post-injury health issues contributed significantly to the model for long-term motor outcomes. The results of the intensity of activities were consistent with a prior study in the US that looked at the complexity of activities (45). This may demonstrate the advantages of providing more intensive complex OT activities for patients in maintaining motor function improvements after discharge. The lack of association of patient level of effort with motor scores was consistent with the US study (45) which showed that the level of effort was not associated with post-discharge motor function in patients who were admitted to IR with a high admission cognitive score (16-20 and ≥21) and it added very little to the power of explanation of the model (approximately between 3% to 0%, respectively) (45).

Earlier studies focused mainly on the association of pre- morbid/comorbid conditions during IR rather than post-discharge health issues with long-term motor outcomes (36, 45, 107). Thus, more studies are warranted on the long-term effects of residual disabilities or post-discharge health issues following TBI. The number of ED admissions after discharge and the living situation did not significantly add to the explanation of the variation of long-term cognitive and motor scores; this might be due to the small percentage of patients who were admitted to ED or living alone after discharge in this dataset.

5.2 Limitations

5.2.1 Study I

1. The lack of data on PTA and GCS in Canadian and large amount of missing information in US sites prevented this researcher from comparing patients' severity of injury at the time of injury and to stratify the population based on these clinical factors.

2. The different referral journey between Canadian and US patients from acute care to IR should be considered in interpreting these results. Lack of availability of IR specifically in remote area or some limitations such as geographical distances, lack of experts, and limited number of beds may prevent patients to access to IR (206). Additionally, structure of hospitals is different in Canada and US. In the US, some acute cares are facilitated by specific rehabilitation units for patients. Thus, they do not experience alternate level of care days (207). Moreover, they have access to more variety of discharge settings from

acute care such as neurobehavioral settings in addition to routine IR that provides different level of services compare to Ontario, Canada (17, 208). Also, there is speculation that patients in the lower cognitive group in the US might be considered as a higher admission cognitive group if they stayed longer in acute care.

3. This study provided informative data on the content and components of therapeutic activities for patients with TBI who were treated in one Canadian and nine US facilities. However, no data were available in the TBI-PBE dataset on the possible clinical reasoning for selecting the type and intensity of activities, and on the professionals, who were responsible for providing these activities. For instance, while OTs are providing more cognitive related interventions in Canada, the SLPs were responsible for delivering cognitive related treatments such as problem-solving activities or orientation and memory related activities in the US (variation in frameworks).

4. Due to the lack of availability of data at three months post-discharge in the US dataset, no comparison analyses were done at this time point between the two countries. Previous studies showed that the trajectory of recovery in patients with TBI has not been steady over time and having more than one time point at follow-up may provide valuable information on the course of functional recovery (96, 100). The third study of this thesis has addressed this gap for Canadian cohorts by focusing on the trajectory of recovery at 4 time points including admission, discharge, three- and nine-months post-discharge.

5. The small sample in the two sub-categories with lower admission FIM cognitive scores (<16 and 16-20), made it impossible to compare patient profile and the content of IR in these two cognitive sub-groups between Canada and the US.

6. Information on follow-up was reported on patients who had data available at nine months post-discharge. While these data assisted us having more patients to study at follow-up, it may have introduced a possible source of selection bias. For instance, while the number in the samples of FIM-Rasch cognitive scores at nine months post-discharge was 358, FIM-Rasch motor scores at nine months post-discharge had a sample size of 349.

7. These findings should be interpreted cautiously, specifically for Canadian sites. Firstly, the sample of this study was not representative of all patients and focused only on patients with a high admission FIM cognitive score who were admitted to TRI in Toronto, Ontario. Canada is divided into 10 provinces and 3 territories, with each managing its own health care independently with different tax-based economics that impacts on quality and quantity of services. Secondly, although the type of activities may be similar among various IR facilities, the intensity of specific activities in each discipline can vary by the number of beds and volume of patients in each facility, and the number of rehabilitation staff in each discipline.

8. This study was novel in the comprehensiveness of information on the different components of IR. However, it is important to emphasize the fundamental differences in health care systems between Canada and the US with the variation in the provision of care in IR (e.g., 3 hours per day rule in the US). Therefore, it is difficult to identify which system is more effective in providing rehabilitation based on these analyses.

9. Comparison was not made between psychologic related activities due to lack of available data at the Canadian sites. It is recognized that psychological treatments are important in providing neurocognitive and neurobehavioral interventions (45, 67).

10. This international study was an important example of cross-border analysis and data sharing. However, it is important to note that controlling for the effects of some variables such as policy of health care delivery, characteristics of therapists, patient and family contribution to the process of rehabilitation are difficult to obtain using quantitative methods.

5.2.2 Study II

1. The contribution of each activity conducted by OT and PT disciplines in the variation of cognitive and motor outcomes was not assessed due to the small sample size of Canadian patients.

2. Patients were not stratified by established clinical characteristics such as GCS score due to the small sample size of Canadian patients.

3. Psychological and SLP treatments were not considered in the model because of missing data, which may have impacted on the total power of the model for both the FIM-Rasch cognitive and motor scores.

4. This study was conducted at a single center in Ontario and does not necessarily reflect all sites in Canada. Each of the provinces or territories in Canada manages its own healthcare independently. Hence, the type of care in the facility in various jurisdictions may vary.

5.2.3 Study III

1. Missing data on secondary insurance payers and therapeutic factors delivered by SLPs and psychologists prevented us from exploring the association of these factors with nine months post-discharge functional recovery.

2. The majority of those lost to follow-up study were older adults, which resulted in less variability of the age of the sample at post-discharge.

4. This study was conducted at a single IR setting in Ontario, Canada. Although the results may be generalizable to patients with high admission cognitive scores that are treated in other IR facilities in Ontario, differences in clinical factors and the variability of economics in healthcare across Canada may preclude the applicability of this study to other provinces.

5.3 Implications

5.3.1 Study I

To the best of our knowledge this is the first study that focuses on a cross-border comparison of IR between Canada and the US using PBE methodology. The results of this study revealed significant variability in IR service provision between facilities in Canada and the US in patients with TBI. These results provide valuable information on components of therapeutic activities in various disciplines for patients with TBI. This helps clinicians and researchers in Canada and the US to be aware of the frequency and intensity of activities in each discipline for patients with high admission cognitive scores considering the variation of clinical factors and functional scores between patients. Additionally, this study provides the foundation for future works to determine the independent contribution of the type and intensity of activities to explain the variation in short and long-term functional outcomes particularly in Canadian patients with TBI.

Lower post-discharge cognitive scores in Canadian patients may show the importance of providing continuous rehabilitation after discharge from IR even for patients who were admitted to IR with high cognitive scores and were discharged with better FIM cognitive and motor scores specifically for patients who are treated in Canadian facilities to prevent functional decline after discharge.

In the US, the structure of the health care system makes it possible for patients to have access to secondary payer insurance to continue care in outpatient or community settings. However, in Canada, the lack of insurance coverage after IR discharge for patients who sustained TBI for reasons other than MVC (who had access to no-fault auto insurance), may contribute to less accessibility to continuous rehabilitation after discharge that might not be compensable only by providing longer RLoS. The provision of community-based health care for patients may provide continuity of care to help patients maximize recovery of function.

5.3.2 Study II

This study provides novel information on the effect of the patient contribution in the process of care as well as the influence of OT and PT activities with respect to their complexity on cognitive and motor outcomes. Findings of this study highlight the advantage of more complex activities in OT and PT programs as a part of treatment goals for patients with TBI. This study helps clinicians in the process of decision making and designing treatments protocol by focusing on complexity of activities while taking into account demographic and clinical factors. Another message of this study for clinicians is the importance of giving more attention to the level of patient’s engagement and participation in the process of treatment specifically for providing cognitive related interventions.

Results of this study suggest that researchers should consider patient level of effort/tolerance in the process of care as well as the intensity of therapeutic rehabilitation activities in addition to traditional demographic and clinical factors in designing future studies in functional recovery. Additionally, from a statistical point of view, this study underscores the importance of adding therapeutic factors to the prediction model of cognitive and motor scores at discharge from IR to improve the explained power of the prediction models for functional outcomes.

5.3.3 Study III

This study provides valuable information on the cognitive and motor recovery for patients with TBI and related practitioners. Informing patients about the path of recovery is presumed to motivate them to be more of an active participant in the process of care.

This study was novel with respect to the inclusion of the therapeutic factors, patient effort and post-discharge health issues in the prediction model of post-discharge outcomes in Canadian patients. It provides a clearer view for clinicians and therapists in rehabilitation about the effects of these factors on long-term functional outcomes. Findings of this study underline the importance of considering these factors during the process of care to maintain the IR functional gains after discharge.

Results of this study contribute to new knowledge that can be used in research on rehabilitation in patients with TBI in Canadian patients. This study leveraged a dataset gathered using the PBE methodology which provided an opportunity to assess more detailed information on real processes and components of IR which are typically not available in the administrative datasets with most commonly focused on patient profile and injury characteristics.

Additionally, this study underlines the importance of funding for projects targeting the impact of outpatient and community-based treatments to maintain patient function after discharge from rehabilitation. More studies are necessary to investigate possible sources of funding to continue rehabilitation post-discharge. Findings of this study also emphasize the importance of attention to post-discharge physical and mental health issues that may lead to long-lasting effects of cognitive and motor disabilities on functional outcomes.

5.4 Future Direction

5.4.1. Study I

1. More international studies with robust analyses are necessary to distinguish the effects of early versus late, intensity of rehabilitation, advanced versus basic activities on functional outcomes while considering clinical and non-clinical factors. Moreover, a commitment of governmental and non-governmental funding agencies is required to foster international collaboration to establish comprehensive datasets for future TBI research.

2. More studies are needed to shed light on the cost-effectiveness of more intensive rehabilitation in a shorter RLoS specifically in Canadian facilities and its effect on functional outcomes.

3. Conducting qualitative and mixed methodology studies will be helpful in investigating the clinical reasoning for selecting specific types of activities in various rehabilitation disciplines, intensity of activities in IR (specifically in Canadian facilities) for patients who are stratified into specific groups based on their demographic and clinical characteristics.

4. To address the generalizability/external validity of the results of this study to facilities in other provinces of Canada, comparison of the TBI-PBE data with the Canadian Institute for Health Information data will be helpful.

5. Exploring the level of patients' function from admission to discharge at multiple time points (e.g., every 2 weeks) will clarify the trajectory of recovery during IR in Canadian patients who were inpatients almost 3 times longer than US patients in IR facilities. This may help team of care in the process of effective discharge planning.

5.4.2 Study II

1. Further studies are needed to focus on factors that are associated with selecting complex versus basic activities using mixed methods to be able to investigate clinical reasoning and patient preference in addition to quantitative factors.

2. More studies are necessary to explore the generalizability of results of this study for patients who are treated in other hospitals using multicenter datasets in Ontario and to compare demographic and clinical characteristics, and staffing levels in various settings.

3. The variety of definitions for intensity of therapy makes it important to use more rigorous definitions for therapy intensity by taking into account RLoS in order to meaningfully compare study results.

4. PBE data were gathered from real clinical contexts with comprehensive data on various aspects of care. Therefore, this study represents foundational work to design more accurate RCTs in future.

5. Given the important role that therapeutic factors play in the variation in functional outcomes, more attention needs to be paid to data gathering on patient and family preference, and their contribution to the process of care. This strategy will provide more opportunity to conduct comprehensive analyses on large datasets while taking into account the effect of these factors.

5.4.3 Study III

1. Future studies are suggested to examine the influence of post-discharge and residual mental and physical disabilities on patient long-term function after injury.

2. Qualitative studies are necessary to inform about socio-cultural, environmental, and financial barriers for access to continuous rehabilitation after discharge from IR.

3. More information is required in future studies on the course of recovery with patients stratified by severity of injury or other established clinical factors.

4. We hypothesized that the FIM-Rasch may decrease the ceiling effect of FIM as a measure of function after discharge. However, using more sensitive outcome measure with higher sensitivity in assessing domains of cognitive and motor scores is suggested in future studies.

5. This study may have shown possible attrition bias with respect to the lack of representation of older adults in the follow-up study. Further study is warranted on the influence of therapeutic factors and patient contribution to long-term outcomes in various age categories.

5.5 Conclusion

In summary, this thesis has provided comprehensive information on process and components of IR in patients with TBI who were admitted to a Canadian facility in Ontario. It has addressed research gaps on the association of treatment with respect to type, intensity and complexity in rehabilitation disciplines with short and long-term outcomes. Comparing components of care during IR between CA and the US sheds light on the differences of provision of care for patients who are treated in North America where common cultural values and client-centered approaches exist. These findings provide novel information for stakeholders to consider the variety of care pathways and to leverage resources to maximize adequate and appropriate care.

This thesis paid particular attention to the effect of patient level of effort in therapy sessions on functional outcomes. It has also addressed the paucity of information on the trajectory of functional recovery by emphasizing 4 time points from admission to nine months post-discharge to control possible selection bias. Also, the follow-up analysis on the trajectory of recovery in males and females with TBI demonstrated the importance of considering the effect of sex in planning therapeutic goals, delivery of care, and the pathway of recovery.

Finally, the three studies in this thesis are good examples of using data that gathered through PBE methodology based on the CER approach which is considered to be a comprehensive methodology to investigate more practical interventions for patients with TBI and for developing clinical guidelines for this population (43, 44).

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Appendix A

International Classification of Diseases, Ninth Revision (ICD 9th)	
800.0 to 801.9	Fracture of the vault or base of the skull
803.0 to 804.9	Other and unqualified multiple fractures of the skull
850.0 to 854.1	Intracranial injury, including concussion, contusion, Laceration, and hemorrhage
873.0 to 873.9	Other open wound to the head;
905.0	Late effects of fracture of the skull and face
907.0	Late effects of intracranial injury without mention of skull fracture;
959.01	Head injury, unspecified.

Appendix B

List of activities by discipline	
Occupational therapy	***Physical therapy***
Advanced personal care	Advanced gait/community mobility/ Stairs
Bathing	Casting and splinting
Toileting	Equipment management
Advanced transfers	Formal assessment
Car transfer	Gait
Toilet transfer	Home evaluation
Tub or shower transfer	Pre-functional
Assessments	Pre-gait/standing
Basic personal care	Preparation time
Feeding	Resting
Grooming	Therapeutic exercise
Lower body dressing	Transitional movements
Upper body dressing	*Bed mobility*
Basic transfers (bed, chair, wheelchair)	*Development sequencing*
Bed mobility	*Sitting*
Casting	*Transfers*
Casting (orthopedic, serial)	Wheelchair mobility
Splinting	***Speech therapy***
Cognitive impairments	Advanced auditory comprehension
Cognitive activity	*Conversation level*
Perceptual activity	*Following multistep commands*
Visual activity	*Sentence/paragraph comprehension*
Community IADL	Advanced expression
Community integration	*Circumlocution/semantic feature analysis*
Community mobility	*Conversation level*
Community transport	*Multimodal communication*
Leisure performance	*Multi-sentence production*
Pre-driving activity	Advanced math/money
Prevocational/vocational	*Budgeting*
Education (educational, sexuality)	*Counting/making change*
Environmental adaptability	*Functional math word problems*
Evaluation (interview, initial evaluation)	*Grade-specific math*
Home IADL	*Time span calculation*
Functional mobility	Advanced orientation and memory
Home management	*Compensation-internal strategies*
Meal management	*Delayed recall*
Money management	Advanced problem solving/reasoning (paper and pencil problem solving)
Physical impairments	Advanced reading/writing
Pre-functional activity	*Analysis*
Upper extremity activity	*Functional reading*
Wheelchair management	*Functional writing*
	Multi-paragraph
	Oral reading
	Paragraphs

Source: Beaulieu CL, et al. 2015

Appendix B continued

List of activities by discipline *Continued*
Social work/case management
Discharge planning
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Education support
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Psychosocial assessment
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Crises intervention
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Utilization review
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Patient advocacy
Patients
Family
Patients and family
Staff
Staff and patients and/or family
Behalf of patients
Source: Beaulieu CL, et al. 2015

Appendix C

Category of activities based on their level of complexity in occupational and physical therapy sessions	
Occupational Therapy	**Physical Therapy**
Basic activities	**Basic activities**
Bed, chair, wheelchair transfer	*Preparation time*
Bed mobility	*Resting*
Serial casting	*Sitting*
Splinting	*Standing*
Environmental adaption	*Basic transfers*
Feeding	*Casting/splintering*
Grooming	*Developmental sequencing*
Lower body dress	*Bed mobility*
Upper body dress	*Wheelchair mobility*
Education	*Equip management*
Sexuality	
Visual activities	
Perceptual activities	
Wheelchair management	
Advanced activities	**Advanced activities**
Bathing	*Therapeutic exercise*
Toileting	*Pre-gait*
Car transfer	*Gait*
Toilet transfer	*Stairs*
Tub-shower transfer	*Community mobility*
Upper extremity activity	*Advanced gait*
Pre-functional activity	*Pre-Functional activity*
Community mobility	
Community transportation	
Community re-integration	
Functional mobility	
Home management	
Leisure performance	
Meal management	
Money management	
Pre-driving activity	
Pre-vocational activity	
Cognitive activity	

Appendix D

List of health issues at time of follow-up that patients received medical attention
Seizures
Headaches
Other Pain
Fatigue
Confusion or not thinking clearly
Memory, concentration, or other thinking skills problems
Medications
Not sleeping/sleeping too much
Swallowing problems
Sexual function problems
Fertility
Spasticity
Vision problems
Hearing problems
Depression
Anxiety
Anger
Apathy
Any physical dysfunction
Social relationships issues
Dizziness
Other

Appendix E

University Health Network
Research Ethics Board
10th Floor, Room 1056
700 University Ave.
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7849

NOTIFICATION OF REB RENEWAL APPROVAL

Date: October 11, 2018

To: Nora Cullen
West Park Healthcare Centre, 82 Buttonwood
Avenue, Toronto, Ontario, Canada, M6M 2C5

Re: 13-7258
Cross border comparison on acquired brain injury
rehabilitation and outcomes

REB Review Type:	Delegated
REB Initial Approval Date:	October 23, 2014
REB Renewal Approval Effective Date:	October 23, 2018
Lapse In REB Approval:	N/A
REB Expiry Date:	October 23, 2019

The University Health Network Research Ethics Board has reviewed and approved the Renewal (13-7258.4) for the above mentioned study.

Best wishes on the successful completion of your project.

Sincerely,
Noam Ami
Ethics Coordinator, University Health Network Research Ethics Board

For: Morris Sherman
Co-Chair, University Health Network Research Ethics Board

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada.

List of Manuscripts

These manuscripts are either published or under reviewed:

1. Zarshenas S, Tam L, Colantonio A, Alavinia M, Jaglal S, Cullen N. Predictors of Discharge Destination from Acute Care in Patients with Traumatic Brain Injury: A Systematic Review. *The Journal of Head Trauma Rehabilitation*. May 31, 2018 - Volume Publish Ahead of Print - Issue – p doi: 10.1097/HTR.0000000000000403.

2. Zarshenas S, Tam L, Colantonio A, Alavinia SM, Cullen N. Predictors of Discharge Destination from Acute Care in Patients with Traumatic Brain Injury: A Systematic Review Protocol, *BMJ Open*. 2017 Aug; 7(8): e016694, doi: 10.1136/bmjopen-2017-016694.

3. Zarshenas S, Colantonio A, Horn S, Jaglal S, Cullen N. Inpatient Rehabilitation for Patients with Traumatic Brain Injury: A Comparison of Canada and the United States. *Physical Medicine and Rehabilitation Journal.*

4. Zarshenas S, Colantonio A, Horn S, Jaglal S, Cullen N. Content of Inpatient Rehabilitation and Influence of Therapeutic Factors on Discharge Outcomes in Patients with Traumatic Brain Injury. *Physical Medicine and Rehabilitation Journal.*

5. Zarshenas S, Colantonio A, Horn S, Jaglal S, Cullen N. Functional Recovery and Predictors of Long-Term Outcomes in Patients with TBI. *Archives of Physical Medicine and Rehabilitation Journal.*