Bailey, David G., The Effect of Aquatic Therapy on Patients with a Complete Spinal Cord Injury in the In-Patient Rehabilitation Setting. Master of Science (Clinical Research Management), November 2018, 89 pp., 4 tables, bibliography, 68 titles.

Although aquatic therapy has been proven to be effective in the treatment of incomplete spinal cord injuries, it is consistently underutilized in the spinal cord injury patient population. Approximately 56% (n=57) of the complete spinal cord injury patients included in this study received aquatic therapy and 44% did not (n=45). This study compared the additional rehabilitation benefit for patients who received aquatic-based therapy in addition to traditional land-based therapy to those who did not. This is an important treatment modality and it has not been studied solely in patients with a complete spinal cord injury. This retrospective study did not demonstrate significantly better outcomes for the group receiving aquatic therapy, but there were significant demographic differences between groups. The results highlight the need for larger and more time intensive studies on aquatic therapy for the complete spinal cord injury population.

THE EFFECT OF AQUATIC THERAPY ON PATIENTS WITH A COMPLETE SPINAL CORD INJURY IN THE IN-PATIENT REHABILITATION SETTING

INTERNSHIP PRACTICUM REPORT

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By

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CHAPTER I

INTRODUCTION

Investigating the efficacy of treatments that are not currently standard of care is important to improve patient outcomes. Aquatic therapy has been shown to be effective in the treatment of sub-acute stroke patients[1], cerebral palsy[2], early-stage Parkinson's disease[3], myocardial infarction, and congestive heart failure[4]. Further, this aquatic therapy is effective in treatment of incomplete spinal cord injury (iSCI), but is underutilized in the rehabilitation setting.[5] Therefore, it is important to investigate its efficacy in treatment of additional diseases which will increase its availability and its utilization. This study, unlike previous aquatic therapy studies, focuses on the complete spinal cord injury population and compares outcomes of patients that received aquatic therapy in addition to traditional care to patients that received traditional care only.

CHAPTER II

BACKGROUND AND LITERATURE REVIEW

An Overview of Spinal Cord Injury

Introduction

Spinal cord injury (SCI) is broadly defined as an injury to the spinal cord that causes motor or sensory deficits. The injury can be either traumatic or non-traumatic in nature and does

not necessarily involve damage to vertebrae. The incidence of non-traumatic injury in North America is estimated at 76 per 1 million in population.[6] The incidence of traumatic spinal cord injury in the United States is estimated at 54 per 1 million in population.[7]

Demographics

Traumatic Spinal Cord Injury

The National Spinal Cord Injury Statistical Center (NSCISC) reported that the mean age at time of SCI between the years 1972 to 2017 was 35.3 years with a standard deviation of ± 17.1 years and mode of 19 years. Overtime there has been an increase in the mean age at time of injury. The mean age of injury from 1972 to 1979 was 28.7 years and during the most recent data collection, from 2015 to 2017, the mean age was 42.7 years.[8] These data were collected through SCI Model Systems (SCIMS) and reflect cases of acute spinal cord injury. Due to the number of funded SCI data collection and treatment centers, SCIMS data account for approximately 6% of new traumatic SCI cases nationally. From 2015 to 2017, there was a greater percentage of non-Hispanic African Americans reported with an acute spinal cord injury compared to the composition of the United States (U.S.) population. Reports from the NSCISC and United States Census Bureau indicate that 21.9% of traumatic SCI cases occurred in Non-Hispanic African Americans, while the same race composes 12.0% of the U.S. population (non-Hispanic only). Native Americans and people of Hispanic descent are under-represented with regards to the incidence of traumatic SCI: 0.7% of traumatic SCI occurred in Native American persons while they compose 1.3% of the general population; 12.8% of traumatic SCI occurred in Hispanic persons while they compose 18.1% of the general population. Asians are also under-represented since 2.7% of traumatic SCI occurred in Asians while they comprise 5.8% of the general

population.[7, 9] Females only represent 22% of new traumatic SCI cases (2015-2017) while they represent 50.8% of the general population of the United States.[7, 9]

There are differences between the demographic data collected from the SCIMS centers and other traumatic SCI inpatient rehabilitation center data repositories for the United States, but there is only a 5-10% difference with regards to race/ethnicity, age, and sex.[10] Therefore, the data above do represent actual disparities in the occurrence of traumatic spinal cord injury on the basis of race/ethnicity and gender.

Non-Traumatic Spinal Cord Injury

A tertiary care center found that from 2008 to 2015 the mean age at time of non-traumatic SCI (NT-SCI) was 53.8 years with a standard deviation of ± 15.4 years and a range of 14 to 88 years. This study excluded individuals that were aged 15 or younger at admission. NT-SCI occurred in Caucasians at a rate of 61.9%, Asians at 6.8%, African Americans at 5.3%, and the remaining were unknown (26.0%).[11] When compared to the U.S. population, this sample under-represents Caucasians, which comprise 76.6% of the general population, and African Americans, which comprise 13.4% of the general population (both non-Hispanic and Hispanic). Asians are slightly over-represented as they comprise only 5.8% of the general population.[9] It is important to note, however, that 26% or 69 of the 265 admissions to this rehabilitation unit were missing or unknown. Females constituted 44.2% of NT-SCI admissions which is a significant proportional increase compared to the 22% seen with traumatic SCI.[7, 11]

Etiology

Review of the SCIMS database indicates that of 32,673 SCI incidents reported between 1973 to 2017, the primary cause of traumatic SCI was an auto accident, which occurred in 10,595 or 32.4% of the incidents. In decreasing rank of causes of traumatic SCI are falls at 7,339

or 22.5%, gunshot wound at 4,997 or 15.3%, motorcycle accidents at 2,004 or 6.1%, and diving at 1,913 or 5.9%. All other etiologies for traumatic SCI comprise the remaining 5,825 incidents or 18% of the traumatic SCIs. Out of the 10,595 auto accidents 7,604 were males, which accounts for 28.9% of traumatic SCI for that gender, and 2,991 were females, which accounts for 47.1% of traumatic SCI for that gender.[8] According to a prospective study by McKinley and colleagues, the primary causes of NT-SCI were spinal stenosis at 53.5% of patients followed by tumor at 25.6%. Minor causes of NT-SCI were ischemia at 8.1%, infection at 7.0%, and myelitis at 4.7%.[12]

Severity of Injury

The NSCISC reported that out of 32,727 SCIMS patients with traumatic SCI, 18.8% were discharged as tetraplegic complete, 32.2% tetraplegic incomplete, 1.3% tetraplegic with minimal deficit, 24.2% paraplegic complete, 18.6% paraplegic incomplete, 1.0% paraplegic with minimal deficit, and 0.6% were normal with minimal deficit for the period of 1972 to 2017.[8] In a study by Kennedy and Hasson, which included 265 NT-SCI patients, 3.4% were discharged as tetraplegic complete, 22.3% as tetraplegia incomplete, 20.4% as paraplegia complete, 50.6% as paraplegia incomplete, and 3.4% of the patient population of unknown injury severity.[11] Tetraplegia is defined as impairment or loss of sensory and/or motor function secondary to damage of the neural elements within the spinal cord. This results in impairment of the arms, trunk, legs, and pelvic organs. This does not include peripheral nerve injuries. Paraplegia is defined as loss of sensory and/or motor function in the thoracic, lumbar, or sacral segments of the spinal cord. In this type of injury, the arms are spared with varying levels of function in the trunk, legs, and pelvic organs.[13]

Presentation of Symptoms

A SCI can arise from a traumatic or non-traumatic source as discussed. Traumatic injuries are more immediate as they are secondary to blunt trauma or to a penetrating injury. Non-traumatic SCI can develop more slowly as in spinal stenosis and spinal tumors. Acute SCI patients have complex pathophysiology and specialized care at an SCI center is important for optimal management.[14] Significant disturbances of the autonomic nervous system can occur secondary to SCI and can be life-threatening as its effects are systemic, such as pulmonary edema, hyponatremia, and autonomic dysreflexia.[15] Autonomic dysreflexia is the result of a SCI at or above thoracic level 6 which can result in acute rises in blood pressure, hyperhidrosis, a pounding headache, and piloerection.[16] Another issue for SCI patients are pressure wounds or pressure ulcers. A multi-center Dutch rehabilitation study found that 36.5% of SCI patients undergoing acute rehabilitation care developed a pressure wound of any stage while 39.4% of those undergoing functional rehabilitation had a pressure wound.[17] Wounds are graded from Stage I – IV with a Stage I as non-blanchable erythema, Stage II as partial thickness, Stage III as full thickness skin loss, and stage IV as full thickness tissue loss.[18]

Prognosis for Treatment Recovery

According to the SCIMS database, the mean change in Functional Independence Measure (FIM) Motor Subscale Total for traumatic SCI was 29.1, starting at 25.2 and increasing to 54.3 upon discharge (1988 – 2017).[8] The motor subscale assesses motor activities related to an individual's activities of daily life (ADL) and the range for this subscale is from 13 to 91 with a higher number indicating a better functional outcome. This increase of 29.1 is significant and more than doubles the average score on admission. While there has been improvement in short-term survival in people with traumatic SCI, long-term survival has not changed over the past 40

years (1973 – 2012). Due to this, mortality, when compared to the general population, has increased. Through utilization of SCIMS data, the Standardized Mortality Ratio (SMR) of people with a SCI has increased at a rate of 2.4% per year.[19] Prior to the collection of SCIMS data in 1973, a study investigating the survival of SCI patients whose injury occurred between 1970 and 1971 indicated that the case fatality rate for traumatic SCI was 25.78% over a period of 6 years after injury, excluding those dead at the scene of injury and dead on arrival at the hospital. This would correspond with SCIMS data which are collected for those that were admitted. The SCIMS data indicate a case fatality rate of 13.1% for the 6 years after SCI.[8, 20] A review of traumatic SCI trends found a 69% decrease in mortality 1 year post-injury (2005 – 2009) compared to data from the 1970s.[21] For people with NT-SCI, the mean change in FIM Motor Subscale Total was 18.8, starting at 37.0 and increasing to 55.8 at discharge (1992 – 1997).[12] Compared to traumatic SCI, survival after NT-SCI is significantly lower despite better functional scores (1997 – 2009). This could possibly be due to the degenerative conditions associated with non-traumatic SCI and the likelihood of metastatic disease for the individuals with tumors. [22, 23]

Assessment of Function

Function can be assessed by many metrics, including the Functional Independence Measure (FIM), American Spinal Injury Association (ASIA) Impairment Scale (AIS), and The Craig Handicap Assessment and Reporting Technique (CHART).[24]

International Classification of Functioning

The International Classification of Functioning (ICF) was developed and implemented by the World Health Organization (WHO). ICF was endorsed by all 191 WHO Member States on May 22, 2001.[25] The ICF is separated into 4 subsets: *Body Structures and Functions*, *Activities*,

Participation, and *Environmental Factors*.[26] All of these combined work together to create a full picture of disability in the context of an individual and are described below.

Body Structures and Functions

Body structure refers to the structural components or tissues of which our bodies are composed, e.g., bones, muscles, and nerves. These three tissue types are important with regards to the classification of spinal cord injuries. Body function refers to the actual movement, action, and sensation created through our tissues and organ systems which depend on the structures and their integration with one another.

The International Standards for Neurological Classification Spinal Cord Injury (ISNCSCI) are used in clinical evaluation of SCI patients and were developed by the American Spinal Cord Injury Association (ASIA).[27] The metrics collected through sensory and functional testing of patients are then used to calculate a score based on the ASIA Impairment Scale (AIS). This score then gives patients a grading for the degree of impairment which is designated as a letter from A – E based on sacral sparing. A patient with a complete injury (A) has no sensory or motor function in S4-S5 and a patient with a sensory incomplete injury (B) has sensory function, which includes S4-S5, preserved below the level of neurological injury, but no preservation of motor function in greater than 3 neurologic levels below the injury. A motor incomplete injury graded as a C indicates motor function with a muscle grade of 0 to 2 for half of greater of the key muscle functions below the level of injury. A motor incomplete injury graded as a D indicates motor function with a grade of 3 or greater for at least half of the key muscle functions below the level of injury.[13] Normal muscle strength over the full range of motion (FROM) receives a score of a 5 and a score of a 0 indicates no muscle activation. The intermediate score of a 3 indicates activation against gravity with FROM.[28]

Activities

The Functional Independence Measure (FIM) has been widely used in the rehabilitation setting as a tool to track patients throughout their stay. FIM contains two subscales, a motor subscale which has a minimum score of 13 and a maximum score of 91 and a cognition subscale which has a minimum score of a 5 and a maximum score of 35. Each activity of daily life (ADL) is given a score from 1 to 7 where a 1 indicates complete dependence, and a 7 indicates complete independence.[29] This measure, in addition to other outcome measures collected throughout the practicum study, is discussed in detail in the materials and methods section.

Participation

The CHART falls under the ICF participation domain. CHART is an assessment tool composed of 6 subscales: physical independence, cognitive independence, mobility, occupation, social integration, and economic self-sufficiency. The full-length CHART form contains 32 items and takes approximately 30 minutes to complete while the short form has 19 items and takes 15 minutes to complete. Each subscale is scored from 0 to 100 with a score of 100 equating to fulfillment that is equal to an individual without disability.[30] This measure has been proven to have high test-retest reliability (r = .93) , validity, and good inter-rater reliability.[31]

Environmental Factors

According to the ICF, environmental factors include products and technology, natural environment and human-made changes to the environment, support and relationships, societal attitudes, and health services, systems, and policies.[32] One instrument used to assess environmental factors and their effect on disability specifically in the 'natural environment and human-made changes to the environment' is the Built and Natural Environment Measure (BNE). The BNE has 18 items and rates each item by level of difficulty on a 5-point scale with a 1 being

'none' and a 5 being 'extreme'. A higher score indicates a higher level of perceived barriers to the build and natural environment. Each of the 18 items are 2 parts with the first part asking about the activity, e.g. 'the level difficulty feeling safe due to crime in the community', and the second part asks if that difficulty is related to the environment. Other topics covered include: communication in public and private settings, whether individuals feel too hot or too cold in community and residential settings, ambulation, and the ability to see objects.[33]

Promotion of Restoration of Function

Land-Based Therapy

Rehabilitation for SCI requires a multidisciplinary approach and for on-land therapy this mainly involves occupational therapists and physical therapists. Occupational therapists focus on upper extremity function as it pertains to ADLs. This focus includes exercises to strengthen a patient's upper extremities, increase the range of motion, improve fine motor control, and incorporate assistive devices as needed. Physical therapists focus on mobility and in this population that pertains to ambulation and wheelchair use. Their treatment seeks to increase strength and endurance of patients. Braces and other orthoses can be incorporated into their care.[34] A study across 6 SCI centers that accounted for 600 traumatic SCI patients estimated the mean time of occupational therapy (OT) was 52.7 ± 35.8 hours. The activities completed in those hours was dependent on the neurological level of injury. The most common activities across all injuries were strengthening and range of motion activities when group and individual therapy time is combined. Individual therapy time focused on ADL.[35, 36] A second study utilizing the same data, found that the mean time of physical therapy (PT) was 58.0 ± 36.2 hours. Further, OT and PT time were the top two rehabilitation activities for all levels of injury composing a combined average of 60% of total therapy time.[36] For PT, the top three activities were range of

motion, strengthening, and transfer training. However, level of injury dictates the activities that are utilized and explains variation in FIM motor scores at discharge. The impact of treatment activity type, frequency, and duration becomes more apparent when patients are grouped by level of injury for analysis.[37]

Aquatic-Based Therapy

Aquatic therapy is used as a therapeutic approach to treat spinal cord injury (SCI) in the rehabilitation setting. A review of the current literature found 5 randomized controlled trials,[38-42] one controlled clinical trial,[43] two single group test-retest studies,[44, 45] one case report,[46] two case-control studies,[47, 48] and one longitudinal study.[49] These studies included a total of 387 patients with spinal cord injury (AIS A-D) associated with the use of aquatic therapy after a SCI. Strong evidence for the effectiveness of aquatic therapy was found in some studies,[40, 47] but others had small sample sizes or did not have a control group and, therefore, could not establish significant causality.[39, 41, 43-46, 48, 49] Therapy duration across all of these studies ranged from 4 weeks to 3 months with an average of 2 hours of aquatic therapy per week. Two studies, one which was a randomized control trial and the other a non-matched, case-control studied the effect of aquatic exercise on pulmonary function in patients with spinal cord injury.[41, 48] The randomized control trial reported improved pulmonary function in SCI patients after aquatic therapy through increases in forced vital capacity (FVC), forced expiratory reserve (FER), forced expiratory volume in 1 second (FEV1), and FEV1/FCV ratio, while the on-land therapy group only had significant improvement in forced expiratory reserve (FER).[41] In the case-control study, both tetraplegic patients and healthy controls underwent isothermic immersion and there was significant improvement in FVC in the SCI patients while the healthy controls showed significant losses in FVC. There were no significant differences in the other pulmonary

parameters (FER, FEV1, FEV1/FCV ratio) between the healthy controls and the tetraplegic patients.[48] In a case-control study, participants with an incomplete spinal cord injury (iSCI) that underwent aquatic therapy had reduced gait differences and improved gait stability when compared to healthy volunteers.[47] Additional evidence for improved gait associated with aquatic therapy is provided by a case study in which a participant's gait and walking confidence, on-land and in the water, was assessed and had improvement on both metrics.[46] However, both studies were conducted using patients with incomplete spinal cord injury (iSCI), and the latter study provides only weak evidence because it did not have a control group. Further, a systematic review of the literature provided strong evidence of the cardiovascular benefits of aquatic therapy in both the complete and incomplete injury population (AIS A-D), but only found weak evidence of improvement in other physical fitness metrics (strength, balance, and body composition).[50] Also, aquatic therapy has been found to decrease spasticity in the spinal cord injury population as measured by spasm severity and oral baclofen use (spasticity medication) in a matched randomized controlled trial of participants receiving on-land therapy only compared to on-land therapy plus aquatic therapy 3 times per week for 20 minutes.[44]

Water is promising as an environment for rehabilitation of spinal cord injury patients, but has been under-utilized for the spinal cord injury patient population due to neurogenic bowel and bladder (fecal and urinary incontinence due to damage of the pelvic splanchnic nerves) and other co-morbidities.[5] As technology has improved, the previously excluded spinal cord injury patients are able to participate in aquatic therapy despite the co-morbidities that require catheter use, tracheotomies, or colostomy bags as long as a specific protocol are followed.[49] In a study of 100 patients with a spinal cord injury with neurogenic bowel or bladder, tracheostomies, or pressure ulcers, no untoward medical complications occurred and there was only one incident of pool

contamination.[51] Current research has focused on incomplete spinal cord injuries of AIS grade C and D.

SPECIFIC AIMS

The goal of this practicum study is to provide initial evidence regarding whether aquatic therapy in addition to traditional care in complete spinal cord injury patients leads to better outcomes compared to patients who receive traditional land-based therapy only.

Objectives and Specific Aims

Objective 1

Examined the effectiveness of traditional land-based therapy alone compared to land-based plus aquatic-based therapy on functional outcomes (Functional Independence Measure, spasticity medication use, and orthostatic blood pressure medication use) for patients with a complete spinal cord injury during in-patient rehabilitation.

Specific Aim 1

To determine whether aquatic-based therapy in addition to land-based therapy results in significantly different outcomes compared to land-based therapy alone. The following hypotheses were tested:

Null Hypothesis (Ho) 1

There is no difference in the amount patients with spinal cord injury improved in Functional Independence Measure (FIM) between the land-based therapy alone and the land-based therapy plus aquatic-based therapy.

Alternative Hypothesis (Ha) 1

Those patients receiving land-based therapy plus aquatic therapy demonstrate significantly greater functional improvement that those receiving land-based therapy alone, based on FIM scores.

Null Hypothesis (Ho) 2

There is no difference between the number of patients that used spasticity medication at admission compared to those using spasticity medication at discharge between the group receiving land-based therapy alone and the group receiving land-based plus aquatic-based therapy.

Alternative Hypothesis (Ha) 2

There is significantly fewer patients that use spasticity medication at admission compared to those using spasticity medication at discharge in the group that received land-based plus aquatic-based therapy.

Null Hypothesis (Ho) 3

There is no difference in the number of patients that used midodrine, octreotide, or florinef to control orthostatic hypotension at admission compared to those using orthostatic blood pressure medication at discharge between the group receiving land-based therapy alone and the group receiving land-based plus aquatic-based therapy.

Alternative Hypothesis (Ha) 3

There are significantly fewer patients that used midodrine, octreotide, or florinef to control orthostatic hypotension at admission compared to those using orthostatic blood pressure medication at discharge in the group that received land-based plus aquatic-based therapy.

Objective 2

To implement a protocol to standardize assessing patient reported outcomes during aquatic based therapy in individuals with complete spinal cord injury. The following hypotheses were tested:

Specific Aim 1

Examined compliance of collecting patient reported outcomes following each aquatic therapy session.

Null hypothesis (Ho) 1

Patient reported outcomes were collected below the 75th percentile for the Physical Activity Affect Scale (PAAS), Pain Scale, and Rate of Perceived Exertion (RPE).

Alternative hypothesis (Ha) 1

Patient reported outcomes were collected within the 75th percentile for the Physical Activity Affect Scale (PAAS), Pain Scale, and Rate of Perceived Exertion (RPE).

SIGNIFICANCE

As previously stated, there is little published evidence regarding the effectiveness of aquatic therapy during in-patient rehabilitation for patients with a complete motor spinal cord injury (AIS classification A and B) to determine whether aquatic therapy improves patient outcomes more than traditional land-based therapy. This practicum study was designed to provide initial evidence from a regional rehabilitation hospital to assess whether injured patients who received both traditional land-based therapy plus aquatic therapy had significantly better

outcomes than complete spinal cord injury patients who receive traditional land-based therapy alone.

MATERIALS AND METHODS

Design and Participants

In this quasi experimental trial, clinical outcomes derived from patient records were compared between two SCI patient groups. The study design focused on examining outcomes between SCI patients who received aquatic therapy plus land-based therapy as part of their clinical care compared to SCI patients who received the current standard of traditional rehabilitation care that did not include aquatic therapy (land-based therapy only). Patient medical records were obtained retrospectively from the electronic medical record (EMR) of Baylor Scott & White Institute for Rehabilitation (BSWIR) who were discharged between January 1, 2017 and December 31, 2017.

Inclusion Criteria

- Undergoing inpatient rehabilitation
- Continent of bowel and bladder or have a foley catheter in place
- AIS class A or B

Exclusion Criteria

- Pressure wound that is classified as stage 3 or 4

Study Groups

Control Group

The control group included patients who received land-based therapy for a minimum of 3 hours per day, 5 days a week, which is the current standard of care. This standard is dictated by the federal government through medicare.[52] This patient group received occupational, speech, and physical therapy. Their receipt of traditional therapy is based on provider preference, as one of the two SCI physicians at BSWIR seeing patients that were included in this study routinely does not prescribe aquatic-based therapy due to the lack of an established evidence base.

Intervention Group

The intervention group received the same land-based therapy that is delivered as the standard of care plus additional aquatic therapy sessions. This group was prescribed the additional aquatic therapy based on the SCI physician's belief that it confers unique benefits to this patient population based on the limited available evidence. Data on the number of sessions study subjects received, the duration of those sessions, and the number of missed sessions is presented in Table 2.

Sample Size

Retrospective Study

Patient charts contained in eRehabData from people who were discharged from January 1, 2017 to December 31, 2017 (n=310) were extracted for use. Duplicate charts and charts of participants that did not meet inclusion or met exclusion criteria were removed and the remaining 102 charts were used for data analysis.

Prospective study

Patients from the Baylor Scott and White Institute for Rehabilitation in-patient population were prospectively enrolled in the study based on inclusion and exclusion criteria.

Independent Variables

The two primary treatment variables included the (a) **duration of aquatic therapy** as recorded in the retrospective case report form and (b) **number of aquatic therapy sessions**. Aquatic therapy treatment was provided by two aquatic therapists at BSWIR. One therapist received a BS degree in Therapeutic Recreation from Penn State University and has 30 years of experience in aquatic therapy. The second therapist received a Doctor of Physical Therapy (DPT) from the University of Texas Southwestern Medical Center and has been a physical therapist at BSWIR for 2 years. The aquatic therapy was ordered on admission or by referral after a care team conference with the physical therapists and the physicians. Patients were prescribed 45 minutes of aquatic therapy, 5 days per week. However, the amount of therapy they actually received was based on scheduling which depends on patient volume and the availability of therapists. The therapists did not exclusively treat SCI patients. The specific aquatic exercise was variable based on level of function and level of spinal cord injury.

Outcome Measures

Functional Independence Measure (FIM)

FIM is a widely used outcome measure in the rehabilitation setting. To complete the assessment, clinicians observe a specific set of 18 daily activities and rate their completion on a scale of 1-7. A score of 1 indicates that total assistance is required (patient contributes < 25% of the work required to complete a task) and a score of a 7 indicates complete independence (patient is able to complete the task in a safe and timely manner).[53] A quantitative review found the mean

inter-rater reliability value for the total FIM score in SCI patients to be 0.86 with a 95% confidence interval of 0.840 - 0.880.[54] Thus, FIM is a reliable measure of function in this population. Additionally, FIM has been found to have a high level of validity.[55] FIM was collected daily by several different clinical staff in accordance with their respective training and role in the clinical setting. The clinicians collecting information included physiotherapists, occupational therapists, speech therapists, nursing staff, and others as it covers many different items and two subscales (motor and cognition). The motor subscale can further be broken down into upper and lower body aspects in addition to activities of daily life (ADL). The value of the motor subscale, the sum of all individual motor items, ranges from 13 to 91, with higher scores indicating better function. The value for the cognitive subscale, the sum of all individual cognitive items, ranges from 5 to 35. The two subscales add up to a value between 18 and 126, with 18 being complete dependence and 126 being complete independence.

FIM appears to have a multidimensionality across these three summations in patients undergoing in-patient rehabilitation.[56] However, most patients appear to reach a ceiling effect on the cognition subscale by discharge as evidenced through research by Hall and colleagues. Their research indicated that 80 to 90% of traumatic SCI patients had a 6 or a 7 on each cognition FIM item at discharge.[57] A ceiling effect is defined as the point at which an independent variable (in-patient rehabilitation), has no effect on a dependent variable (FIM score).[58] The Minimal Clinically Important Difference (MCID) is the difference that is required for there to be a clinically significant effect. One method to calculate the MCID is to multiply the Standard Error of the Mean (SEM) for a metric by 0.5. For example, SEM for FIM gain across all levels of spinal cord injury is 13.2.[57] This SEM was calculated with data collected from the Spinal Cord Injury Model System. Taking that value and multiplying it by 0.5 yields a MCID of 6.6 points

for the FIM. Therefore, a change of 6.6 points is required to have a clinically significant improvement in function for the SCI patient population.

Spasticity Medication Use

Use of anti-spasmolytic drugs was collected from the chart reviews and was input into the Access database. Two data points were taken; one at admission and the second at discharge. Data were collected comparing only the use and dis-use of medication, not the specific dosing. Prescribed medications included cyclobenzaprine, metaxalone, methocarbamol, diazepam, baclofen, and tizanidine.[59]

Orthostatic Hypotension Medication Use

Use of drugs for orthostatic hypotension was collected from the chart reviews and was input into the Access database. Two data points were taken, one at admission and the second at discharge. Data were only collected in the context of use and non-use. Prescribed medications included midodrine, octreotide, and florinef.

Discharge Wheelchair Type

The type of wheelchair that was used on discharge was collected from the chart reviews and was input into the Access database. The type of wheelchair patients used after discharge is indicative of a mobility change and the study participants that have a higher level of function will be able to use a manual wheelchair only. Power only or both manual and power are also possible and indicate a greater need for assistance in mobility.

Physical Activity Affect Scale (PAAS)

The PAAS scale is based upon exercise-induced feeling states and uses a Likert Scale of 0 – 4 with a zero being 'Do Not Feel' and a 4 being 'Feel Very Strongly'. This ranking task was done for 12 different descriptors. Four subscales of affect were assessed and are the following:

Positive Affect, Negative Affect, Tranquility, and Physical Exhaustion.[60] The Physical Activity Affect Scale was created in a response to the much longer Subjective Exercise Experiences Scale (SEES) and Exercise-Induced Feeling Inventory(EFI).[61] This assessment was taken in a questionnaire format after study participants completed each aquatic therapy session.

Pain Scale

The pain scale that was used in the prospective study has a scale of 1 – 10. The values of 1 – 2 indicate 'No Pain' while 9 – 10 indicate 'Very Severe' pain. Aquatic and recreational therapists asked study participants to rate their pain using this scale at the end of each aquatic therapy session. The prevalence of pain in the spinal cord injury population is commonly cited as 60 – 65% and a majority of patients localize pain below the level of injury.[62]

Rate of Perceived Exertion

In 1970, Dr. Gunner Borg constructed the Rate of Perceived Exertion (RPE) scale to estimate the level of effort and exertion individuals experience during an activity and it rated activities from a 6 - 20. This scale was later converted to the CR10 scale and rates perceived exertion from 0 – 10.[63] The CR10 scale was used and administered by aquatic and recreational therapists. A score of a 1 is described as 'Very Light Activity' and a 10 is described as 'Maximal Effort Activity'. A score of a '0' it is excluded as is quantified as 'At Rest'. The Borg CR10 RPE scale has high test-retest reliability and is valid when compared to the traditional 15-category RPE.[64]

Statistical analysis and Data Management

Baylor Institute for Rehabilitation eRehabData©

Patient outcome data in the form of Inpatient Rehabilitation Facility Patient Assessment Instruments (IRF-PAIs) is stored within eRehabData and was input into an Access database. The retrospective case report forms are based on these data.

Descriptive Statistics

Means, standard deviations (SD), and standard error of the mean (SEM) were used for continuous data. Median and interquartile ranges were used to summarize the aquatic therapy session data which included the number of sessions, the duration in minutes, and the number of breaks during the session in minutes. Counts and percentages were used to describe categorical data.

Demographic and Injury Data

The demographic data for this study included gender, race, ethnicity, and age at the time of injury. Additionally, AIS impairment scale, level of injury and if a participant is quadriplegic or paraplegic was used.

Between Group Analysis

Functional Independence Measure (FIM), spasticity medication use, and use of medication to control orthostatic hypotension were compared between the on-land therapy only group and on-land plus aquatic therapy group. In Table 3, the numeric outcomes were summarized with means and standard deviations or medians and interquartile ranges and compared using t-tests or Mann-Whitney U tests, respectively. Categorical variables were summarized with counts and percentages and compared using chi-square or Fisher's exact tests. In Table 4, regression analysis was used to determine if there was an association between aquatic

therapy groups and the outcomes as discharge, while controlling for the age at admission, race/ethnicity, Medicare as the primary payer, cause of injury, length of stay, and the status of the given outcome measure at admission. Binary outcomes were modeled with logistic regression and continuous outcomes were modeled with linear regression.

Ethics

The Baylor Institute for Rehabilitation registry protocol was reviewed by the Baylor Scott & White Institutional Review Board and approved on 12/10/2015 and 01/19/2018 (appendix B). The research proposal and protocol were reviewed by the North Texas Institutional Review Board and approved on 7/25/2018 (appendix B).

RESULTS

There were 102 patients with spinal cord injuries eligible for this analysis, with 57 of these patients (56%) having received aquatic therapy during inpatient rehabilitation stay. Table 1 summarizes and compares patient characteristics at admission. As shown in Table 1, there were significant differences between the Control and Intervention groups. Those patients who received aquatic therapy were younger, more likely to be African American or Hispanic, less likely to have Medicare as the primary payer, had a longer length of stay, and were twice as likely to be discharged home.

Table 2 summarizes the aquatic therapy sessions that were delivered to 57 patients using means and standard deviations, medians and interquartile ranges, and minimum to maximum. The average number of sessions that study subjects received was 9.5 ± 8.1 sessions and the average duration of each session was 34.4 ± 7.6 minutes.

TABLE 1: Summary of Patient Characteristics

	All (n=102)	Aquatic Therapy (n=57)	No Aquatic Therapy (n=45)	p-value
Age at Admit	40.1 ± 16.6	36.6 ± 14.8	44.4 ± 17.9	0.0191*
Male Gender	78 (76.5%)	46 (45.1%)	32 (31.4%)	0.2569
Race/Ethnicity				0.0349*
White	54 (52.9%)	27 (26.5%)	27 (26.5%)	
African American	30 (29.4%)	20 (19.6%)	10 (9.8%)	
Hispanic	14 (13.7%)	10 (9.8%)	4 (3.9%)	
Other	4 (3.9%)	0 (0%)	4 (3.9%)	
BMI	26 ± 6.6	25.2 ± 6	26.9 ± 7.1	0.1916
Medicare	18 (17.6%)	5 (4.9%)	13 (12.7%)	0.0081*
Cause of Injury				0.0211
Fall	17 (16.7%)	8 (7.8%)	9 (8.8%)	
Sports	13 (12.7%)	11 (10.8%)	2 (2%)	
Vehicular	43 (42.2%)	19 (18.6%)	24 (23.5%)	
Violence	23 (22.5%)	17 (16.7%)	6 (5.9%)	
Other	6 (5.9%)	2 (2%)	4 (3.9%)	0.9438
Paraplegic	48 (47.1%)	27 (26.5%)	21 (20.6%)	
SCI level				0.9818
Cervical	54 (52.9%)	30 (29.4%)	24 (23.5%)	
Thoracic	43 (42.2%)	24 (23.5%)	19 (18.6%)	
Lumbar	5 (4.9%)	3 (2.9%)	2 (2%)	
ASIA Impairment				0.3295
A - Complete	73 (71.6%)	43 (42.2%)	30 (29.4%)	
B - Sensory Incomplete	29 (28.4%)	14 (13.7%)	15 (14.7%)	
Length of Stay	40 (28 - 57)	46 (31 - 68)	33 (24 - 48)	0.0029*
Discharge Disposition				0.0226*
Home	63 (61.8%)	42 (41.2%)	21 (20.6%)	
Home Health	18 (17.6%)	7 (6.9%)	11 (10.8%)	
Skilled Nursing Facility	14 (13.7%)	4 (3.9%)	10 (9.8%)	
Short Term Hospital/Intermediate Care	7 (6.9%)	4 (3.9%)	3 (2.9%)	

Values are mean ± SD (% of total)
Abbreviations: BMI, Body Mass Index; SCI, Spinal Cord Injury; ASIA, American Spinal Injury Association; SD, Standard Deviation
*Statistically Significant

TABLE 2: Summary of Aquatic Therapy Sessions

	Mean ± St. Dev	Median (Q1, Q3)	min - max
Sessions Scheduled	12.1 ± 8.9	10 (6, 17)	1 - 38
Sessions Missed	2.6 ± 2.6	2 (1, 3)	0 - 11
Sessions Attended	9.5 ± 8.1	8 (3, 15)	0 - 34
Session Duration (minutes)	34.4 ± 7.6	30 (30, 38.1)	19.1 - 60
Breaks During Session (minutes)	0.8 ± 0.9	0.5 (0.3, 1)	0 - 5

Values are mean ± SD
Abbreviations: SD, Standard Deviation; min, minimum; max, maximum;
Q1 is the first quartile; Q3 is the third quartile.
n = 57 patients

Table 3 summarizes patient outcomes at admission and discharge. The data reveal there were no statistically significant differences between groups either at admission or upon discharge on the primary outcomes of FIM motor subscale, FIM cognition subscale, FIM total, and the secondary outcomes of spasticity medication use, orthostatic blood pressure medication use, blood pressure, and discharge wheelchair type.

Finally, the results of the regression analyses are presented in Table 4. These data show that despite controlling for the patient characteristics, the outcome measures are not statistically significant. Spasticity medication use, and orthostatic blood pressure medication use are presented as odds ratios and average blood pressure, average heart rate, and FIM scores are presented as Beta coefficients.

TABLE 3: Summary of Outcomes

	All (n=102)	Aquatic Therapy (n=57)	No Aquatic Therapy (n=45)	p-value
FIM Motor				
Admission	21.4 ± 8.8	21.5 ± 9.3	21.3 ± 8.3	0.9169
Discharge	42.7 ± 17.9	44.3 ± 17.5	40.6 ± 18.5	0.3086
Change	21.3 ± 11.9	22.8 ± 11.3	19.3 ± 12.4	0.1430
FIM Cognition				
Admission	25.9 ± 5.4	26.4 ± 4.2	25.2 ± 6.6	0.2447
Discharge	30.7 ± 4.4	31.1 ± 3.2	30.2 ± 5.6	0.2850
Change	4.8 ± 3.7	4.7 ± 3.5	5 ± 3.9	0.6851
FIM Total				
Admission	47.2 ± 11.1	47.9 ± 9.8	46.4 ± 12.5	0.5190
Discharge	73.4 ± 19.8	75.4 ± 17.7	70.8 ± 22.2	0.2453
Change	26.1 ± 12.9	27.5 ± 12.6	24.3 ± 13.3	0.2205
Change per day	0.8 ± 1	0.8 ± 0.6	1 ± 1.3	0.3039
Spasticity Medication Use				
Admission	72 (70.6%)	42 (41.2%)	30 (29.4%)	0.4399
Discharge	66 (64.7%)	40 (39.2%)	26 (25.5%)	0.1933
Orthostatic Blood Pressure Medication Use				
Admission	10 (9.8%)	4 (3.9%)	6 (5.9%)	0.2686
Discharge	18 (17.6%)	10 (9.8%)	8 (7.8%)	0.9755
Average Systolic Blood Pressure				
Admission	115.7 ± 13.9	114.3 ± 13.3	117.5 ± 14.7	0.2615
Discharge	114.4 ± 14.1	112.9 ± 14.5	116.3 ± 13.5	0.2301
Change	-1.4 ± 13.1	-1.5 ± 13.4	-1.2 ± 13	0.9219
Average Diastolic Blood Pressure				
Admission	68.4 ± 9.7	67.9 ± 9.4	69.1 ± 10.1	0.5158
Discharge	66.2 ± 8.9	65.9 ± 8.7	66.5 ± 9.2	0.7182
Change	-2.3 ± 9.9	-2 ± 8.9	-2.6 ± 11	0.7564
Average Resting Heart Rate				
Admission	79.1 ± 12.6	79.5 ± 12.6	78.5 ± 12.7	0.7153
Discharge	73 ± 11.2	71.9 ± 10.4	74.3 ± 12	0.2845
Change	-6.1 ± 12.1	-7.5 ± 12.2	-4.2 ± 11.9	0.1725
Discharge Wheelchair Type				0.1763
Power Only	43 (42.2%)	21 (20.6%)	22 (21.6%)	
Manual Only	52 (51%)	31 (30.4%)	21 (20.6%)	
Manual and Power	4 (3.9%)	4 (3.9%)	0 (0%)	
Unknown	3 (3%)	1 (1%)	2 (2%)	

Values are mean ± SD (% of total)
Abbreviations: FIM, Functional Independence Measure.

TABLE 4: Regression Results of Outcomes at Discharge

Discharge Outcomes	Odds Ratio (95% CI)/ Beta (se)*	p-value
Spasticity meds	1.76 (0.49, 6.31)	0.3855
Orthostatic blood pressure meds	0.31 (0.07, 1.33)	0.1134
Average Systolic Blood Pressure	0.69 (2.45)	0.7764
Average Diastolic Blood Pressure	2.36 (1.72)	0.1700
Average Heart Rate	-1.36 (2.03)	0.5029
FIM		
Motor	0.92 (2.16)	0.6700
Cognition	0.10 (0.65)	0.8810
Total	1.48 (2.62)	0.5721

Values are Odds Ratio (Beta).

*Odds ratios are interpreted as the odds of the given outcome for a patient who received aquatic therapy vs. the odds for patients who did not. Beta coefficients are interpreted as the average point increase/decrease a patient who received aquatic therapy will have vs. a patient who did not receive aquatic therapy.

DISCUSSION

The present practicum study was designed to provide initial evidence regarding whether aquatic therapy, in addition to traditional care, in complete spinal cord injury patients leads to better outcomes compared to patients who receive traditional, land-based, therapy only. The study design focused on examining outcomes between SCI patients who received aquatic therapy as part of their clinical care compared to SCI patients who received the current standard of care that did not include aquatic therapy. Analyses of the data indicate that there are no statistically significant differences between patients that received aquatic therapy in addition to traditional land-based therapy and those that received land-based therapy only in regard to spasticity

medication use, orthostatic blood pressure medication use, blood pressure, resting heart rate, FIM scores, and discharge wheel chair type. Regression analyses were performed to assess the differences between the two groups' outcomes while accounting for their demographic differences. Both groups obtained at least the MCID for change on the motor subscale for the FIM (22.8 ± 11.3 for the aquatic therapy group and 19.3 ± 12.4 for the group that did not receive aquatic therapy). The changes in the cognition subscale for both groups did not meet the MCID with a change of 4.8 ± 3.7 points for the aquatic therapy group and 4.7 ± 3.5 for the group that did not receive aquatic therapy, but as mentioned, the cognition subscale has a significant ceiling effect for the SCI population. A Brazilian study of aquatic therapy found the same to be true of the cognition subscale, but did find that the aquatic therapy group significantly improved compared to the control group on the total motor subscale and the transfer items on the FIM.[43] This study is discussed in further detail later in this section.

There were significant differences in the patient of characteristics between the two groups in our study, but they were mitigated in the regression analysis. The discharge disposition of patients showed that a greater percentage of those that received aquatic therapy were discharged home (42, 21) instead of home with home health (7, 11), or a skilled nursing facility (4, 10). The length of stay (LOS) was also significantly higher in the group that received aquatic therapy at 46 days while the land-based therapy only group stayed for 33 days. The median LOS according to SCIMS for traumatic SCI is 43 days for 2015 to 2017 which is based off of 2,429 admissions at SCIMS centers.[8] The median length of stay for both groups was 40 days, but the extent of aquatic therapy utilization for the SCI population was unclear and it is not something that is tracked by SCIMS so it is difficult to weight the medians for the groups accordingly. The average age at admission for the aquatic therapy group was 36.6 years where as the land-based

therapy only group was 44.4 years. The average age at time of injury for SCIMS was 42.7 years for 2015 to 2017 so the land-based therapy only group was again more comparable to SCIMS data.[8] It might be that the patients wanting to commit to the additional aquatic therapy tend to be younger which in this study the average age difference was 7.8 years. Further, the aquatic therapy group had more African American (20, 10) and Hispanic subjects (10, 4). There were also differences in the primary insurance: only 5 or 4.9% of the group that received aquatic therapy having Medicare and 13 or 12.7% of the land-based therapy only group having Medicare. There was no data to indicate if having Medicare decreases the likelihood that you will receive aquatic therapy during in-patient rehabilitation, but that could be a metric to be investigated further. Overall, 18 or 17.6% of the patient population that was studied had Medicare as the primary payer.

The group that received aquatic therapy were scheduled 12.1 sessions on average and attended an average of 9.5 sessions. Session duration was 34.4 minutes on average with an average break of 0.8 minutes. Using those numbers, the average study participant receiving aquatic therapy received about 5 hours and 19.2 minutes of aquatic therapy during their in-patient rehabilitation. Based on the median LOS of 40 days, patients received 8.0 minutes of aquatic therapy per day or 55.9 minutes per week. The Brazilian study referenced earlier had significant differences on some of the FIM metrics, but those patients received an average of 30 sessions each of a duration of 45 minutes. Their intervention group received greater than 3 times the number of sessions and sessions that lasted approximately 10 minutes longer. However, they only had a total of 16 study subjects with 8 in each group.[43]

Objective 2 of this practicum study was completed as intended, but there was not sufficient data collected for statistical analysis. Patient reported outcome data was only collected

on 7 study subjects for a total of 28 aquatic therapy sessions. For future use, the prospective case report forms have been standardized and are present in Appendix A. The aquatic therapists now have, as part of their electronic medical record (EMR) documentation, a place to record the patient reported outcome measures that include the Physical Activity Affect Scale (PAAS), Pain Scale, and the Rate of Perceived Exertion (RPE). These measures can now be input into the EMR for collection by researchers at a later date. Having it as a part of their documentation appears to be the most efficient way to capture the data at this time. This can be a model for collection of other measures in other studies and should not be limited to aquatic therapy studies.

STUDY LIMITATIONS

Missing or incomplete data

Missing data is the result of incomplete data entry by therapists into patients' charts that are used in the retrospective chart review. This missing data cannot be filled in after the fact and will be unknown. Data can be missing for any of the many metrics that are being studied. The same limitation exists for prospective trials. Even though the data entry is being done in real-time, therapists can still incompletely collect data or fail to enter all of the required data.

The scope of data collection

For the retrospective study, the metrics that have been measured are fixed. Investigators could not ask additional questions or request that additional patient assessments be completed by the therapists. This limits the scope of retrospective data collection and analysis. Other questions could include income, marital status, and occupation.

Lack of random assignment

Subjects were assigned to the two treatment protocols based on provider preferences. There is a protocol for assigning the physicians to patients, but that is not the same as a study level randomization where study subjects are assigned to two treatment arms at random by the investigators. This random assignment was not possible as this is a retrospective study. This lesser amount of randomization could limit the between-group outcome measure analysis as the composition of each group could differ. However, some of the differences between the study groups are adjusted for in the regression analyses.

Lack of previous research studies

Aquatic therapy for patients with spinal cord injuries is a new treatment modality and, therefore, has not been extensively studied. Furthermore, no published studies exist that specifically examine aquatic therapy in the complete spinal cord injury patient population. Thus, guidance for data collection and the metrics used are not well standardized for this treatment modality in this population.

Physician Preferences

Bias in the prescription of aquatic therapy by the one SCI provider is not an issue in this study because they are the only provider doing so. This however does limit the generalizability of the study as other SCI providers might have different protocols for the prescription of aquatic therapy.

Prospective Study

Early in the data collection for the prospective portion of this study, the EMR in-use at the study site was changed which created additional documentation work for the individuals doing the data collection. Therefore, not enough data were collected for analysis in the practicum

report. A new template for collection of the prospective data in the charts of eligible SCI patients has been created to mitigate this issue. The data that are collected going forward will then be used for future analyses.

Use of Two Different Therapists

During the period from which data was collected there was two different aquatic therapists that provided care to the intervention group. Both had a different level of experience, are in different stages of their respective careers, trained during separate time periods, and were taught at different schools. Although the therapy is specific to the individual patient's needs, the specific procedures that they follow and techniques that the two therapists use may be different. This could lead to a difference in the specific care that a patient would receive based on the therapist they were assigned to. It is difficult to estimate this possible qualitative difference in the delivery of care by the two therapists and the specific healthcare provider information was not collected.

SUMMARY AND CONCLUSIONS

Based on the results of this small retrospective study, aquatic therapy did not result in significantly better functional outcomes than traditional land-based therapy. In this sample of 102 participants, 57 of which received aquatic therapy and 45 did not. The main differences in this sample were the patient demographics, but the reasons for these differences were not investigated in this study. The study subjects that received aquatic therapy were 7.8 years younger on average. This could indicate that younger people might be able to better tolerate the additional therapy and therefore are more likely to go home without home health over those who

were older and were in the control group. As mentioned, there was a significant difference in the LOS for subjects receiving aquatic therapy with that cohort staying 13 median days longer. Perhaps the additional length of stay impacted the differences seen in the discharge dispositions between the two groups. Insurance could also be seen as a modifier for the two groups. An aspect to be investigated further is the impact of one's insurance provider on a patient's health and healthcare delivery in the in-patient rehabilitation setting.

Future studies should be done using a prospective study design with random assignment to the intervention group and the study protocol should ensure patients at least 25 – 30 sessions of a duration of 45 minutes per session. Ideally the length of stay and other significant differences seen in this study would be controlled for through the random assignment. Other measures such as the Modified Modified Ashworth Scale (MMAS) and the Spinal Cord Independence Measure III (SCIM III) could be included as outcome measures. These should be an improvement on the collection of spasticity medication use and could possibly be an improvement over FIM. The MMAS is used to evaluate the spasticity and it has very good inter-rater reliability for the upper and lower limb assessments.[65, 66] This is a revision of the Modified Ashworth Scale (MAS) and it modifies the scoring. This previous scale has scale has been studied in the SCI population and has excellent inter-rater reliability and substantial test-retest reliability.[67] The SCIM III has excellent internal consistency ($\alpha = 0.84 – 0.89$) and excellent inter-rater reliability (0.91 – 0.98). This assessment was specifically created for the spinal cord injury population.[68] It is possible that the FIM was not sensitive enough to detect a difference between the two study groups. SCIM III and MMAS could be used along with FIM to investigate the sensitivity of FIM in measuring change in the SCI population.

BIBLIOGRAPHY

1. Tripp F, Krakow K. Effects of an aquatic therapy approach (Halliwick-Therapy) on functional mobility in subacute stroke patients: a randomized controlled trial. *Clin Rehabil.* 2014;28:432-439.

2. Lai CJ, Liu WY, Yang TF, Chen CL, Wu CY, Chan RC. Pediatric aquatic therapy on motor function and enjoyment in children diagnosed with cerebral palsy of various motor severities. *J Child Neurol.* 2015;30:200-208.

3. Carroll LM, Volpe D, Morris ME, Saunders J, Clifford AM. Aquatic Exercise Therapy for People With Parkinson Disease: A Randomized Controlled Trial. *Arch Phys Med Rehabil.* 2017;98:631-638.

4. Becker BE. Aquatic therapy: scientific foundations and clinical rehabilitation applications. *PM R.* 2009;1:859-872.

5. Recio AC, Stiens SA, Kubrova E. Aquatic-Based Therapy in Spinal Cord Injury Rehabilitation: Effective Yet Underutilized. *Curr Phys Med Rehabil Rep.* 2017;5:108-112.

6. New PW, Cripps RA, Bonne Lee B. Global maps of non-traumatic spinal cord injury epidemiology: towards a living data repository. *Spinal Cord.* 2014;52:97-109.

7. National Spinal Cord Injury Statistical Center. Spinal Cord Injury Facts and Figures at a Glance. Birmingham, Alabama: University of Alabama at Birmingham; 2018.

8. National Spinal Cord Injury Statistical Center. 2017 Annual Statistical Report for the Spinal Cord Injury Model Systems Public Version. *Annual Statistical Reports.* Vol 2018. Birmingham, Alabama: University of Alabama at Birmingham; 2018.

9. United States Department of Commerce. United States Census Bureau QuickFacts: UNITED STATES. Vol 2018: U.S. Department of Commerce; 2018.

10. Ketchum JM, Cuthbert JP, Deutsch A, et al. Representativeness of the Spinal Cord Injury Model Systems National Database. *Spinal Cord.* 2018;56:126-132.

11. Kennedy P, Hasson L. An audit of demographics and rehabilitation outcomes in non-traumatic spinal cord injury. *Spinal Cord.* 2016;54:1020-1024.

12. McKinley WO, Seel RT, Hardman JT. Nontraumatic spinal cord injury: incidence, epidemiology, and functional outcome. *Arch Phys Med Rehabil.* 1999;80:619-623.

13. Kirshblum SC, Burns SP, Biering-Sorensen F, et al. International standards for neurological classification of spinal cord injury (revised 2011). *J Spinal Cord Med.* 2011;34:535-546.

14. Jan L, Thumbikat P. Pathophysiology, presentation and management of spinal cord injury. *Surgery.* 2015;33:238-247.

15. Karlsson AK. Overview: Autonomic dysfunction in spinal cord injury: clinical presentation of symptoms and signs. *Prog Brain Res.* 2006;152:1-8.

16. Khurana RK. Autonomic Dysreflexia. In: Aminoff M, Daroff R, eds. *Encyclopedia of the Neurological Sciences.* Vol 1. 2nd ed: Elsevier Inc.; 2014:345-347.

17. Verschueren JH, Post MW, de Groot S, van der Woude LH, van Asbeck FW, Rol M. Occurrence and predictors of pressure ulcers during primary in-patient spinal cord injury rehabilitation. *Spinal Cord.* 2011;49:106-112.

18. Kottner J, Raeder K. Assessment and Documentation of Pressure Ulcers. In: Thomas D, Compton G, eds. *Pressure Ulcers in the Aging Population. Aging Medicine.* Vol 1. Totowa, NJ: Humana Press; 2013:47-65.

19. Shavelle RM, DeVivo MJ, Brooks JC, Strauss DJ, Paculdo DR. Improvements in long-term survival after spinal cord injury? *Arch Phys Med Rehabil.* 2015;96:645-651.

20. Kraus JF, Franti CE, Borhani NO, Riggins RS. Survival with an acute spinal-cord injury. *J Chronic Dis.* 1979;32:269-283.

21. Devivo MJ. Epidemiology of traumatic spinal cord injury: trends and future implications. *Spinal Cord.* 2012;50:365-372.

22. van den Berg ME, Castellote JM, Mahillo-Fernandez I, de Pedro-Cuesta J. Incidence of nontraumatic spinal cord injury: a Spanish cohort study (1972-2008). *Arch Phys Med Rehabil.* 2012;93:325-331.

23. van den Berg ME, Castellote JM, de Pedro-Cuesta J, Mahillo-Fernandez I. Survival after spinal cord injury: a systematic review. *J Neurotrauma.* 2010;27:1517-1528.

24. Sabharwal S. *Essentials of Spinal Cord Medicine*. New York: Demos Medical; 2014.

25. Organization WH. International Classification of Functioning, Disability and Health (ICF). Geneva: World Health Organization; 2001.

26. Rouquette A, Badley EM, Falissard B, Dub T, Leplege A, Coste J. Moderators, mediators, and bidirectional relationships in the International Classification of Functioning, Disability and Health (ICF) framework: An empirical investigation using a longitudinal design and Structural Equation Modeling (SEM). *Soc Sci Med.* 2015;135:133-142.

27. Hawryluk GWJ, Nakashima H, Fehlings M. Classifying Spinal Cord Injury. In: Winn HR, ed. *Youmans and Winn Neurological Surgery*. 7th ed. Philadelphia, PA: Elsevier, Inc.; 2017:2292-2306.e2296.

28. Naqvi U, Sherman A. Muscle Strength Grading. *StatPearls*. Treasure Island (FL): StatPearls Publishing; 2018.

29. Stineman MG, Shea JA, Jette A, et al. The Functional Independence Measure: tests of scaling assumptions, structure, and reliability across 20 diverse impairment categories. *Arch Phys Med Rehabil.* 1996;77:1101-1108.

30. Mortenson B, Mak J, Zhu J. Craig Handicap Assessment & Reporting Technique (CHART). Vol 2018: Spinal Cord Injury Research Evidence; 2015.

31. Whiteneck GG, Charlifue SW, Gerhart KA, Overholser JD, Richardson GN. Quantifying handicap: a new measure of long-term rehabilitation outcomes. *Arch Phys Med Rehabil.* 1992;73:519-526.

32. Meyer C, Grenness C, Scarinci N, Hickson L. What Is the International Classification of Functioning, Disability and Health and Why Is It Relevant to Audiology? *Semin Hear.* 2016;37:163-186.

33. Heinemann AW, Lai JS, Wong A, et al. Using the ICF's environmental factors framework to develop an item bank measuring built and natural environmental features affecting persons with disabilities. *Qual Life Res.* 2016;25:2775–2786.

34. Fallah A, Dance D, Burns AS. Rehabilitation of the Individual with Spinal Cord Injury. In: Conerly K, ed. *Essentials of Spinal Cord Injury: Basic Research to Clinical Practice*. New York: Thieme; 2013:271-281.

35. Foy T, Perritt G, Thimmaiah D, et al. The SCIRehab project: treatment time spent in SCI rehabilitation. Occupational therapy treatment time during inpatient spinal cord injury rehabilitation. *J Spinal Cord Med.* 2011;34:162-175.

36. Whiteneck GG, Gassaway J, Dijkers MP, et al. Inpatient and postdischarge rehabilitation services provided in the first year after spinal cord injury: findings from the SCIRehab Study. *Arch Phys Med Rehabil.* 2011;92:361-368.

37. Teeter L, Gassaway J, Taylor S, et al. Relationship of physical therapy inpatient rehabilitation interventions and patient characteristics to outcomes following spinal cord injury: the SCIRehab project. *J Spinal Cord Med.* 2012;35:503-526.

38. Geigle P. Comparison of Lokomat and Aquatic Exercise for Individuals with Chronic Incomplete Spinal Cord Injury: University of Maryland; 2016:NCT01407354.

39. Zivi I, Maffia S, Ferrari V, et al. Effectiveness of aquatic versus land physiotherapy in the treatment of peripheral neuropathies: a randomized controlled trial. *Clin Rehabil.* 2018;32:663-670.

40. Jones ML, Evans N, Tefertiller C, et al. Activity-based therapy for recovery of walking in individuals with chronic spinal cord injury: results from a randomized clinical trial. *Arch Phys Med Rehabil.* 2014;95:2239-2246 e2232.

41. Jung J, Chung E, Kim K, Lee BH, Lee J. The effects of aquatic exercise on pulmonary function in patients with spinal cord injury. *J Phys Ther Sci.* 2014;26:707-709.

42. Zhang Y, Wang YZ, Huang LP, et al. Aquatic Therapy Improves Outcomes for Subacute Stroke Patients by Enhancing Muscular Strength of Paretic Lower Limbs Without Increasing Spasticity: A Randomized Controlled Trial. *Am J Phys Med Rehabil.* 2016;95:840-849.

43. Silva MCRD, Oliveira RJD, Conceição MIG. Effects of swimming on the functional independence of patients with spinal cord injury. *Rev Bras Med Esporte.* 2005;11:237e-241e.

44. Kesiktas N, Paker N, Erdogan N, Gulsen G, Bicki D, Yilmaz H. The use of hydrotherapy for the management of spasticity. *Neurorehabil Neural Repair.* 2004;18:268-273.

45. Stevens SL, Caputo JL, Fuller DK, Morgan DW. Effects of underwater treadmill training on leg strength, balance, and walking performance in adults with incomplete spinal cord injury. *J Spinal Cord Med.* 2015;38:91-101.

46. Wall T, Falvo L, Kesten A. Activity-specific aquatic therapy targeting gait for a patient with incomplete spinal cord injury. *Physiother Theory Pract.* 2017;33:331-344.

47. Tamburella F, Scivoletto G, Cosentino E, Molinari M. Walking in water and on land after an incomplete spinal cord injury. *Am J Phys Med Rehabil.* 2013;92:e4-15.

48. Thomaz S, Beraldo P, Mateus S, Horan T, Leal JC. Effects of partial isothermic immersion on the spirometry parameters of tetraplegic patients. *Chest.* 2005;128:184-189.

49. Recio A, Kubrova E. Effectiveness of Aquatic Therapy Among Spinal Cord Injury Patients With Complex Medical Conditions. *Arch Phys Med Rehabil.* 2017;98:e60.

50. Li CX, Khoo S, Adnan A. Effects of aquatic exercise on physical function and fitness among people with spinal cord injury. *Medicine.* 2017;96.

51. Recio A, Cabahug P. Safety of Aquatic Therapy for Adults with Complex Medical Conditions Amount Chronic Spinal Cord Injury. *J Spinal Cord Med.* 2016;39:568.

52. Medicare Benefit Policy Manual. In: Services CfMM, ed. *Chapter 1.* Vol 110.2.2 - Intensive Level of Rehabilitation Services. Rev. 112 ed. CMS.gov2017.

53. Mackintosh S. Functional independence measure. *Aust J Physiother.* 2009;55:65.

54. Ottenbacher KJ, Hsu Y, Granger CV, Fiedler RC. The reliability of the functional independence measure: a quantitative review. *Arch Phys Med Rehabil.* 1996;77:1226-1232.

55. Alexander MS, Anderson KD, Biering-Sorensen F, et al. Outcome measures in spinal cord injury: recent assessments and recommendations for future directions. *Spinal Cord.* 2009;47:582-591.

56. Saltychev M, Lähdesmäki J, Jokinen P, Laimi K. Pre- and Postintervention Factor Structure of Functional Independence Measure in Patients with Spinal Cord Injury. *Rehabil Res Pract.* 2017;2017:1-7.

57. Hall KM, Cohen ME, Wright J, Call M, Werner P. Characteristics of the Functional Independence Measure in traumatic spinal cord injury. *Arch Phys Med Rehabil.* 1999;80:1471-1476.

58. Taylor T. Ceiling effect. In: Salkind NJ, ed. *Encyclopedia of Research Design*. Thousand Oaks, CA: SAGE Publications, Inc.; 2010:133-134.

59. Jackson KC, Argoff CE, Dubin A. Skeletal Muscle Relaxants. In: Benzon HT, ed. *Practical Management of Pain*. 5th ed. Philadelphia, PA: Elsevier; 2014:569-574.e561.

60. Carpenter L, Tompkins S, Schmiege S, Nilsson R, Bryan A. Affective Response to Physical Activity: Testing for Measurement Invariance of the Physical Activity Affect Scale Across Active and Non-Active Individuals. *Meas Phys Educ Exerc Sci.* 2010;14:1-14.

61. Lox C, Jackson S, Tuholski S, Wasley D, Treasure D. Revisiting the Measurement of Exercise-Induced Feeling States: The Physical Activity Affect Scale (PAAS). *Meas Phys Educ Exerc Sci.* 2000;4:79-95.

62. Norrbrink Budh C, Lund I, Ertzgaard P, et al. Pain in a Swedish spinal cord injury population. *Clin Rehabil.* 2003;17:685-690.

63. Borg G. *Borg's Perceived exertion and pain scales*. Champaign, IL: Human Kinetics; 1998.

64. Robertson RJ, Noble BJ. Perception of Physical Exertion: Methods, Mediators, and Applications. *Exerc Sport Sci Rev.* 1997;25:407-452.

65. Ghotbi N, Nakhostin Ansari N, Naghdi S, Hasson S. Measurement of lower-limb muscle spasticity: intrarater reliability of Modified Modified Ashworth Scale. *J Rehabil Res Dev.* 2011;48:83-88.

66. Ansari NN, Naghdi S, Mashayekhi M, Hasson S, Fakhari Z, Jalaie S. Intra-rater reliability of the Modified Modified Ashworth Scale (MMAS) in the assessment of upper-limb muscle spasticity. *NeuroRehabilitation.* 2012;31:215-222.

67. Akpinar P, Atici A, Ozkan FU, et al. Reliability of the Modified Ashworth Scale and Modified Tardieu Scale in patients with spinal cord injuries. *Spinal Cord.* 2017;55:944-949.

68. Nitsch KP, Stipp KL. Measurement Characteristics and Clinical Utility of the Spinal Cord Independence Measure-III Among Individuals With Spinal Cord Injury. *Arch Phys Med Rehabil.* 2016;97:1601-1603.

CHAPTER III

INTERNSHIP SITE

My research internship practicum was completed at the Baylor Scott & White Institute for Rehabilitation (BSWIR) in Dallas, Texas. BSWIR is an in-patient rehabilitation hospital with 92 beds that shares the Baylor University Medical Center (BUMC) campus with 6 other hospitals. Many of the patients that stay at the rehabilitation hospital come from the Level I Trauma Center. The internship was mainly completed at the research office in BSWIR while survey delivery for the Patient Report of Intermittent Catheterization Experience (PRICE) study and screenings for the Workout on Wheels Internet Intervention (WOWii) study were completed at an out-patient clinic at the Baylor Tom Landry Center.

JOURNAL SUMMARY

At the Baylor Scott & White Institute for Rehabilitation I spent my time on other projects in addition to the practicum study. These studies included Workout on Wheels Internet Intervention (WOWii), Patient Report of Intermittent Catheterization Experience (PRICE), Traumatic Brain Injury Model Systems (TBIMS), and Group Lifestyle Balance Traumatic Brain Injury (GLB-TBI). My work in these projects constituted screening of patients, correspondence with the offices of medical providers, delivery of surveys to patients, and correspondence with study subjects to assist in data collection. These responsibilities greatly developed me in my role as a clinical researcher and the patient interactions taught me much in regard to communication and development of rapport with study subjects.

Also included in my internship were various trainings on the Functional Independence Measure, empathy, informed consent, hospital protocol, and the safety and confidentiality of patients. These trainings were given by various therapists at the institute, administrative staff, the education department, and the chaplain. In addition to these trainings I had the opportunity to attend the Physical Medicine & Rehabilitation (PM&R) Grand Rounds. These sessions included a variety of rehabilitation and healthcare topics including the treatment and management of sports related concussions, the response of the UT Southwestern trauma department after the shootings at the Black Lives Matter rally in Dallas, and how sleep deprivation affects the performance of medical and surgical residents in the United States.

APPENDIX A

CASE REPORT FORMS

Retrospective Case Report Form

Eligibility		
Inclusion: All answers must be, "yes," for questions 1-3 in order for the subject to be eligible.		
1. Was the participant undergoing inpatient rehabilitation?	☐ Yes	☐ No
2. Was the participant continent of bowel and bladder or had a foley catheter in place?	☐ Yes	☐ No
3. Was the participant an AIS A or B?	☐ Yes	☐ No
Exclusion: All answers must be, "no," for question 4 in order for the subject to be eligible.		
4. Did the patient have a wound that was classified as stage 3 or 4?	☐ Yes	☐ No

Demographic and Injury Information	
1. Gender *gender* 1 – Male; 2 – Female	☐
2. Ethnicity *ethnicity* 1 – Hispanic; 2 – Non-Hispanic; 9 – Unknown/Missing	☐
3. Race *race* 1 – American Indian/Alaska Native; 2 – Asian; 3 – Native Hawaiian/Pacific Islander; 4 – Black or African American; 5 – White or Caucasian; 6 – More than one race; 9 – Unknown/Missing	☐
4. Date of Birth *dob* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
5. Injury Date/Onset Date *doi* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
6. Insurance type *Ins* 1 – Private Insurance; 2 – Self-pay or uninsured; 3 – Medicaid; 4 – Medicare; 5 – Tricare; 6 – Other; 9 – Unknown/Missing	☐
7. Discharge disposition *dcdisp* 1 – Private Residence (house/apartment); 2 – Nursing Home; 3 – Adult Home; 4 – Correctional Institution; 5 – Hotel/Motel; 6 – Homeless; 7 – Hospital; 8 – Other; 9 – Unknown/Missing	☐
8. Inpatient Rehab Admission Date *ipadmdate* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
9. Inpatient Rehab Discharge Date *ipdcdate* Enter 09/09/9999 if unknown/missing.	☐☐/☐☐/☐☐☐☐
10. Number of rehabilitation interruptions Enter 99 if unknown.	☐☐

11. What was the mechanism of injury if traumatic? *mechInj* 1 – Motor Vehicle; 2 – Motorcycle; 3 – Bicycle; 4 – ATV/ATC/Go-Cart; 5 – Other Vehicular; 10 – Gunshot Wound; 11 – Assaults with Blunt Instrument; 12 – Other Violence; 13 – Water Sports; 14 – Field/Track Sports; 15 – Gymnastic Activities; 16 – Winter Sports; 17 – Air Sports; 18 – Other Sports; 19 – Fall; 20 – Hit by Falling/Flying Object; 21 – Pedestrian; 77 –Other Unclassified; 88 – N/A, non-traumatic; 99 - Unknown	☐☐
12. Is the subject a paraplegic or tetraplegic? *paratet* 1 – Paraplegic; 2 – Tetraplegic; 8 – N/A, non-SCI; 9 – Unknown	☐
13. What is the level of spinal cord injury (for SCI only)? *scilevel* 1 – Cervical; 2 – Thoracic; 3 – Lumbar; 4 –Unknown	☐
14. What is the subject's ASIA Impairment Scale? *ais* 1 – A (Complete); 2 – B (Sensory Incomplete); 3– Unknown	☐

PI Signature: _____Date:_____

Outcome Measures

1. FIM
   0-7; 9 – Unknown/Missing

	Admission	Discharge
1. Feeding	☐	☐
2. Grooming	☐	☐
3. Bathing	☐	☐
4. Dressing upper body	☐	☐
5. Dressing lower body	☐	☐
6. Toileting	☐	☐
8. Bladder management	☐	☐
9. Bowel management	☐	☐
10. Bed, chair, wheelchair transfers	☐	☐
11. Toilet transfers	☐	☐
12. Tub or shower transfers	☐	☐
14a. Walking on admission	☐	■
14b. Wheelchair on admission	☐	■
14c. Walking/wheelchair–mode at d/c (w/c/9)	■	☐
14d. Walking/wheelchair at discharge	■	☐
15. Stairs	☐	☐
17. Comprehension	☐	☐

18. Expression	☐	☐
22. Social interaction	☐	☐
26. Problem solving	☐	☐
27. Memory	☐	☐

Outcome Measures	
2. Was the participant taking any medication for spasticity?	Admission: ☐ Yes ☐ No; Discharge: ☐ Yes ☐ No
3. Was the patient taking any medication for orthostatic blood pressure control?	Admission: ☐ Yes ☐ No; Discharge: ☐ Yes ☐ No
4. What is the number of total aquatic therapy sessions?	☐☐
5. What is the number of missed aquatic therapy sessions?	☐☐
6. For each aquatic therapy session, how long was the session and how many rest breaks did the patient require?	Aquatic therapy session / Duration / Amount of rest breaks

Prospective Case Report Form

Physical Activity Affect Scale					
Use the following scale to indicate the extent to which each word describes how you feel at this moment					
	Do Not Feel	Feel Slightly	Feel Moderately	Feel Strongly	Feel Very Strongly
1. Upbeat	0	1	2	3	4
2. Calm	0	1	2	3	4
3. Energetic	0	1	2	3	4
4. Tired	0	1	2	3	4
5. Peaceful	0	1	2	3	4
6. Miserable	0	1	2	3	4
7. Worn-out	0	1	2	3	4
8. Relaxed	0	1	2	3	4
9. Fatigued	0	1	2	3	4
10. Discouraged	0	1	2	3	4
11. Enthusiastic	0	1	2	3	4
12. Crummy	0	1	2	3	4

Pain Scale										
	None		Mild		Moderate		Severe		Very Severe	
How would you rate your pain?	1	2	3	4	5	6	7	8	9	10

Rate of Perceived Exertion									
Very Light Activity	Light Activity		Moderate Activity			Vigorous Activity		Very Hard Activity	Maximal Effort
1	2	3	4	5	6	7	8	9	10

Rate of Perceived Exertion	
How hard do you feel like your body is working during this activity?	
Maximal Effort Activity Feels almost impossible to keep going. Cannot maintain for more than a very short time. Completely out of breath. Unable to talk.	**10**
Very Hard Activity Very difficult to maintain exercise intensity. Can barely breathe. Can only say a few words.	**9**
Vigorous Activity Borderline uncomfortable. Short of breath. Can only speak a sentence.	**8** **7**
Moderate Activity Somewhat comfortable but becoming noticeably more challenging. Breathing heavily. Can hold a short conversation.	**6** **5** **4**
Light Activity Feels like you can maintain for hours. Easy to breathe. Can carry a conversation.	**3** **2**
Very Light Activity Hardly any exertion, but more than sleeping, watching TV, etc.	**1**

APPENDIX B

IRB DOCUMENTS

IRB Acknowledgement of Key Study Personnel Change – 06/18/2018

IRB Acknowledgement – Key Study Personnel Change

To: Simon Driver, PhD

Copy to: Libby Callender, Simon Driver, PhD

Date: June 18, 2018

Re: 015-287
Baylor Institute for Rehabilitation Registry Protocol

Reference Number: 315717

This review included the following components:

List of Personnel to Add to the Project

Name	Role on the Project
David Bailey	Research Associate/Other Research Staff

If you need additional assistance, please contact the IRB Specialist at 254-771-4869 or 214-820-9692.

Baylor Institute for Rehabilitation Registry Protocol Revision Approval – 01/19/2018

IRB Approval – Expedited Review of Revision

To: Simon Driver, PhD

Copy to: Libby Callender, Simon Driver, PhD

Date: January 19, 2018

Re: 015-287
Baylor Institute for Rehabilitation Registry Protocol
Reference Number: 308888

Your proposed revision was reviewed by a designated member of Baylor Scott & White Research IRB Red via expedited review.

This review included the following components:

Submission Components			
Submission Form			
Form Name		Outcome	
Revision Form		Approved as Presented	
Study Application			
Form Name		Outcome	
Study Application - Review by BSWRI IRB		Approved as Presented	
Study Document			
Title	Version #	Version Date	Outcome
BIR Umbrella Protocol v2 1-17-18	Version 1.5	01/17/2018	Approved

This revision was determined to be eligible for expedited review as it is a minor change to previously approved research, during the period (no more than one year) for which the research is approved. Further we have determined that this change does not present an increase in risk or a significant change to the overall risk to benefit ratio.

Your submission has been approved. This approval is effective on 01/19/2018. Any aspect of your previously submitted project that is not specifically addressed in this submission remains approved as previously presented. Your expiration date and scheduled continuing review are unchanged.

If this submission includes changes to the informed consent document(s), re-consent is required in accordance with the plan as outlined in the revision request form. If re-consent is not appropriate for some of the subjects involved in the study, this would have been documented in this section of the form.

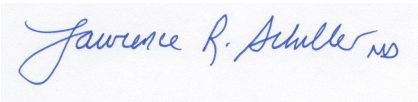
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Scott & White Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Specialist at 214-820-9989 (NTX) 254-771-4836 (CTX).

Sincerely,



Signature applied by Lawrence R. Schiller on 01/20/2018 12:58:33 PM CST

Baylor Institute for Rehabilitation Registry Protocol IRB Approval Letter – 12/10/2015

BAYLOR Research Institute
Affiliated with Baylor Health Care System

IRB Approval – Expedited Review of New Study

To: Simon Driver

Copy to: Libby Callender, Simon Driver

Date: December 10, 2015

Re: 015-287
Baylor Institute for Rehabilitation Registry Protocol
Reference Number: 094850

Your new proposal was reviewed by a designated member of Baylor IRB Red via expedited review.

This study was determined to be eligible for expedited review as it involves no greater than minimal risk to the subjects and fits into the following category(ies) from the 1998 approved list:
Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

This review included the following components:

Study Application	
Form Name	Outcome
Study Application - Review by BRI IRB	Approved as Presented

Study Document			
Title	Version Number	Version Date	Outcome
Umbrella registry Form 15	Version 1.1	11/12/2015	Approved
BIR Umbrella Protocol v1 9.22.2015	Version 1.1	11/12/2015	Approved
Umbrella registry Form 34	Version 1.0	11/12/2015	Approved
Umbrella registry Form 18	Version 1.0	11/12/2015	Approved

Your submission has been approved. The approval period begins on 12/10/2015 and expires on 12/09/2016. Your next continuing review is scheduled for 10/10/2016.

This study is approved to be conducted at the following locations:
Baylor Institute For Rehabilitation, Main-Dallas, BIR-Inpatient Therapy

The following individuals are approved as key study personnel (research team members & administrative support):
Callender, Libby; Driver, Simon; Dubiel, Rosemary, DO; Reynolds, Megan, MS; Sikka, Seema, MD; Watford, Monica; Woolsey, Ann, MS

Based on the information provided in your submission, the IRB has determined that this study qualifies for a waiver of informed consent in accordance with 45 CFR 46.116 (d) and a waiver of HIPAA Authorization 45 CFR 160 and 164.

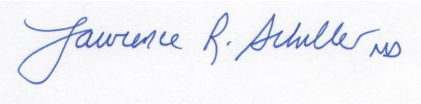
All events that occur on this study including protocol deviations, serious adverse events, unanticipated problems involving risks to subjects/others, subject complaints or other similar events must be reported to the IRB in accordance with the respective policies.

Remember that this study is approved to be conducted as presented. Any revisions to this proposal and/or any of the referenced documents must be approved by the IRB prior to being implemented. Additionally, if you wish to begin using any new documents, these must receive IRB approval prior to implementation of them in the study.

IRB approval may not be the final approval needed to begin the study. All contractual, financial or other administrative issues must be resolved through Baylor Research Institute prior to beginning your study.

If you need additional assistance, please contact the IRB Specialist at 214-820-9989.

Sincerely,



Signature applied by Lawrence R. Schiller on 12/10/2015 10:27:19 PM CST

University of North Texas Health Science Center IRB Approval – 07/25/2018

UNT Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board
BOARD ACTION

IRB Project #: 2018-017 Date Submitted: July 23, 2018

Principal Investigator: Stephen Mathew, PhD (with CRM student: D. Bailey)

Project Title: Baylor Institute for Rehabilitation Registry Protocol (BIR Umbrella)

Sponsor Protocol #:

Department: Clinical Research Management / GSBS Contact Info: x 5407

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project. Approval, when given,is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

The Principal Investigator must notify the IRB immediately if any new potential Conflict of Interest arises or if CITI educational training lapses for any of the Key Personnel involved with the study.

☑ Project has received approval through: **July 25, 2019**

☐ Informed consent(s*) approved as submitted on :

You **MUST** use the version (s) attached rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

*Including:

☐ Study Protocol dated _____ approved as submitted.

☐ Investigator's Brochure _____ approved as submitted.

☐ Protocol Synopsis approved as submitted on: _____

☐ Amendment _____ to the protocol approved as submitted.

☐ Progress Report/Continuing Review completed, project has received approval through: _____

☐ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "tracked changes" version showing the markup and one "clean" copy of the revised protocol synopsis, informed consent, and advertisements to the IRB for review. ***YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.***

☐ Project is disapproved for the reason(s) outlined (see attached).

☐ Consideration of the project has been **DEFERRED** pending resolution of the issues(s) outlined (see attached).

☐ Completion of project is acknowledged and all required paperwork has been received.

☑ Special Findings/Other

The UNTHSC IRB acknowledges that the activity is conducted under the oversight of the Baylor Scott and White IRB (Protocol # 015-287). Dr. Mathew serves as the faculty contact for this CRM internship project.

Chairman, Institutional Review Board

7/25/18
Date

IRB Form 2 (revised March 2011)

Board Action-page 2

PI: Stephen Mathew, PhD

IRB Project #: 2018-140

Date: 07/25/2018

SPECIAL FINDINGS:

☐ CHILDREN: The Board found the participation of children to be approvable under Subpart D of the federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR 46.404** ☐ **21 CFR**

☐ COGNITIVELY IMPAIRED: The Board found the participation of cognitively impaired subjects to be approvable under federal regulations. Specifically, the research satisfies the requirements of:

☐ **45 CFR 46.111 (b)** ☐ **21CFR 56.111 (b)**

☐ PREGNANT WOMEN: The Board found the participation of pregnant female subjects to be approvable under Subpart B of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.204 (a) - (i)**

☐ FETUSES/NEONATES: The Board found the involvement of fetuses/neonates to be approvable under *Subpart B* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR**

☐ PRISONERS: The Board found the participation of prisoners to be approvable under *Subpart C* of federal regulations. Specifically, the research satisfies the requirements of: **45 CFR 46.305 (a), (b) and (c)**

☐ OTHER:

OTHER

☑ **Expedited Review Procedures (under 45 CFR 46)**

Project ☑ Approved ☐ Approved for Continuation ☐ Modifications approved **under the provisions of:**
45 CFR 46.110 (b)(1) category (7) **45 CFR 46.110 (b) (1) category (5)**

Registry project; analysis of medical records

☐ **45 CFR 46.110 (b) (2)** minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

☑ **HIPAA Waiver:** The Board finds this study meets all legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i) (2) (i)-(v) and approves the request under:

Expedited Review Procedures (21 CFR 56.110 and 45 CFR 46.110)

☑ **Informed Consent Waiver:** The Board finds this project qualifies for a **Wavier of Informed Consent** under the provisions of **45 CFR 46.116 (d) (1), (2), (3) & (4)**

☐ **Other IRB Approved Research Documentation Includes:**

☐ **Other Comments:**

APPENDIX C

INTERNSHIP PRACTICUM JOURNAL

Day 1 – Tuesday, May 29, 2018

I arrived at 7:30 am today and had some time to send a few emails prior to entering the office. After that I met with Libby and she set me up with a laptop computer to use during the internship. As I expected, my first attempt at logging into the next work was unsuccessful and I was referred to the help desk. It took about an hour to get everything worked out, but I was good to go after that. Later, I was given a tour of the rest of the campus and was shown the best places to eat, varying departments, and the hand museum. The online training modules for research and for Baylor were next which took several hours but are a necessity for my participation in research. Finally, I ended the day with a lead for my research proposal to study the efficacy of aquatic therapy in patients with spinal cord injuries.

Day 2 – Wednesday, May 30, 2018

Today I went to the parking office first thing in the morning to get a badge and a parking pass. Therefore, I got to the research office at 9 am which was later than the previous day. I started to work on a literature review of published work in aquatic therapy. Around 1 pm, I attended a staff meeting in which the group reviewed administrative goals and a strategy to create a concise set of core values for the Baylor Scott & White Health facilities. Staff members received badge buddies for voluntarily creating commitments for themselves going forward

which was great. Libby reviewed proper practice in the creation and presentation of research abstracts and posters. This was especially helpful to me as I have not, previously, presented a project in that format. Next, the team met with previous traumatic brain injury patients for their annual advisory board meeting for ongoing research projects in this field. It was fortunate that my internship started this week, otherwise I would have missed this valuable meeting. The board meeting greatly expanded my limited knowledge on the subject. I got to meet some traumatic brain injury survivors and their family members who serve as board members. Their input on the current research projects and collaborations of the institute gave me some insight into the struggles they have had throughout their experience. I now have a good idea of the varying levels of brain injury and how they affect patients long term. Also, I gained an appreciation of how important it is to engage stakeholders in the community and receive face-to-face input to create future directions and correct possible issues that will impact the lives of others.

Day 3 – Thursday, May 31, 2018

I am still getting used waking up early to drive from Richardson to Downtown Dallas for my internship, so this morning was a bit slow, but I'll get used to it. Despite any struggles I had getting going, I got in at 7:28, which was just before the cafeteria opened for breakfast. A few minutes later and I was on my way. Thankfully, I was able to gain access to the main office around 7:35 so that my food did not get cold. After breakfast, I continued to work on my literature review throughout the day and learned much more about to aquatic therapy and other rehabilitation methods for patients with spinal cord injuries. Around 11:00 I gathered up and mailed the birthday cards for the first half of June. This wasn't hard, but it did offer a break from the articles that I was reading at the time. After that I ate lunch and continued my compilation of

publications. Now, I have enough information to have a good idea of the past and present research in relation to aquatic therapy.

Day 4 – Friday, June 1, 2018

Today was a shorter day and I got there early again and left earlier than usual. Most of my day was spent reviewing additional literature and adding to the spreadsheet I created. Unfortunately, there isn't too much that I can do yet because I need additional resource access. Sadly, there were not any meetings today, but this gave me an opportunity to ask questions about the research project and learn about a health literacy study that the research department has going. Lacy was very nice to review the survey process with me. In addition to all of the progress I made, I had Libby setup a meeting with the resident that is currently working on the project.

Week 1 summary

At the start of my research internship I did not know what to expect. I met with Libby a couple of weeks earlier at a luncheon in Fort Worth, but this was my first week at the research site. There are many ongoing projects in addition to the study I am participating in, so I'm sure that I will have plenty to do once I have access to clinical data and other network applications to help me with my duties as an intern. I am excited to learn more about clinical research and to get to know people better next week. I'll also have a better idea of what exactly I'll be doing for the next 6 months. Everyone I've met so far is nice and I look forward to working with them. I should have a committee meeting within the coming weeks to discuss my research proposal and the content of my internship practicum.

Day 5 – Monday, June 4, 2018

Today is the start of the 2nd week and is likely what people think of as a normal start to a Monday. The weather was bad, and I could see the eventual doom coming as I got closer to the

research institute. There was heavy rainfall and I was not surprised when I got soaked on my walk from the parking lot. All things equal, it could have been worse, but I have now added a raincoat and an umbrella to the things I haul around in my car. Anyways, I didn't have too much planned for today as I went deep into the existing research on aquatic therapy last week. In the meantime, I updated the display board on the first floor with fresh publications along with Amiee. Some of my creativity did come out as color was added to the board to make the publications more appealing to the patients and visitors who walk by. Hopefully they stop to look at some of the recent work that the institute has done along with the ongoing studies that are open for enrollment. From what I have seen, throughout my literature review, sample size hurts many studies as a low sample size limits the statistical power of the data and the applicability of the study. This can be secondary to lack of funding. However, many of the participants might not be appropriate for the investigation based upon the inclusion and exclusion criteria, but the more signups, the better. There was another staff meeting today to discuss the status of current studies and objectives for this month. This was important as I now have additional information on the current activities of the office in addition to people delegating more tasks to me. Hopefully I can offer assistance in the ongoing studies.

Day 6 – Tuesday, June 5, 2018

Today I arrived around 8:15 and started to review the research I've done so far on the aquatic therapy study in preparation for the meeting tomorrow. A new intern, Ryan Totz, from the University of North Carolina, Chapel Hill started today and will continue his internship for the next 8 weeks. He will be working on a stroke project in addition to the curriculum his program has set for him. After I helped him get setup, I was informed that there were additional trainings I had to do from CITI. This took up much of the time I had left in the office today, but I

finished all of it prior to leaving. In the afternoon, I went to Walk and Roll with a DOC along with other people from the office. It was a good break from work and it gave me some exercise for the day. We had a group of about 15 for the event and one of the doctors discussed the importance of diet and exercise for health and maintenance of a normal weight. Dr. Zhang mentioned that 70% of weight control is diet based and 30% is exercise related. I agree with that assessment and I took approximately 2,000 steps at the event, on the circular track we walked. When I got back to the office I finished a few things and printed my CITI certificates for future use.

Day 7 – Wednesday, June 6, 2018

I arrived at about 7:45 today and Ryan arrived later, and we worked on our respective projects in the morning. He continued with the project he selected for his 8-week internship in aquatic therapy with individuals who have had cerebrovascular accidents (CVA)s. This was mentioned in a few articles I read, but I do not have an in-depth understanding of it yet. Perhaps as I do more research I will attain additional knowledge in this subject. Later that day, I was introduced to Jim who has been a volunteer for the past several years. It's great for him to have donated his time for that long.

Day 8 – Thursday, June 7, 2018

Today I got to the office at 7:30. After this, I worked on access to Baylor's Integrated Research Information System (iRIS) since I will use this later in my internship. This required a few emails to my coordinator and some interaction with the help desk for Baylor Scott & White of North Texas. There was a typo in my username for iRIS, but that is now fixed. For the remainder of the day I looked up articles outside of my state project, aquatic therapy for spinal

cord injuries, to further familiarize me with the standard of care for aquatic therapy and documentation.

Day 9 – Friday, June 8, 2018

Traffic today was not too bad, but I left about 25 minutes later than usual so I got to the office at 7:55. Aimee let me in since I was the first person to the office and do not have a key. I checked my email and I had one that confirmed access to select network, which I need to access studies the research office is doing. This is a good step toward actually doing clinical work. Due to this, I spent most of my morning doing the modules associated with it. Hopefully, now that this is complete, I'll have access to E-Rehab Monday so I can start extracting data for my project and for other ongoing projects. Later in the afternoon I met with Leah Holderbaum who is an occupational therapist at the institute to talk about a new study analyzing catheter use in patients with spinal cord injuries. This is exciting because I will be working directly with patients and I haven't had much experience in that area. I still need to work on delivering the questions, but my practice with her was a good start.

Week 2 Summary

From my experiences this week, I am well on my way to participate in research projects that the institute is doing. I hope to help with a few studies by delivering surveys and make more progress on my project next week. After meeting with my committee members, next Friday, I will have a better idea of their expectations of me and have additional guidance for my research project.

Day 10 – Monday, June 11, 2018

Today I arrived at 7:50 for an 8 am meeting in regard to the aquatics study, I will be working on once it is approved by my committee. I believe the meeting when well and we now

know more information on the current status of the prospective portion of the project. There are issues with EPIC documentation that need to be resolved and we need to work on creating a database for entry of study related data. Later that day, I went to a START class for patients with spinal cord injuries in which the staff reviewed the anatomical aspects of a spinal cord injury and physiological changes that come with such injuries. It was informative, and I think it gave the patients that were there a good introduction to the care they will receive at the institute. After that, I worked on finding a different metric to assess patients' affect after exercise and a more abbreviated scale for the rate of perceived exercise (RPE). The current metrics take too long to go through and patients appear to become easily disinterested in the questions. We still need to work out a better solution for measurement of affect, but I was able to locate a different scale for RPE.

Day 11 – Tuesday, June 12, 2018

I made it to the office at 7:15 today despite the unfortunate collision I sustained with another vehicle on the commute. No one was hurt and at the end of the day, cars are repairable. I attended the Physical Medicine & Rehabilitation Grand Rounds where Dr. Zhang presented research on *The Effect of Atlanto-Occipital and Atlanto-Axial Joint Injections on Headache Relief.* This was very interesting as I had not previously heard of joint injections of that area of the spinal cord. In addition, it appears to be a promising therapy for those with chronic migraines from a traumatic injury. Shortly after I got back to the office, Ryan and I headed over to the trauma ICU rounds. I learned a great deal from that team in regard to the management of those patients and mostly took notes over treatment regimens and the different drugs they are using to later refresh me on pharmacology. After rounds, I attended the trauma conference for that department. There the fellows presented an observational study that analyzed the risks and

benefits of enteral nutrition up to the time of transport to the operating room. Certain patient populations were excluded such as patients undergoing gastrointestinal surgeries proximal to the pylorus and patients with a non-secure airway. The study showed good results in increasing the caloric intake of patients and reducing total hospital admission time by 50%. ICU stay was unchanged, and no adverse events were reported. Later, when I got back to the research office, I continued to work on my research proposal and then headed home after that.

Day 12 – Wednesday, June 13, 2018

Today I got here at 7:40 am and waited for instruction on entry of a Toronto Empathy Questionnaire that participants completed earlier this year. This took the majority of the morning as there were hundreds of surveys to enter. Later that day I was asked to find past study participants' charts that are now deceased in order to file their death certificates with their charts. These individuals participated in a study that is still ongoing, so the majority of their charts were still in the office. These charts are then sent off to be stored separately and for the de-identification process as there will be no additional data collected on them. I found this humbling as many of these people passed after much participation in the studies as evidenced by their thick files. I did not look past verification of their identity as I did not need to know. I finished the day with a few organizational tasks and then I headed home.

Day 13 – Thursday, June 14, 2018

I arrived at the institute at 7:25 to meet with Cherissa Ard, an occupational therapist that works with spinal cord injury patients. The first patient I saw, I met up with Leah Holderbaum who I met last week. This went well as she was working with an individual with central cord syndrome, a non-traumatic cause of spinal cord injury. In fact, all of the additional patients I saw with Cherissa were non-traumatic patients. With these patients she worked on improving the

strength and coordination of their upper extremities in order to increase their independence. This was accomplished through games, practicing transfers, and upper extremity exercise that included stretching. She was busy all day and taught me many things in relation to transverse myelitis, spinal stenosis, Amyotrophic Lateral Sclerosis among others. We saw many of the patients twice during the day in an attempt to reinforce the strategies she taught them in the morning and to add to their previous therapy with new tasks. All of the individuals we worked with were highly motivated to learn new things and regain independence in their daily life. At the end of the day, I made a few edits to my research proposal handout and left soon after.

Day 14 – Friday, June 15, 2018

Today I made it to the office at 7:30 to prepare for my upcoming committee meeting. Prior to the meeting, I reviewed the notes I had, literature from my review, and the handout that I created. I met with my master's committee at 9:30 to discuss my research proposal and the handout I created. I received a lot of input from them in regard to my proposal. These included the use of specific language, clarification of aims, and investigation of possible sources of bias. After the meeting, I worked on the suggested revisions and read additional literature regarding current protocols. Ideally I will have access to additional study documents next week for this clarification. Later I organized a few things for Dr. Grobe as she was cleaning out her office in an effort to increase efficiency and reduce the amount of time spent looking for documents and files.

Week 3 Summary

This week furthered my understanding of the aquatic therapy project and of spinal cord injuries. I have work to do on the internship practicum proposal prior to submission, but my committee members offered their input and I have meetings with them next week.

Day 15 – Monday, June 18, 2018

I arrived at the office at 7:35 today. In the morning I worked on my research proposal by citing sources and adding information to my literature review which took a few of hours. At 10:30, I went with Lacy to the outpatient rehabilitation clinic which is located at the Baylor Tom Landry Health and Wellness Center. While there, I shadowed her as she screened patients for the Work Out on Wheels Internet Intervention (WOWii) project. This project examines the effectiveness of an online fitness intervention for patients with spinal cord injuries over a 16-week period. This includes weekly online modules that study participants complete each week in addition to a weekly online video conference with other participants. This conference brings study participants together to discuss challenges they are having and the motivating factors to exercise. After shadowing her for a couple of patients, I screened the remaining patients that were interested in the project. I look forward to screening more patients and becoming more involved in this project.

Day 16 – Tuesday, June 19, 2018

Today I arrived at the research institute at 7:30 for the new employee orientation for the Baylor Scott & White Institute for Rehabilitation (BSWIR). This orientation was based upon patient care guidelines and administrative tasks of the in-patient rehabilitation center. Through this process, I learned much about the rehabilitation aspect of healthcare, such as the 60% rule that requires 60% of the patients who are admitted to meet specific criterion. Also, I learned that patients are required to receive a total of 15 hours/week of therapy by an occupational therapist, physical therapist, or a speech therapist to qualify for in-patient therapy. This is spread over 5 days and does not include other activities, such as recreational therapy. Additionally, some of the patients do not have the energy required to do much more than this. Around mid-day the

chaplain at the institute, Nestor Bunda, talked to us in regard to the needs of patients which entail time, information, management of pain, and exemplary care. This includes, communication, the opportunity to explore spirituality, the opportunity to discuss preferences, and the permission to express feelings with the end goal of creating a place in which the patient is the center of our care. Additional staff from the occupational therapy, speech therapy, wound care, and the education department talked to our group later in the day. These therapists covered objectives from their clinical care that applied to new employees and we finished the day with empathy training. The last part will be important as I continue to interact with patients. I left at 5, upon the conclusion of the orientation.

Day 17 – Wednesday, June 20, 2018

I arrived today at 7:45 and started making some edits to my practicum proposal once I got setup. I then met with Dr. Grobe through Zoom at 9:30 to discuss the proposal and create a plan for the rest of the week so that I can meet the required deadlines and have a good proposal. This involved creating proper objectives and aims, working on the background section for her later review, and completing the methodology section. Soon after that meeting, I re-convened with Dr. Grobe, Lacy, and Amber to discuss ongoing objectives for the WOWii project. We decided to focus on setting up Actigraph activity monitors to collect data on the participants and compare that data to the polar watch data in addition to faxing medical approvals and sending informed consent forms to participants that were fully cleared for the study. I spent the rest of my day faxing medical approvals to participants' designated providers and organizing the Actigraph activity monitors.

Day 18 – Thursday, June 21, 2018

I got to the office today at 7:40. From 8 – 10 the team met to learn how to use the metabolic cart for studies. This system is used to measure patients' resting metabolic rate over a period of 30 – 45 minutes depending on setup time and the measurement parameters. The initial calibration is the most time consuming and it is reset after each test to achieve a $FeCO_2$ concentration of 1%. After that I worked on the aims and objectives for my proposal to prepare for my meeting with Libby. From 2 – 3 PM, Pricilla and I, met with Matthew Watts from the compliance department to review informed consent protocols at the research institute. This was a good review and added additional information to my previous classes that either weren't covered or was institute specific. The institute specific guidelines included the template Baylor uses, assent regulations, vulnerable population protocol, tips for informed consent collection, and other documentation. After that I met with Libby to go through my draft of aims and objectives for my aquatic therapy project. She ensured their accuracy and added to them in addition to providing guidance on the rest of the practicum proposal.

Day 19 – Friday, June 22, 2018

Today was the Baylor Scott & White Research Institute (BSWRI) orientation so I arrived at 7:15 to allow time to walk to the Sammons Cancer Center. After an introduction to the research institute by Michelle Acker, we began our video conference with the Central Texas group. It was a small orientation with 5 of us from North Texas and 3 people from Central Texas. We went through a lot of material on the internal operations of the institute which included contracting, coverage analysis, and budgeting. Next, we received a review of the Institutional Review Board procedures at Baylor Scott & White and were given a tutorial on Baylor's iRIS. This orientation continued into the afternoon where we discussed study development from start

to finish. This included study feasibility, recruitment, initiation visits, and personnel specific responsibilities. Most importantly, the orientation covered the informed consent process and the importance of a good medical history in drug trials. This mirrored the intro to clinical research class I took and added Baylor Scott & White specific requirements. I expect to be putting the knowledge I gained from the orientation to use in the coming months as my internship progresses.

Week 4 Summary

I spent time attending orientation sessions put on by the Institute for Rehabilitation and the Research Institute. There was some overlap in the sessions as they are both part of Baylor Scott and White system and are intertwined, but they covered different aspects. The orientation on Tuesday covered rehabilitation specific topics and the Friday orientation covered research as a whole. The remaining time during this week was split between team meetings, the WOWii project and my practicum proposal. The things that I learned this week will be applied to the rest of my internship.

Day 20 – Monday June 25, 2018

Today I arrived at the office at 7:40. At that time, I began work on my objectives and aims for the research proposal. This mainly included expanding the aims and objectives that I worked on last week and adding them to my proposal. I then started to work on other parts of the proposal which included the research design and methodology. I did not have much information for this and took much of it from my original handout. Later in the morning, I organized the WOWii files in alphabetical order and separated the participant files that were lacking a faxed medical approval from their providers. This took a while but will save me and the rest of the team time in the long run as we were having to look through all of the files to a participant's file.

In the afternoon I read additional studies on aquatic therapy in other populations to familiarize me with the aquatic therapy protocols outside of the spinal cord injury population. I then left at 4:15.

Day 21 – Tuesday June 26, 2018

Today I got to the office at 8:20. After I got setup I started to write up the summary and the background for the practicum proposal. This involved using my literature review and to cite sources and add to the background I need to have in the proposal. Also, I had to find literature-based support for the aspects of aquatic therapy that assist aquatic therapists in their sessions such as buoyancy and the viscosity of water compared to air. Outside of my proposal, I faxed medical approvals throughout the day for the WOWii project. This included new approval forms for patients that had recently been screened and repeat faxes to providers that had not responded in several weeks to a fax. It was decided that after 3 faxes we would follow-up with providers to ensure we had the correct fax number and re-fax a medical approval if necessary or request that the provider's staff present the form within the next week to the provider for their review. I spent the rest of the day calling those offices and either leaving a voicemail if appropriate or obtaining a good fax number if I was able to reach an individual at the office. I couldn't get to everyone on the list so there will be more calls later in the week. Things started to wind down around 3:30 – 4 as many offices were now closed or were closing soon and I headed home at 4:00.

Day 22 – Wednesday June 27, 2018

Today I arrived at 8:20. Once I got in, Lacy set me up with the documents and materials I would need to mail out informed consent forms. I then started reviewing my proposal and the literature review to prepare for my meeting with Dr. Grobe at 11:30 to discuss the practicum proposal that I submitted to her yesterday. She had many edits and revisions for me to make prior

to submitting a full draft to Dr. Gwirtz to review. The current draft I had was very short in comparison to a full draft in terms of detail, extent, and quality. After meeting with Dr. Grobe I reviewed the notes that she made and then spent the next couple of hours mailing informed consent forms. After that I returned to my proposal since I needed extra time to add everything that I need to add. I then left at 4:30 with some progress on the objectives and specific aims section of the proposal. Here I needed to delineate the hypotheses associated with the individual aims and re-write the aims and objectives to match those hypotheses.

Day 23 – Thursday June 28, 2018

I arrived at 7:45 and started my day by reading through the materials Dr. Gwirtz emailed so that I could have the correct formatting for my proposal and adjusted the draft accordingly. After that I sent out a few more informed consent packets to study participants for the WOWii project. I then spent the rest of the day working on the methods section of the proposal. This involved researching the validity, precision, and other properties of all of the outcome measures of the project. The main method I focused on today was the Functional Independence Measure (FIM). There were many overview articles that covered the history and development of the measure which was created to aid in assessment of functional outcomes during and after discharge from the rehabilitation hospital. The difficult part about this literature review was finding information as it pertains to spinal cord injury patients. I did eventually find what I needed, but it took a lot of searching. I then worked on the other measures and a few other items in the proposal such as the appendix and the summary before heading home at 4:20.

Day 24 – Friday June 29, 2018

Today I arrived at 7:50. During the morning I continued working on the practicum proposal and added the ethics statement, limitations of the study, and wrote up the general

internship experience section of the proposal. I then took about an hour break to mail out birthday cards for past Baylor Institute for Rehabilitation study participants. This involved packaging the cards with a returnable form to update their information as needed and decorating the birthday cards. After I finished with the cards I edited my proposal and added to the different sections. I was able to complete most of the methods section, fix formatting issues, and revise portions of the proposal during this time. I then met with Libby at 3 for about 45 minutes to review the proposal in its current form. I gained input for this review and need to follow up with Dr. Bunting and the aquatic therapists next week to get their input on a few aspects of the project. I then made a few more edits and left at 4:10.

Week 5 Summary

I made headway on my practicum proposal this week, but still had a lot of work ahead of me as I work toward a final proposal. The WOWii project is coming along as providers return the medical approval forms I sent and participants respond to the informed consent packets. I should be able to wrap up my proposal next week for Dr. Gwirtz and the rest of the committee to review.

Day 25 – Monday July 2, 2018

I arrived 7:50 and started working with input that Libby gave me last week. She had many additional items for me to address and I had a lot to add to my analysis of the outcome measures and other items in the research design and methodology section of the practicum proposal. I also addressed remaining items from Dr. Grobe's edits last week. In the afternoon I sent out a few additional informed consent forms that remained from last week. After taking a break from my project to do that, I continued my review of the existing literature to support the outcome measures used in my project. I left at 4:15 pm.

Day 26 – Tuesday July 3, 2018

Today I got to the office at 7:00 because I thought the Physical Medicine & Rehabilitation Grand Rounds was the first Tuesday of the month, but I was mistaken. This wasn't a total loss because I had a few things to keep me occupied. One of which involved tracking down which medical approvals had been sent multiple times and recording when other outstanding approvals were supposed to be returned. This gave me a good idea of the people I needed to call later this week. I continued working on my proposal throughout the day, specifically the background section. I decided to re-write this part of the proposal because the first couple of drafts were not sufficient and were disorganized. I had to go back and work through the articles in my literature review to get a more accurate picture of the current research. This came together well, and I recycled some of the points I had from previous drafts. I then left at 3:30 since I got in much earlier than usual.

Day 27 – Wednesday July 4, 2018

Independence Day

Day 28 – Thursday July 5, 2018

Today I got to the office at 7:40. Throughout the morning I added to my proposal but took a break around 9 to do a mock interview for the health literacy project with Lacy and Pricilla. Afterward I met with Loraine Gargiulo, the aquatic recreation specialist who has worked with the study participants, to discuss the amount of therapy that patients receive, the types of exercises they undergo, and current research on the subject. She added to my understanding of aquatic therapy in context of the spinal cord injury population and of rehabilitation in general. After adding that information to my proposal, I looked for a metric to define an appropriate level of compliance in the recording of patient reported outcomes and could not find anything in the

literature. After discussing this with Dr. Driver I decided to use a percentile range for this of greater than or equal to the 75th percentile. This type of data analysis is involved with other aspects such as FIM improvement and patient satisfaction scores across rehabilitation hospitals. Although it does not have an impact on ratings or funding, it should be reported somewhere. After I wrapped up my additions and edits for the day I left at 4:20 pm.

Day 29 – Friday July 6, 2018

Today I arrived at 7:45 and made some final edits to my practicum proposal prior to sending it to Dr. Gwirtz. This involved revising grammar, a few formatting changes, and adding information as needed. That process continued until about 9:00 and then I started working on the WOWii project and sent out some medical approvals in addition to informed consent forms. The available addresses and fax numbers took until lunch to complete. After lunch, I continued my work of sending out medical approvals to newly screened participants' primary care providers or spinal cord injury specialists. This involved creating new folders for the screened participants, both eligible and ineligible, and folders for their participant correspondence. This is done to maintain de-identified study data separate from the files that contain identifying information of the participants. Later I called physician offices for the pending faxes of greater than two weeks and of new participants that did not have a fax number listed. This is done to ensure that the medical approval form arrives at the correct location. I then left at 3:30 because there were no additional offices to call or additional filing to do.

Week 6 Summary

This week saw I completed my practicum proposal draft for review by my major professor, Dr. Gwirtz. Luckily I was able to obtain input from many people to come to this point in the project and hopefully it is satisfactory to my committee members. Outside of that, my time

was spent on the WOWii project. There is more to come next week as I progress through my internship and the ongoing activities of the research office.

Day 30 – Monday July 9, 2018

I arrived at 7:30 and started my day by sending faxes to provider offices that I had not followed up with yet and called offices that did not pick up the phone last week. After this I went through and edited my past journal entries to make sure that grammatical errors were corrected and that they had flow. After I finished this and completed a few administrative tasks for the WOWii project I left at 4:00 pm.

Day 31 – Tuesday July 10, 2018

I got to the institute at 7:00 for the Physical Medicine and Rehabilitation Grand Rounds. The topic this month was the management of sports-related concussions. This began with an overview of what defines a concussion in the context of sports which is neurometabolic dysfunction and not necessarily a structural neuronal injury. According to the data presented, girls take about one week longer (29 days vs. 21 days) to recover from a concussion and a prior concussion puts individuals at a greater risk to have another concussion. As with most things in medicine, management of patients after they sustain a concussion requires an inter-disciplinary approach. After I got back from the Grand Rounds, I joined the research meeting for the health literacy project. Pricilla is heading up this project, but it was important for me to be there as we discussed telephone survey protocol. After that I collected information for a Zoom meeting guide that will be part of the welcome packet for WOWii participants. Next I cleaned some of the polar watches to prepare them for use by study participants and then left at 4:00.

Day 32 – Wednesday July 11, 2018

I arrived at 8:30 today and mailed out a few informed consent forms for the WOWii project. This was followed by faxes and calls to provider offices which took most of the morning to complete and I completed other administrative tasks related to WOWii. Later I reviewed my proposal that was submitted last week and read additional articles. After this I left at 4:00.

Day 33 – Thursday July 12, 2018

Today I arrived at 8:15 and cut Therabands for WOWii project participants to use for exercise as they move through the program. These along with a Polar watch and handcycle will be boxed up and sent to the intervention group. There were 52 6' sections that we needed for this group of local and distance participants, so it took a while to measure and cut the different colors. After this I went to the BUMC Trauma Grand Rounds. The topic today was the effectiveness of transporting patients to the hospital first and then providing interventional care compared to staying at the scene, providing care, and then transporting patients to the hospital. The emergency interventions usually have to be done within the 'Golden Hour', which is defined as the hour between life and death. For individuals to live, the Lethal Trauma Triade of hypothermia, coagulopathy, and acidosis has to be addressed. The conclusion here was it depends on accessibility to a critical care hospital which affects the transport time, degree and type of injury, and the training and qualifications of the personnel that are on the ambulance all of which require consideration. When I got back to the research office I started programming Polar watches to send out to participants, but only got a few done because it was late in the day, I left at 5:00 pm.

Day 34 – Friday July 13, 2018

I arrived at 8:00 today and started working on the equipment and technology packages for participants in the intervention group for Cohort 4. This included new participants that were randomized to the intervention group and participants that were previously wait-list control and are receiving the intervention now. Programming, addressing, and boxing up the packages took the morning to complete. After all of them were ready I loaded them up and took them to the nearest FedEx location. Shipping them took a while since there were 10 packages to ship and the FedEx employee manually entered each address for me to check prior to shipment of each package. After I got back to the research office I logged all of the tracking numbers into a spreadsheet and updated the electronic tracking log with participant addresses for future contact. After completing that I left at 4:00 pm.

Week 7 Summary

This week I attended a couple of Grand Rounds presentations, one for Physical Medicine and Rehabilitation and the other for BUMC Trauma. Both were very interesting, and I learned a lot from them. The rest of the week was spent corresponding with provider offices, setting up technology packages, and mailing the packages to participants. It was a good week, and much was done to move along this cohort for the WOWii project.

Day 35 – Monday July 16, 2018

I arrived today at 8:00 and started working on the birthday cards for TBI Model Systems. This took a while to do because there were many study participants that had birthdays at the end of this month. After this, I coordinated with Cindy Durklin, the project coordinator for TBI Model Systems and collected a few documents from subject charts. She needed these for her ongoing work on the project. After I completed that task I documented the FedEx packages I sent

out last week and printed out proof of delivery forms for the packages that had been delivered thus far. These are mostly for future reference and are important to ensuring that the study participants receive the packages they will use in the program. The Polar watches are important for their fitness tracking as well as our data collection for the study. I then left at 5:00 pm.

Day 36 – Tuesday July 17, 2018

I arrived at 8:00 today and spent the morning calling provider offices to follow up on medical approval forms. After that I corresponded with a few of the participants and sent medical approval forms via email for them to give to their providers at upcoming appointments. Then I prepared Therabands to be shipped out in equipment packages later this week. After I completed a few administrative tasks for the WOWii project I left at 4:30 pm.

Day 37 – Wednesday July 18, 2018

Today I arrived at 8:30 and started my day by building technology packages for the local participants. This occupied my time for most the day since I programmed watches and set up WOWii accounts for the distance participants. Amber and I completed a lot of the needed packages and I left at 6:00 pm.

Day 38 – Thursday July 19, 2018

Today I arrived at 8:00 and started working on the technology packages again. A couple hours later I started to work on the items that I needed to submit with my research proposal to the Institutional Review Board for UNTHSC. This included Conflict of Interest training, printing out my CITI trainings, and signing a few forms. After this I worked on the edits that Dr. Gwirtz made to my proposal and submitted it to my committee members for their review. Later I added additional edits from Dr. Grobe and sent a new draft to the committee. Once I was done with my

proposal work for the aquatic therapy project I loaded up the 15 packages that were ready to be shipped to distance participants and headed to FedEx. I left their location at 5:00 pm.

Day 39 – Friday July 20, 2018

Today I arrived at 9:30 and called to check-in on the packages that were dropped off yesterday to ensure that they would be sent out today and to address any questions that the FedEx office might have. I also updated the tracking document with these new packages and printed out delivery confirmations for the remaining packages from the previous mail out. Next, I broke down all of the extra packaging for the hand cycles and took them down to be recycled. After completing a few additional tasks, I left at 3:30 pm.

Week 8 Summary

I split my work this week between the aquatic therapy project and the WOWii project. At its conclusion I submitted my research proposal and it was approved by my master's committee. The next step is to receive approval from the North Texas Institutional Review Board.

Day 40 – Monday July 23, 2018

I got to the institute today at 8:30 and started my day by tracking the FedEx packages that we sent out last week. This involved tracking them online and then printing out delivery confirmation if they had been delivered. After that I worked on paperwork for the Graduate School of Biomedical Science. For this I had to create, scan, and email forms to my professors for them to sign and file in-order for me to graduate at the end of the fall semester. In the afternoon I created a spreadsheet for the gift card mailouts for WOWii study participants that completed their post-intervention survey. This survey captures data on their self-perceived ability to conduct certain health-promoting behaviors, problems they encounter in conducting those behaviors, physical activity, disease prevention, and healthcare utilization. All of these data were

collected from study participants at different times for later analysis. After completing this I left at 4:30 pm.

Day 41 – Tuesday July 24, 2018

I arrived at 8:30 today and started by cleaning and then syncing Actigraph monitors that we had received from study participants. This involved uploading their activity data for future analysis and taking notes on which monitors returned no data at all. The majority of the monitors had about 30% battery charge left so those were put on the charger as well. After this I cut a few additional Therabands and organized envelopes with the different Polar watch components. In the afternoon I and the other new research employees attended a training for the Functional Independence Measure (FIM) instrument that clinicians use to assess patients who receive in-patient care. This is used to define the burden of care for each Activity of Daily Life (ADL) that is assessed. Further, FIM is used on admission to ascertain how long a patient will need in-patient rehabilitation care, weekly to quantify improvement during the patient's stay, and during the last full day of a patient care. In this training, the group learned how to rate each activity on a scale of 1 – 7, with a 1 being complete dependence and a 7 being complete independence. After the training I programmed a watch for mail out tomorrow and sent out a couple informed consent forms. I left at 5:15 pm.

Day 42 – Wednesday July 25, 2018

I arrived today at 7:45 and to start my day I, organized a few files for the WOWii project and then removed all of files which had the pending medical approvals for follow-up. I then proceeded to contact all 18 of the providers and then organized the files into either provider follow-up if I faxed them an additional form or left a message for to the provider or participant

follow-up if the provider requested more participant information or we had incorrect contact information for their provider. This process took me all day and I left at 5:00 pm.

Day 43 – Thursday July 26, 2018

I arrived today at 8:20 and started my day by doing a few tasks for WOWii. Then I went to a transfer training. In this training, Evan, Christa, and I learned how to safely and efficiently transfer patients from their beds to a wheel chair and vice versa. We also learned the precautions that pertain to certain patients. For example, patients with back precautions have to avoid bending, lifting, and twisting (BLT). In addition, we had the opportunity to use the Hoyer Lift to transfer Evan out of one of the spare beds. After the training I worked on a few medical approvals by calling and faxing forms to provider offices. Later I cut all of the yellow Therabands that we did not sent to participants with the rest of their equipment package because we were out of stock. At the end of the day, I completed a couple of equipment packages and organized the FedEx file for the WOWii project. I then headed to FedEx at 4:45.

Day 44 – Friday July 27, 2018

I arrived today at 8:00 and started working on the birthday cards for TBI Model Systems. These cards cover study subjects for the first half of July. I took a break from that task and setup a couple equipment packages before lunch. We then headed to lunch downtown for Ryan Totz's last day since he will be heading back to North Carolina this weekend. After lunch I headed back to the office and called a few provider offices to try and get a couple more approvals before the end of the week. I'll have to call one of them next week as they were closed. The highlight today though was receiving Institutional Review Board (IRB) approval from North Texas IRB, for UNTHSC. With this I can finally start working on my thesis project. I then left at 3 pm to drop-off the packages at FedEx.

Week 9 Summary

This week I worked on the WOWii project, paperwork for my master's degree, and TBI Model Systems. The majority of my time was spent working on various aspects of the WOWii project. In addition, I attended a transfer training and a FIM training, both of which will be useful going forward. Also, my thesis project received IRB approval, so I can now start on my project.

Day 45 – Monday July 30, 2018

Today I arrived at 9:15. I then started my day by corresponding with some of the WOWii project participants to mail their equipment packages and gathered the materials that I needed for later in the project. After this I finished the birthday cards for August 1st – August 15th that I started last week. Next, I called a few offices for provider follow up and left voicemails for some of them. After completing a few administrative tasks, I left at 5:30 pm.

Day 46 – Tuesday July 31, 2018

I arrived at 8:30 am and started by re-sending a couple of informed consent form packets that had not been received by participants a week after I mailed the first set. I then worked on the FedEx tracking to follow-up on the packages that were still pending delivery. After this I met with Amber to sit in on an informed consent call to familiarize me with the process for distance participants. Later I edited my previous journal entries and tested Evan's GLB Mobile App. At the end of the day, I sent a couple of faxes to providers that Dr. Grobe discussed the WOWii study with this afternoon. After these were filed I left at 5:20 pm.

Day 47 – Wednesday August 1, 2018

I arrived at 8:30 am and sent an additional fax to one of the providers from yesterday. I then follow-up with FedEx in an attempt to track down one of the packages that was misplaced. After this I printed out the approval forms and other study related documents for the aquatic

therapy project and filed them in one of the filing cabinets for easy access. I then finished the day with some data entry for Nestor's empathy project and left at 5:20 pm. Nestor's empathy project required entry of survey data for the empathy seminars of the past year that he and a few others delivered to clinical staff.

Day 48 – Thursday August 2, 2018

I arrived at 8:00 am and started on the data entry for Nestor's project. This process continued the rest of the day with the occasional WOWii follow up and I left at 4:30 pm. It was a long day, but I managed to enter about half of the surveys into an online database.

Day 49 – Friday August 3, 2018

I arrived at 8:15 today and continued my work on Nestor's project. The data entry of the surveys lasted the majority of the day and I took a break to work on my journal in the afternoon. After this I left for home at 3:30 pm.

Week 10 summary

Much of my time this week was spent on the WOWii project and I started entering data from Nestor's empathy seminars. It was a busy week, but I believe I accomplished a lot and will continue to work on the surveys next week.

Day 50 – Monday August 6, 2018

I arrived at 8:30 am today and followed up with FedEx. After this I finished the data entry for Nestor's project. There weren't that many additional surveys to enter so it only took a couple hours. After this I called a few provider offices to follow-up on the medical approvals. Later I attended a staff meeting that updated everyone on the ongoing research projects that the research office is currently completing. This included additional information on the status of the office going forward as it will most likely be moved by the end of the year. This will be done to

increase the amount of available therapy space on the 2nd floor. This included a discussion of possible electronic data storage for study files as the office might not have the same level of in-office, hard copy, storage that it currently has. Following this the research department met with other clinical staff and providers for Research Education and Quality Improvement Projects (REQUIP). This included discussion of TBI Model Systems and the use of ecological momentary assessments in the clinical setting. The implementation of these assessments is a logistical challenge and does not appear to have a standard method of delivery. I then organized a few files for WOWii and left at 5:00 pm.

Day 51 – Tuesday August 7, 2018

I arrived today at 9:45 and worked on my journal from last week. After this I broke down boxes and took the rest of the recycling down that had accumulated over the past couple of weeks. Later in the afternoon, the research department proceeded to Walk and Roll with a Doc where Dr. Hamilton talked about Calcium regulation and the detrimental effects of vitamin deficiency. I worked the desk for this event and signed in attendees while ensuring they filled out the correct forms. After the event we tested the app for GLB – TBIMS and conducted surveys. These activities ended around 2:30 pm.

Day 52 – Wednesday August 8, 2018

Today I arrived at 8:30 am and organized the informed consent forms that we had received over the past couple of weeks for Amber to sign and updated the online tracking log as needed. There were also a few gift card receipts from WOWii participants, so I scanned those and emailed copies to those participants for their records. These were then filed in the participant's file. After this I collected information from some of the WOWii files for comparison to the online tracking spreadsheet. Later I started entering data to track the screening

assessments of the study participants. These were filled out upon first contact with prospective participants and now needed to be analyzed as part of a continuing review. The screening date, demographics, recruitment information, and other metrics were entered. This took the rest of the day and I left at 5:00 pm.

Day 53 – Thursday August 9, 2018

I arrived today at 8:20 am and started working on the eligibility tracking again. I then met with Libby for an update on the aquatic therapy project and afterward I continued the data entry for WOWii which lasted into the early afternoon. I then met with Christa for her to practice the study protocol that will be used for spinal cord injury patients. This included measuring my resting metabolic rate (RMR), completion of surveys, and a mock lab draw. Later I called one of the provider's offices and created a technology package for a participant that completed their informed consent form today. After completing these tasks, I left at 5:00 pm to drop off the package at FedEx.

Day 54 – Friday August 10, 2018

I arrived at 8:15 today and worked on the eligibility tracking data entry until noon. After this I started editing and completing my journals from the past week. Near the end of the day I created an additional equipment package and left for FedEx at 3:00 to ship it.

Week 11 summary

Most of my week was spent working on the WOWii project and I started collecting data for the continuing review of the study. This was done for every participant that has been screened for the duration of the project. This data entry is mostly complete, but I will have to work on it next week as well. I also attended a couple research meetings this week.

Day 55 – Monday August 13, 2018

Today I arrived at 8:30 and spent some of the morning sending out additional materials to current WOWii participants. After that I completed some of the eligibility tracking data entry and checked a few entries from previous days as a quality control measure. I then spent the afternoon completing the data entry for the continuing review minus a few dates for the first two WOWii cohorts. I left at 5:00 pm.

Day 56 – Tuesday August 14, 2018

Today I arrived at 7:00 for the Physical Medicine and Rehabilitation Grand Rounds. The topic this week was sleep deprivation and as collected from resident surveys. This is the 2nd most common stressor for medical residents. This sleep deprivation can lead to life-threatening medical errors. To address this problem, residents were limited to 80 hours/week as part of NY State Department of Health Code 405 which was later adopted by the ACGME in 2003. This deficiency in proper sleep leads to negative health outcomes for residents such as weight gain, increased alcohol consumption, and increased use of sleep medications. The attendees were also given strategies to combat deprivation. After this I added the dates that were missing from the tracking document for the continuing review of the WOWii project which completed my part of the data entry. In the afternoon, I completed my journal entries from last week, edited them, and submitted the journals for review. After doing this and making a couple of calls for WOWii I left at 4:45 pm.

Day 57 – Wednesday August 15, 2018

Today I arrived at 8:20 am and started working on the TBI Model Systems birthday cards for August 15th – 31st. In addition to sending out the hand decorated ones, I designed an electronic birthday card for a study participant that could not be reached by regular mail. This

had all of the same information from the regular cards, but I added a photo of BIR and had to upload the different parts of the card as pictures. After this I followed up on the FedEx packages that were still pending delivery and created a couple of equipment packages just in-case we managed to enroll additional participants later this week. Things are winding down as the 4th cohort starts this upcoming Monday. In the afternoon I called a couple of provider offices and followed up on the data entry that I worked on the past few days. I completed a few additional administrative tasks and then left at 4:30 pm.

Day 58 – Thursday August 16, 2018

I arrived today at 8:30 am and spent the morning mailing a few items for the WOWii project and organizing some files. For the rest of the day I completed other tasks as needed and created a guide for the Green Initiative at the office. The institute does not regularly collect recycled items, so the research office has created an initiative to reduce the generation of waste. After this, I left at 5:00 pm.

Day 59 – Friday August 17, 2018

I arrived today at 8:20 am and started by checking a few screening forms for the WOWii continuing review. This involved corresponding with Amber to ensure that she had the correct values in the master document. After this I scanned the most recent informed consent forms for a local participant and a distance participant for the continuing review process. This took the rest of the morning. After this I completed a few administrative tasks for Cindy for her work on the TBI Model Systems study. This was followed by data entry for the Esko Stroke Retrospective Therapy Database which took a few hours to complete. We then received a last minute medical approval via fax, so I wrote up a FedEx Air Bill for the participant and gathered materials to ship out. I then left the office at 5:05 pm.

Week 12 Summary

I spent this week working on the WOWii project as the team prepares for Cohort 4 to start on this upcoming Monday. In addition, I worked on the TBI Model Systems study and entered data for the Esko Stroke Retrospective study. At the Physical Medicine and Rehabilitation Grand Rounds presentation, this Tuesday, I learned how to better manage my sleep schedule to minimize daytime drowsiness and maximize productivity.