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## UNIVERSITY OF SAN DIEGO

## Hahn School of Nursing and Health Science

## DOCTOR OF PHILOSOPHY IN NURSING

# DOES PARTICIPATION IN A MULTI-MODAL ACTIVITY-BASED PROGRAM IMPACT FUNCTIONAL RECOVERY AND QUALITY OF LIFE IN ADULTS WITH SPINAL CORD INJURY?

By

## Carolyn S. Gerber, PhD(c), MSN, RN

## A dissertation presented to the

## FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE

## UNIVERSITY OF SAN DIEGO

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Requirements for the degree

## DOCTOR OF PHILOSOPHY IN NURSING

## April 2014

**Dissertation Committee** 

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Ann Mayo, DNSc, RN, FAAN

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## Dedication

This dissertation is dedicated to the special people in my life who allowed me time to work on this, who were encouraging and supportive as I balanced this with life.

To God: Thank You for the knowledge, motivation and focus to see this process through. In addition, thank You for Your hand in removing barriers, opening doors and allowing me to write instead of having writers block. I give You all the thanks, praise and gratitude for always being with me, picking me up and carrying me when I needed You the most!

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To my USD PhD Student Colleagues: you were absolutely a blast to attend graduate school with as we accomplished milestones together!

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#### Abstract

The purpose of this study was to explore the relationships between relevant personal factors, participation in a multi-modal activity-based training program, and the program's impact on an individual's level of functional recovery, and overall quality of life in adults with Spinal Cord Injury (SCI). A descriptive, correlational design was performed on a secondary analysis dataset to conduct this study. Inferential statistics were performed with mixed ANOVA's on measures of ASIA UEM and LEM scores, EuroQol, and SWLS to compare their means. The study proposed that participation in a multi-modal activity-based training program would be associated with greater functional recovery, less dependency on others for ADLs, fewer costly secondary diagnoses, and an improved quality of life. This study was undertaken to explore a relatively under-studied area. In the parent study a total of 29 cases were examined at a private outpatient clinic for patients with SCI in Southern California using a non-blinded, non-randomized controlled design over a 6-month period. These 29 cases were not evenly distributed, with the experimental group who participated in the multi-modal activity-based program having more cases (n = 21) than the control group (n = 8). Additionally, in the experimental group there were more men (n = 18) than women (n = 3) (Table 1). Within the experimental group, more than three-fourths constituted cervical site injury cases (n = 19)compared to thoracic site injury cases (n = 2) (Table 1). Further breaking down the level of SCI, participants with cervical site injuries were slightly older ( $\mu = 35.74$ , sd = 14.13) compared to participants with thoracic site injuries ( $\mu = 24.50$ , sd = 4.95)(Table 1). Given the small overall sample size, the skewed number of participants in the experimental group prevents any meaningful examination of group differences.

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#### CHAPTER 1

#### STATEMENT OF THE PROBLEM

Spinal cord injuries (SCI) are devastating to otherwise healthy individuals and can dramatically change the level of physical functioning and overall quality of life (Cheng, Mayle, Cox, Park, Smith, Corcoran-Schwartz, ... Carragee, 2012; Lim & Tow, 2007; Scivoletto, Morganti, Ditunno, Ditunno, & Molinari, 2003; Waters, Adkins, Sie, & Yakura, 1996). The Centers for Disease Control and Prevention (CDC) stated that SCI account nationally for about 12,000 to 20,000 new cases of SCI's every year. Currently, about 265,000 people in the U.S. are living with an SCI (Spinal Cord Injury (SCI): Fact Sheet). According to the CDC, financial costs for medical needs alone average roughly \$15,000-\$30,000 per affected individual annually. An estimated lifetime cost, depending on the severity of the injury, can be anywhere from \$500,000 to more than \$3 million dollars. Moreover, while costs to persons with SCI are high, their families are also significantly affected emotionally, as family members now become caretakers over many different areas of the person's life with SCI (Scivoletto et al., 2003).

A large amount of the cost for patients with SCI is largely due to physical comorbidities, including dysfunction of the cardiac, pulmonary, integumentary, urinary, and endocrine systems (Harness & Astorino, 2011; Harness, Yozbatiran, & Cramer, 2008; Lim & Tow, 2007; Meyers, Mitra, Walker, Wilber, & Allen, 2000; Scivoletto et al., 2003). Adults with SCI who refrain from exercise tend to gain weight, which leads to cardiovascular disease making this a leading cause of morbidity and mortality (Harness & Astorino, 2011; Hicks et al., 2003). In addition, as more patients with SCI survive longer after injury, physical co-morbidities are coupled with psychological challenges and

alcohol and drugs abuse (Meyers et al., 2000). Chronic pain and a decrease in quality of life further complicate existing co-morbidities (Hicks et al., 2003; Meyers et al., 2000).

Therefore, it can be posited that a reduction in co-morbidities and an improved health status in the SCI population have the potential to decrease costs and significantly enhance the quality of life (Hicks et al., 2003; Ku, 2007; Lidal, Veenstra, Hjeltnes, & Biering-Sorenson, 2008; Meyers et al., 2000; Rossignol, Schwab, Schwartz, & Fehlings, 2007; Scivoletto et al., 2003). Within the last decade, regular exercise in the SCI population has been shown to reduce co-morbidities, improve health and fitness, and ultimately improve recovery (Hicks et al., 2003; Jones et al., 2012). Whether the SCI is relatively new or long-term, rehabilitation options offer a chance at regaining some functional capabilities that may ultimately affect one's overall quality of life. Initiating appropriate treatment early will optimize the chances of maximizing functional recovery in SCI patients (Lidal et al., 2008; Lim & Tow, 2007; Steeves et al., 2007).

#### **Background and Significance**

According to the National Spinal Cord Injury Association (NSCIA) (2010), approximately 30 new spinal cord injuries occur each day in the United States (National Spinal Cord Injury Association, The NSCIA difference). CDC determined the four major causes of SCI in the United States: (a) motor vehicle accidents (46%); (b) falls (22%); (c) violent acts (16%); and (d) sports accidents (12%) (Spinal Cord Injury (SCI): Fact Sheet). Specifically, the National Spinal Cord Injury Database stated 84.1% of all SCIs occur in adults ages 18-45, with another 10% in ages 46-60 and approximately 6% in ages greater than 60 years of age (Waters et al., 1996).

According to the NSCIA, one of the oldest and largest civilian organizations in America serving patients with SCI and their families nationwide, there are many costs a person encounters when living with a SCI (NSCIA, 2010). These costs include medical, personal, professional and familial resources (Lim & Tow, 2007; Scivoletto et al., 2003). The Medical Dictionary (2013) estimates costs to the American economy from SCI through payments and the loss of productivity overall are more than \$10 billion each year (Medical dictionary, Spinal Cord Injury).

The spinal cord is defined as the thick, whitish cord of nerve tissue extending from the medulla oblongata down through the spinal column, from which the spinal nerves branch off to various parts of the body. Spinal cord injury (SCI) is defined as damage to the spinal cord, causing loss of sensation and motor control. In addition, SCI most commonly occur due to: acceleration, deceleration or deformation forces applied at a distance. Vertebral column may be damaged through: fracture and compression of one or more elements, dislocation of elements or both fracture and dislocation. Vertebral injuries most often in adults: C1-C2, C4-C7, and T10-L2 with motor and sensory function loss dependent on the location of the SCI. Stabilization and nerve regeneration is dependent on: the location of injury, type of injury, presence of inflammatory responses and process of scarring. Chances for nerve regrowth and repair are higher if Schwann cells remain intact (Huether & McCance, 2012).

SCI's are differentiated depending on the level and severity of the injury to the spinal cord. The higher the injury on the spinal cord the more severe the damage to the neurological system. In addition to the level of the injury, severity of the injury is defined as completeness of the injury and the subsequent neurological impacts. Therefore severity

of the SCI injury is further broken down into complete versus incomplete, depending on the degree of transection of the spinal cord.

The American Spinal Injury Association (ASIA) Impairment Scale is known internationally and recognized as the "gold standard" for measuring functional changes in SCI patients. In addition, ASIA is a valid indicator of functional recovery (Curt, Schwab, & Dietz, 2004; Steeves et al., 2007). It is further described as the instrument most often utilized and acceptable for measuring impairments (Marino, 2007).

In the ASIA scale, the detectable amounts of sensory and motor function are measured on a continuum from Level A (lowest function) to Level E (highest function). The ASIA Scale defines "complete" as absolutely no sensory or motor function and "incomplete" as having partial sensory and motor function (Young, 2014). For example, Level A is usually indicative of patients without any motor or sensory function. As the scale progresses to Level E, patients usually exhibit intact sensory and motor functions (Young, 2014).

In the SCI arena, ASIA impairment scale is now further described by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSI). Furthermore, the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSI) recommends that the motor score(s) indicate the extent of neurological impairment. Specifically, the motor scores reflect a summary of motor function, whereby 25 is the highest score for each extremity and when considering either upper or lower extremity scores together, the highest score would then be 50. When considering measuring the upper extremity motor scores (UEMS), C5 through T1 is included in the scoring and a maximum of five points can be assigned to each of the five sections. In

addition, for the lower extremity motor scores (LEMS), L2 through T1 is included in the scoring and similarly to the UEMS, a maximum of five points can be assigned to each of these five sections (Kirshblum, 2011).

The six point scale for measuring muscle function is defined as follows: zero being "total paralysis"; one being "palpable or visible contraction"; two being "active movement, full range of motion (ROM) with gravity eliminated"; three being "active movement, full ROM against gravity"; four being "active movement, full ROM against moderate resistance in a muscle specific position"; five being "(normal) active movement, full ROM against full resistance in a muscle specific position expected from an otherwise unimpaired person" (Kirshblum, 2011, pg 19). Scores should be added together for both sides of the body, meaning the addition of both scores equals a total motor score for either UEMS or LEMS. The ISNCSI manual recommends all neurological examinations be performed on participants while they are in the supine position, assuring accurate testing of individual muscles and valid score comparisons throughout the journey of SCI recovery (Kirshblum, 2011).

#### **Functional Recovery**

Although SCI has been studied for many decades on an international scale, the focus of much research has been on initial treatment and care (Carpenter, 1994; Lidal et al., 2008). Until recently, the term "below the level of injury" was common in discussions regarding recovery below the level of the injury to the spinal cord. New terminology recently has been adopted in which the term "functional recovery" refers to any recovery of neurologic function below the level of the injury.

Functional recovery includes measurement of improvements and should be noted in activities of daily living (ADL) (Curt et al., 2004; Steeves et al., 2007). Functional recovery also encompasses measurement of meaningful recovery of a patient's sensorimotor functions and needs to be recognized as a considerable change (Filli & Schwab, 2012). Reorganization of neural pathways is one component that is necessary for functional recovery to occur, whether through activity or plasticity. Activity-based or dependent methods are key in reorganizing neural pathways related to motor functions, by connecting spinal neurons and regenerating supraspinal axons (Curt et al., 2004). Functional recovery is most noted in sections around the spinal cord where the primary injury occurred, being less pronounced in the thoracic levels (Filli & Schwab, 2012).

#### **Reorganization of Neuronal Pathways**

In recent animal research using a rat model with a complete transection of the thoracic spinal cord, researchers demonstrated that the spinal cord might be capable of regenerating, and the brain and spinal cord capable of reorganizing after an initial injury (Curt et al., 2004; Farooque et al., 2006; Filli & Schwab, 2012; Stiles & Jernigan, 2010). Since 45% of all SCIs consist of complete injuries with an expected poor outcome, these findings regarding fiber regeneration and growth of neurons in an animal model suggest implications for future research in humans (Curt et al., 2004; Filli & Schwab, 2012).

When a normal brain is developing and undergoing organization, it requires input from all the major sensory systems (Stiles & Jernigan, 2010). If elements of sensory input to the brain are missing, as occurs in an SCI, brain organization occurs through alternative patterns. These alternative organizational patterns are accompanied by the formation of new neural pathways, depicting an essential property of brain development

in mammals, called the capacity for plastic adaptation (Farooque et al., 2006; Hawryluk, Rowland, Kwon, & Fehlings, 2008; Rossignol et al., 2007).

Researchers have documented that the nervous system requires continuous input in order to obtain fresh knowledge and to cultivate functional neural systems (Greenough, 1987). Greenough (1987) has labeled this phenomenon "learning dependent on experience". Such learning can be altered either through high volumes of input or denial of input altogether, and these two methods have been shown to have significant effects on both the structure and organization of the brain (Greenough, 1987). The development of the neurons is a process, which follows a specific order and utilizes patterns occurring on a regular basis over a period of time (Curt et al., 2004; Stiles & Jernigan, 2010).

#### Multi-Modal Activity-Based Program

For most people with SCI in the US, the acute care setting is the first point of contact where healthcare professionals are involved in planning and implementing their care. Rehabilitation and discharge planning ideally should commence on admission, even before the patient has surgery to stabilize the spine. Previously used therapies, such as methylprednisolone, a treatment widely given for many years as a neuroprotective, is now being stopped due to major side effects and the inability to produce a desired result (Filli & Schwab, 2012). Newer options, most of which are designed to enhance functional recovery through stimulation of neuronal recovery, have now emerged as early-implementable choices for SCI patients.

Body Weight-Supported Treadmill Training (BWSTT) is defined as when approximately half of the patient's with SCI weight is offloaded with a harness system, whereby staff members manually assist patients with taking each step on a motorized

treadmill (Wirz et al., 2005). The use of BWSTT by spinal cord injury patients results in the strengthening of their lower extremity muscles and improvement in their motor skills when compared to their state prior to BWSTT (Wirz et al., 2005). Scientists theorized BWSTT might be able to prevent not only the atrophy of muscles, but also cease bone loss in patients with SCI (Giangregorio et al., 2005).

The new international standard of care for patients with SCI is psychophysical rehabilitation training to improve functional recovery, known as a multi-modal activitybased training program (Filli & Schwab, 2012; Hutchinson, Gomez-Pinilla, Crowe, Ying, & Basso, 2004). Research prior to 2008 was on "activity-based" rehabilitation and was focused physical therapy with the addition of BWSTT and FES, focusing on neurorecovery, hence where the term "multi-modal" originated. These programs are multi-modal because they consist of a range of modalities including, but not limited to: active assistive, load bearing, developmental sequencing, upper/lower body cycle ergometry, resistance training, whole body vibration, and balance/coordination exercises (Harness, 2014). These modalities are used with participants on an individual case-bycase basis. Use is determined by their functional status and the effect the modality has on the participant's body (Harness, 2014). Most of the SCI programs and research have focused on bodyweight supported treadmill training or functional electrical stimulation to achieve client goal(s). Project Walk includes these modalities, however, they are not the focus of the program. Therefore, use of the term "multi-modal" to describe the intense exercise program differentiates this rather new treatment modality from the traditional activity-based therapy (Harness, 2014).

Such multi-modal activity-based programs are individual because they are designed for each client based on their current functional ability. As an example, Project Walk was designed to enhance functional recovery, using the principles of neuronal development and plasticity described in the previous section. After training in a rehabilitation institute, almost 75% of patients with incomplete SCI regained some walking function: around speed, distance, and ADL's versus patients with complete SCI (Filli & Schwab, 2012). In addition, activity-based therapy programs (ABT) are relatively new, yet becoming popular as another therapy option for SCI rehabilitation as they are designed to recover neural function (Harness & Astorino, 2011).

Activity-based therapy has been defined as "activation of the neuromuscular system below the level of the lesion, with the goal of retraining the nervous system to recover a specific motor task" (Behrman & Harkema, 2007). As part of a comprehensive plan of care, healthcare professionals need to identify those patients with SCI who might be candidates for participation in a multi-modal activity-based training program. Promoting optimal health early on in patients with SCI is challenging, yet required for the multi-modal activity-based training program to be completely utilized.

#### Quality of Life

Within the last two decades, more attention has been placed on important aspects of the person's recovery with a SCI, including: functional level, management of activities of daily living (ADLs) and the relationship between exercise, functional recovery, and overall quality of life (Hammell, 2007; Hicks et al., 2003; Ku, 2007; Lidal et al., 2008). In addition, researchers assert that regaining the ability to walk and enhancing quality of life should be the ultimate goals for a patient with SCI rehabilitation (Curt, et al., 2004;

Filli & Schwab, 2012; Hicks et al., 2003; Hicks et al., 2005; Lidal et al., 2008; Morganti, Scivoletto, Ditunno, Ditunno, & Molinari, 2005). As a result, research has become focused on persons with SCIs as ordinary people who are attempting to manage with circumstances which are extraordinary; therefore, their goals for a successful rehabilitation are centered around issues such as, perception and acceptance of self (Carpenter, 1994).

Little information regarding the relationship between rehabilitation and quality of life has been available to date (Hammell, 2004; McKinley, Santos, Meade, & Brooke, 2007; Thuret, Moon, & Gage, 2006). Much research has focused on the cost of successful rehabilitation programs, which require a high financial commitment, including: cost for therapy, food, travel, transportation, and potential relocation. Such costs have created obstacles to therapy for many patients with SCI (Harness, 2013). The financial burden of a successful rehabilitation program provides an enormous barrier to patients with SCI to be facing at a time when they most likely are unable to work.

Other factors limiting patients' access to a successful rehabilitation program include: changes to current healthcare benefits such as, coverage limits on therapy, or the complete lack of coverage for rehabilitation programs (Filli & Schwab, 2012; Hicks et al., 2005; Ku, 2007; Scivoletto, 2003;Thuret, Moon & Gage, 2006; Harness, 2013). Therefore, a relationship between successful rehabilitation and quality of life can be deduced. Financial factors and availability constitute barriers when it comes to achieving functional recovery and subsequent enhanced quality of life.

The phenomena associated with participating in a multi-modal activity-based training program include: functional recovery and quality of life, however, they have not

been well researched and are not completely understood (Wirz et al., 2005). In a recent study, researchers documented that patient outcomes and ASIA motor scores were significantly improved following participation in such a program (Harness et al., 2008). From these findings, it can be posited that participation in multi-modal activity-based programs may also be related to such positive outcomes, such as, an increased ability to perform ADLs independently, fewer hospitalizations for co-morbidities, and the resumption of meaningful work.

The EuroQoL (EuroQol Group, 1990) is a measure of health-related quality of life. EuroQoL, and the SWLS, which indexes a global perception of satisfaction with one's quality of life, were analyzed for the change in means against the intervention (after it was performed) and changes in ASIA motor scores. The EuroQol (1990) was actually developed by the EuroQoL Group in 1987 (Brooks, 1996; Wu et al., 2002). It consists of five items, which index the perceived health-related quality of life in the respondent. Its validity has been established at (.86) and its reliability at (.93) (Erhart et al., 2010; Wu et al., 2002). The EuroQol has been used in other studies of persons with SCI (Marcel & Dijkers, 2005) as well as a variety of other populations facing chronic health conditions (Hurst, Kind, Ruta, Hunter, & Stubbings, 1997; Wu et al., 2002).

The Satisfaction with Life Survey (SWLS) was developed by Diener, Emmons, Larsen, & Griffin in 1985 (Diener, Emmons, Larsen, & Griffin, 1985). The SWLS (Diener et al., 1985) was designed to measure global cognitive judgments of satisfaction with one's life. It consists of five items designed to assess a global cognitive appraisal of one's satisfaction with life (Neto, 1993). Its validity and reliability are well established across a variety of populations (Lyubomirsky & Lepper, 1999) with validity at (.54) and

reliability at (.82-.87 range, with an average of .85) (Beuningen, 2010; Pavot & Diener, 1993; Vasser, 2008).

At this time, there is a tremendous gap of knowledge regarding the relationships between participation in a multi-modal activity-based training program, functional recovery and overall quality of life. Further in-depth research is needed to evaluate the phenomena and the outcomes associated with this particular type of rehabilitation program. The proposed study is designed as a beginning step in creating a knowledge base for future research to elucidate more fully the personal and environmental factors supporting optimal outcomes for persons with SCI.

#### **Study Purpose and Specific Aims**

The overall purpose of this study is to utilize a secondary analysis to explore the relationships between relevant personal factors, participation in a multi-modal activity-based training program, level of functional recovery, and overall quality of life in a group of adult persons with SCI. The specific aims of this study are to:

1) Examine the effects of a multi-modal activity-based therapy program on quality of life (QoL) outcomes (SWLS and EuroQol) in individuals with chronic spinal cord injury.

1.a Compare between-group (experimental vs. control group) differences in QoL outcomes (SWLS and EuroQol).

1.b For individuals in the experimental group, examine the relationship between functional recovery (e.g., improvements in ISNSCI motor scores) and QoL outcomes (SWLS and EuroQol).

2) Examine the relationship between the intensity of exercise (level of participation) and QoL outcomes (SWLS and EuroQol).

3) Examine the relationship between injury (level of injury) and personal characteristics (age, gender), and intensity of exercise.

#### **Research Questions**

These specific aims will address the following research questions:

1) Does participation in a multi-modal activity-based therapy program result in improvements in patient-reported quality of life (SWLS and EuroQol) and are these improvements associated with the degree of functional recovery observed?

2) Is there a positive association between level of participation (intensity of exercise) and improvements in QoL outcomes (SWLS and EuroQol)?

3) Is the level of participation in a multi-modal activity-based therapy program related to injury (level of injury) or personal (age and gender) characteristics?

#### **Conceptual Framework**

The World Health Organization (WHO) International Classification of Functioning, Disability, and Health Model of Functioning (ICF) is the conceptual framework guiding this study. Over the last two decades, much debate has occurred around factors of a patient's environment and its long-term influence on patients (Fougeyrollas, Noreau & Boschen, 2002). In 1980, these debates led the WHO to recognize the environment as a significant factor affecting the health and overall wellbeing of people who have disabilities, (Fougeyrollas et al., 2002; Lollar, 2002), with subsequent development of the International Classification of Impairments, Disabilities, and Handicaps (ICIDH) (International Classification of Impairments, Disabilities, and

Handicaps, a manual of classification relating to the consequences of disease, 2013). In 2001, WHO was motivated by further debate and revised the ICIDH model, creating a more systemic approach, with a new name, the International Classification of Impairments, Activities and Participation (ICIDH-2) (Ditunno et al., 2000).

ICIDH-2, which is now known as the International Classification of Functioning, Disability and Health (ICF), has become the new international standard (Fougeyrollas et al., 2002). ICIDH-2 established and organized function and disability, and how these health domains interact with a person's overall health, specifically the environment and personal contextual factors (Biering-Sorensen et al., 2006; Lollar, 2002). The model is based on the assumption that the concept of disability encompasses three main components: 1) how body functions are impaired; 2) how activities are limited; and 3) how participation is restricted (Biering-Sorensen et al., 2006; Lollar, 2002). In addition, Nagi proposed that "functioning" could further be defined at the human level and added a functional limitation domain, which is delineated by the effect of impairments on actions (Marino, 2007).

#### Application of the Model

For the purposes of this study, personal factors to be examined include: age, gender, and level of spinal cord injury. Participation in a multi-modal activity-based training program is viewed as an environmental factor designed to enhance level of functional recovery (capability) and subsequent overall quality of life (health condition).

#### **Implications for Nursing**

As the Affordable Care Act is implemented, development of innovative ways of supporting the health of vulnerable populations such as, patients with SCI is becoming increasingly important. In collaboration with a multi-disciplinary team, nurse scientists are in a prime position to conduct research designed to have a high impact on the outcomes and overall health of an aging population with SCI (Curt et al., 2004; Giangregorio et al., 2005; Hicks et al., 2003; Jones et al., 2012; Lidal et al., 2008; Noreau, Fougeyrollas, & Boschen, 2002; Waters et al., 1996; Wirz et al., 2005). Nurses will globally need to create and educate a new way of thinking in healthcare, enabling them to be overall better advocates for patients with SCI. Nurses are the face of healthcare and usually the first point of contact for a patient with a SCI and their families.

Findings from a recent study suggest that healthcare professionals view death as a better option than living with a high level SCI, a view reflective of overall societal views and beliefs (Hammell, 2004). Therefore, an important step for nurses will be questioning their own pre-existing expectations of recovery for patients with SCI and sharing newer research regarding rehabilitation options, which promote functional recovery. Additionally, nurses in Emergency Departments and critical care units who see patients with SCI early in their trajectory will need to work in collaboration with other nurses to identify patients/families with SCI in need of early education. Such education should include: providing the patient and family with the options for functional recovery after an SCI, the importance of these different options, and the many benefits of optimal recovery (Filli & Schwab, 2012). New diagnostic techniques which can be implemented soon after the SCI, include, diffusion weighted magnetic resonance imaging. Diffusion weighted magnetic resonance imaging can aid healthcare professionals in identifying patients who

are potentially excellent candidates for interventions, such as, participation in a multimodal activity-based training program (Filli & Schwab, 2012). Such information needs to be communicated to patients and families in a clear manner and as soon as possible.

Findings from this proposed study would provide a beginning knowledge base, regarding the relationships between participation in a multi-modal activity-based training program, functional recovery, and overall quality of life. It will offer valuable and timely knowledge, which can be used to design future studies regarding the specific ways in which a multi-modal activity-based training program impacts patients with SCI and the benefits associated with participation. Future research efforts may include examination of optimal timing for the adoption of such a program, specifically during the initial acute care stay. Dissemination of findings from this study will also increase nurse, physician and therapy specialists' awareness of a new option in the rehabilitation arena and refer patients with SCI to the appropriate resources for treatment.

In the traditional understanding of SCI, as presented in both medical and nursing schools, the primary message often has been that when a spinal cord is damaged, that is it, and nothing more can be done for the patient. However, nurses can make a difference in the lives of patients and families by giving an alternative positive message to patients with SCI early in their care. Persons in crisis will sometimes hear selectively, and what nurses say regarding the patient's ultimate functional recovery and quality of life has great import. In a very real way, nurses influence the course the patient and family choose to participate in after the initial SCI. Nurses will need to be excellent resources, strong advocates, and a voice of encouragement for patients with SCI and their families, as the first impression may be all that is remembered after the initial injury. Findings

from this study will increase knowledge regarding new options, such as a multi-modal activity-based training program, which has the potential to enhance patient outcomes of functional recovery and quality of life following SCI.

#### CHAPTER II

### **REVIEW OF THE LITERATURE**

The purpose of this chapter is to provide a summary of the literature about SCI and a new rehabilitation option. It will include methods for testing (functional recovery and overall quality of life) for this population, who are predisposed to secondary diagnoses, which ultimately affects their lives around function and overall quality of life. Studies will be presented which support the critical need to identify patients with SCI early, educating them, and referring them to a successful rehabilitation option. Although a new rehabilitation now exists, it is unclear how it affects functional recovery and overall quality of life. Gaps in the literature are identified to establish the timely necessity for this study.

#### Introduction

The overall purpose of this study is to utilize a secondary analysis to explore the relationships between relevant personal factors, participation in a multi-modal activity-based training program, level of functional recovery, and overall quality of life in a group of adult persons with SCI. The specific aims of this study are to:

1) Examine the effects of a multi-modal activity-based therapy program on quality of life (QoL) outcomes (SWLS and EuroQol) in individuals with chronic spinal cord injury.

1.a Compare between-group (experimental vs. control group) differences in QoL outcomes (SWLS and EuroQol).

1.b For individuals in the experimental group, examine the relationship between functional recovery (e.g., improvements in ISNSCI motor scores) and QoL outcomes (SWLS and EuroQol).

2) Examine the relationship between the intensity of exercise (level of participation) and QoL outcomes (SWLS and EuroQol).

3) Examine the relationship between injury (level of injury) and personal characteristics (age, gender), and intensity of exercise.

#### The WHO Conceptual Model

The WHO conceptual model was the conceptual framework, which guided this study. This framework was chosen because the premise is that patients' with SCI function and disability, as health domains, interact with a person's overall health, specifically the environment and personal contextual factors (Biering-Sorensen et al., 2006; Definitions of International Classification of Functioning, Disability and Health, 2013). When healthcare personnel recognize patients with SCI early on for participation in a multi-modal activity-based program and refer them appropriately, they potentially affect their functional outcomes and therefore, may also affect their overall quality of life. When patients with SCI follow up with this new rehabilitation option, they may improve functional outcomes and over the years their overall quality of life. The patients with SCI will be able to make important decisions around their future and job opportunities, instead of worrying about secondary diagnoses and how to pay for their medical needs.

Traditionally for many, the term disability has been extremely frustrating and confusing as more than 50 different definitions exist in the legislation. However, with the new ICF model, perhaps terminology will now be able to be used consistently for comparisons in studies and begin to make a difference in this arena (Lollar, 2002). From a public health standpoint and in accordance with the Healthy People 2010 agenda, the ICF will influence researchers on everything from how to assess factors of the

environment to increasing training for people in public health to adding in new curricula addressing health and disability issues (Lollar, 2002).

#### **Principal Literature Review**

A comprehensive literature search was conducted using Cumulative Index to Nursing Allied Health Literature (CINAHL) Plus with full text, Google Scholar and evidenced-based medical reviews: Medline, OVID, PubMed. Key search terms were: Spinal cord injury, age, gender, SCI rehabilitation, multi-modal activity weight-based program, weight-based training program, spinal cord injuries and rehabilitation, SCI and functional recovery, body weight-supported treadmill training, plasticity, central pattern generators, conceptual framework in SCI and quality of life, ICF, activity-based program, activity weight-based program, body weight-supported treadmill training spinal cord injury weight-based program, body weight-supported treadmill training program. Additional articles were found from cited articles using their reference lists.

According to 2004 data from the Model Spinal Cord Injury Systems (MSCIS), of all 987 SCI cases, less than 1% had complete neurologic recovery. Ninety-four percent (94%) of the cases with neurological complete injuries showed no improvement after five years (Lim & Tow, 2007). These statistics are staggering when considering how devastating SCI can be with loss of function and overall quality of life. In order to accurately assess improvements in functional recovery, attention to how the initial neurological and ASIA examinations are performed is critically important (Ditunno, Burns, & Marino, 2005; Lim & Tow, 2007).

## Gender

Since 2004, scientists started proposing gender does play an important part in the initial injury and recovery of the spinal cord. In regards to gender, a study from 2004 with

14, 333 patients who were grouped by the severity of their injury, beginning with their injury to one-year ASIA motor scores showed more improvement in women than men (Sipski, Jackson, Gomez-Marin, Estores & Stein, 2004). The study focused on outcomes around neurological changes and motor function, and female subjects statistically showed significantly better functional outcomes and higher ASIA motor scores.

In addition, a study from 2006 followed 20 mice for 14 weeks after compression to a section of their spinal cords, discovering at the time of initial injury and recovery of function, gender did influence the mice and their gross motor outcomes (Farooque et al., 2006). Moreover, the effects of estrogen on limiting cellular damage at the injury site was thought to be neuroprotective in nature, due to: increased blood flow, anti-inflammatory properties, the prevention of cell destruction or death, and inhibiting leukocytes from travelling to the site (Farooque et al., 2006).

#### Age

In a study from 2003, 284 subjects having a new SCI were placed into two groups, those less than 50 years of age (group 1) and those greater than 50 years of age (group 2) (Scivoletto et al., 2003). Group 1 showed a higher incidence of complete injuries and an increased independence around: bowel and bladder control, greater recovery of neurologic function, and walking independently, whereas group 2, showed a higher incidence of incomplete injuries with a reduction in length of stay days, an increase in complications and the probability in having incomplete injuries (Scivoletto et al., 2003). Therefore, even though older patients had shorter length of stay days, younger patients showed greater improvement in functional recovery and the ability to walk

independently, resulting in the need for additional medical care and multiple strategies in attempting to achieve some functional recovery in older patients.

#### **Neuronal plasticity**

Since the 1900's, scientists have been researching different aspects of function and recovery in patients with SCI. Fast forward to today, where it has now become a barely containable excitement at the possibility of adding the different pieces of research, the interventional therapies and activity-based training programs, together in order to determine if science could further improve overall quality of life outcomes in patients with SCI. In recent years, attention has been increasingly piqued around exactly how and the location of the damage in the spinal cord, as scientists are trying to decipher if the specific area of the spinal cord which is damaged, may directly impact how messages flow from the brain to the extremities and back again to the brain.

Scientists studying patients with SCI are well aware that the ability of a patient with a SCI to reduce the flexion reflex is often significantly reduced or absent. The loss of the flexion reflex is tremendous as this particular reflex produces the stepping movement in the limb joints. In the past, Laufband motorized treadmill training has shown in mammals and primates to increase the quality and number of steps taken while the body's weight is supported. In a small study from 1992, nine subjects (five of whom were paralyzed in at least one lower extremity, and the other four were without complete paralysis of at least one lower extremity) with Laufband treadmill training after only several weeks, four subjects were tested for walking on a still surface and Laufband was removed when no longer needed. Subjects were required to visualize shifting of their weight, while training on the motorized Laufband treadmill. Four subjects who prior to

the study had complete paralysis in one lower extremity were able to ambulate on a still surface after the Laufband treadmill training (Wernig & Muller, 1992). The researchers believe that the support for the body's weight, the stabilization of the joints, and some spasticity (not severe) were instrumental in the subjects learning to step and ambulate post SCI.

In 2004, researchers in the United Kingdom (UK) predicted spinal cord regeneration would probably only travel one to two segments caudal to the level of the SCI and patients with thoracic SCI (who would experience smaller advances) were better candidates for upcoming trials to avoid further advancement of the injury compared to patients with cervical SCI (Ellaway et al., 2004).

#### **Central Pattern Generators**

Central pattern generators are defined as " autonomous network of neurons capable of generating a locomotor pattern independent of supraspinal inputs" (Lim & Tow, 2007). In addition, central pattern generators (CPG) are thought to be key in the ability of a patient with SCI to walk again (Effing, Meeteren, Asbeck, & Prevo, 2006). CPG's are important when discussing the plasticity of the spinal cord, specifically caudal to the exact level of injury. Scientists predict any neural regeneration caudal to the exact level of SCI will be key in re-establishing the spinal interneurons and motoneuron connections, which directly impact recovery of function (Ellaway et al., 2004).

In 2005, for the first time researchers demonstrated in babies, who were not yet able to independently ambulate, that they could step in a coordinated fashion with a splitbelt treadmill running at the same speed and also with the belts going at different speeds (Yang, Lamont, & Pang, 2005). This is remarkable and breakthrough neuroscience

research demonstrating different stepping patterns: some steps were dependent on the other leg for stepping and in some instances the pattern generators were able to function independently without the other limb (Yang et al., 2005).

Neuronal plastic adaptation or neural plasticity is now thought to be instrumental in the recovery of a patient with SCI. Newer scientific discoveries are bringing to light how plasticity and the environment can positively affect the brain and spinal cord (Stiles, 2012). In addition, how this new knowledge can be utilized to assist patients at the time of their SCI, recovery and throughout their journey. Neural pathways are thought to be the conduit, which carry impulses from the brain to the extremities and back. Therefore at the time of a spinal cord injury these neural pathways become disrupted, thus making it extremely difficult for impulses to travel successfully to the intended extremity (Stiles, 2012). Moreover, the integrity of the peripheral nerves in patients with SCI involving the levels caudal to the injury, may limit the flow of the afferent impulses from the brain to the spinal cord (Wirz et al., 2005). The author noted that automated locomotor training is key in producing as much locomotor improvements as possible in patients with SCI.

How does the human brain and spinal cord actually develop and function from in utero throughout adulthood? Is enough understood about these concepts and how they enhance or improve the potential affects of therapy on spinal cord injury patients? Some of what is known to scientists is related to the anatomy and physiology of the brain and spinal cord.

The term "experience expectant" has been introduced and developed to capture the idea that the early experience of the organism plays an essential role in normal brain development, particularly in the early postnatal period (Greenough et al., 1987).

Although cortical patterning begins in the embryonic period, it remains malleable for an extended period of time. Typical postnatal experience is necessary for the emergence of normal patterns of neocortical organization. When that input is lacking, brain areas develop differently, and the specific pattern of development reflects the kinds of input that the organism actually received. At later ages, the developing (and even the mature) nervous system continues to require input to acquire new knowledge and to develop functional neural systems (Stiles, 2012). As previously stated, when input is lacking, the brain is thought to reorganize into alternative patterns. Plastic adaptation is therefore the actual development of these alternative patterns of organization, which allow for new neuronal pathways to transport impulses from the brain to the extremity and back (Stiles & Jernigan, 2010).

#### Multi-Modal Activity-Based Training Program

Common occurrences in patients with SCI immediately after an SCI injury, is the presence of muscles atrophying in conjunction with the loss of bone density, and additional losses again at six months, one year, two years and at three years post injury, making them highly susceptible to fractures (Giangregorio et al., 2005). The authors noted, fractures were thought to occur mostly at the time of a transfer from one place to another and specifically around the knees.

Curt, Schwab & Dietz (2004), described how actual recovery of function depends on whether the neural pathways are able to recover, regenerate, or reorganize through other uninjured neural pathways. The authors further proposed the key manner in which to accomplish this rewiring in the neural pathways is through activity-dependent training. Activity-dependent training is thought to stimulate circuits in the spinal cord to connect

from the new supraspinal axons to the spinal neurons (Curt et al., 2004).

In the past 20 years, there is increasing evidence that BWSTT positively affects the alignment of one's posture, recovery of motor function, and the increased ability to ambulate after an SCI (Giangregorio et al., 2005; Hicks et al., 2005; Wirz et al., 2005). Whether patients have a complete or incomplete injury, increased motor strength in the lower extremities, improved ability to ambulate, and the ability to control posture have been documented for the past 15 years. In addition, the authors noted, after specific treadmill training intervention, the plasticity of the neural centers were positively affected caudal to the injury (Wirz et al., 2005).

Conversely, the authors found the subjects with the greatest impairment or the lowest ASIA motor scales, actually showed the most improvement in how long they could train and the speed at which they could ambulate compared to lesser impaired subjects with higher initial ASIA motor scores (Hicks et al., 2005; Wirz et al., 2005). Although BWSTT seems to be a promising therapy, figuring out the necessary volume of training, setting a standard for how to assess functional ambulation, and how to maintain functional results long-term after the BWSTT therapy, has researchers still searching for answers (Hicks et al., 2005).

In an Italian study in 2004 of 22 subjects (of which 11 were SCI who were completely unable to step), to determine how BWSTT assisted subjects to step again, the results were as follows: subject with SCI locomotor responses learned new motor strategies, which replaced lost function in the SCI population; the new locomotor responses appeared to be similar to the original ones; and the new regenerated motoneuron pools showed plasticity of the spinal cord (Grasso et al., 2004).

In lieu of the physical demand on healthcare staff when assisting patients with SCI into BWSTT, motorized gait orthosis (DGO) has been developed as an additive to BWSTT. DGO is thought to add value through stimulating lower extremities muscles as well as alleviating not only costly, but labor intensive work for healthcare personnel (Hicks et al., 2005; Wirz et al., 2005). In a study of 20 subjects with incomplete SCI's over 8 weeks, who received BWSTT and DGO therapy, 16 were reported to later ambulate with a variety of devices for support of the lower extremities. In addition, the authors found subjects improved their over-ground abilities through not only speed, but also distance, ultimately with subjects who were most impaired showing the greatest improvement (Wirz et al., 2005). Therefore, the improvement in subjects with SCI around their ability to ambulate reflected the regeneration and reorganization of the spinal cord and neural pathways. While BWSTT seems promising, researchers have yet to fully study and research adding additional therapies and assessing their role in functional recovery of a patient with a SCI.

Scientists are hopeful that by increasing muscle mass in patients with SCI, they will have improved peripheral blood flow and as the pressures while seated decrease, could therefore, show a reduction in pressure ulcers (Giangregorio et al., 2005). Activity-based therapy programs have recently become more readily used in the SCI population, as they specifically attempt to recover as much neural function as possible in both motor and sensory realms (Harness et al., 2008; Harness & Astorino, 2011; Lorena, Datta, & Harkema, 2012).

Currently there are only two research articles addressing the particular phenomena (activity-based programs and functional recovery) and the gaps associated with it

(Harness et al., 2008; Lorenz et al., 2012). An additional article which described the different experimental methods researchers have tried to assist animals with spontaneous recovery (Filli & Schwab, 2012). Intense exercise or physical activity has correlated with functions (physiological) and outcomes (health) improving in patients with SCI who are greater than one year post-injury (Jones et al., 2012). Regular intense exercise and a successful rehabilitation program after an SCI are extremely important for patients and their functional recovery (Harness et al., 2008; Hicks et al., 2003).

Currently, one study with human subjects has researched a multi-modal activitybased training program and its effects on functional recovery (Harness et al., 2008). In this study, conducted in southern California, 29 human subjects were placed in a multimodal activity-based training program, individual to their abilities for 6 months. The experimental group who received the multi-modal activity-based training program showed statistically significant improvements in motor scores over the control group who did not receive the activity-based program (Harness et al., 2008).

#### **Functional Recovery**

Because the literature for SCI has been focused on care and treatment, there is a tremendous gap around functional recovery and how this impacts activities of daily living. In addition, due to the fact patients with SCI are now living longer, not only are their activities of daily life important, quality of life challenges continue to surface and are becoming front and center in this arena.

In reviewing the literature there are many studies in the field of SCI, however, to date, very few studies involve human subjects. The published studies in the last couple of decades have typically involved the following subjects: mice, rats, cats, and monkeys.

Scientists have begun to research different pieces to this multi-faceted question of what happens during a spinal cord injury, what is the best approach for therapy and what can be expected in terms of recovery below the level of the injury (Ellaway et al., 2004)?

Italian researchers believe functional recovery is possible if the neuronal circuits can be reactivated, and new motor neuro pathways most likely need to be developed to replace lost pathways (Grasso et al., 2004). Therefore, a lack of functional recovery in patients with SCI may be due to a very low level of activity in the lower extremities and the inability to control their posture (Grasso et al).

Although the function of walking is complicated, it has been discovered, the stronger the lower limb strength in patients with SCI, the higher probability of regaining the function of ambulation increases (Morganti et al., 2005). The authors discussed if patients with SCI could have had a longer length of stay and additional time spent in training, the probability of further increasing strength and promoting better ambulation may have been accomplished. In addition to BWSTT, patients with SCI have shown the ability to regain specific shapes to stepping regarding pre-injury ambulation motions (Morganti et al).

In a study from Switzerland of 39 subjects with SCI, the following was discovered: during spinal shock, spinal reflexes (SR) could not be evoked; after spinal shock SR's were noted with a weak locomotor pattern; strengthening of the locomotor pattern was noted around 3-4 months post SCI; at 5-6 months both early and late SR's were present; at one year, the locomotor pattern was decreased as the training session ended, this activity occurred with a low early SR's and an increased late SR's; from 2-15 years post SCI, the absence of early SR's is in conjunction with over tiring during the

training period; and in subjects with SCI sensory-motor incomplete chronic injuries, the early SR's were present and exhaustion was noted to be absent during training (Dietz, Grillner, Trepp, Hubli, & Bolliger, 2009).

Researchers believe the neurons responsible for SR responses in patients with SCI are thought to be from the same spinal neural pathways, which produce locomotion. Additionally in subjects with chronic complete SCI, SR's were always able to be produced and in subjects with chronic incomplete SCI (ASIA C) when an early SR was present and exhaustion was absent, was thought to be due to the body relearning how to step (Dietz et al., 2009).

In a recent study from 2012, functional recovery for 337 patients with incomplete SCI's over time was conducted (Lorenz et al., 2012). Subjects who were farther out from their initial injury recovered function slower and subjects with an ASIA grade at C recovered slower than subjects with an ASIA grade D. The authors proposed the state of the spinal cord and neural pathways was most likely the reason for functional recovery in terms of extent and the time since the subjects initial SCI (Lorenz et al). Furthermore, neuro plasticity appeared to occur over time as functional recovery (ability to stand independently or continue to stabilize their trunk) was regained in response to the training, unless subjects were less than a year post injury, then spontaneous recovery could not be excluded. Therefore, subjects who were several years post injury required additional training to achieve similar functional recovery as did subjects who were less than a year post injury (Lorenz et al).

## Quality of Life

Quality of life is starting to get more and more attention as the ultimate goal of rehab and what survivors with SCI really are striving for as they are now living longer lives (Hicks et al., 2003).

In a qualitative study from Canada of 15 SCI subjects (with high injuries), common themes evolved: autonomy, care for themselves, independence, and quality of life (Hammell, 2004). They saw their injury as "life-disrupting" and needed to find a new definition for themselves (pg. 615). Therefore quality in life was noted to be dependent on: "right to live in the community, opportunity to control one's life and care, the ability to engage in meaningful and purposeful occupations, and the experience of close relationships with friends and families" (pg. 617).

Researchers have discovered an improved perception of quality of life with BWSTT, however, after the training therapy ceased, the improved QoL scores were unable to be maintained by patients with SCI (Hicks et al., 2005). Therefore, a continuation of the BWSTT should result in QoL scores being maintained. In a BWSTT study from 2005, 14 subjects with chronic incomplete SCI's (all dependent on wheelchairs, 11 of the subjects were unable to independently stand or walk) were followed for one year; all subjects improved their ability to ambulate on the treadmill (including gains in speed and endurance) with an improvement in satisfaction with their lives (using the SWLS) (Hicks et al., 2005). This is the longest prospective trial in an outpatient population to date and also the highest adherence of subjects during and after a study. The authors' noted, subjects for the most part that gained achievements through training, were generally sustained through follow up. Conversely, subjects who were unable to achieve independent ambulation abilities; were also the ones in the months

following, who lost any gains previously achieved during BWSTT. Therefore it can be posited, adherence in a training program is key for patients' with SCI functional recovery and quality of life.

BWSTT is considered to contribute to other important areas in life, other than improvements in ambulation, including: the shape of muscles and an increase in muscle fibers, improved lipid panels and glucose levels, a better heart rate, and blood flow to the lower extremities after only 6 months of BWSTT (Hicks et al., 2005). Therefore leading to an improvement in overall health, through a decrease in secondary diagnoses, which improved their overall quality of life. The authors noted, subjects seemed to have a positive change in QoL with even small improvements, which may not be considered statistically or scientifically significant by researchers, however, the improvements were important to the patients with SCI (Hicks et al).

From a meta-synthesis of 64 papers and four books, quality of life ranked as the ultimate goal for rehabilitation after SCI, and was recommended as the key outcome for determining whether rehab was effective (Hammell, 2007). There are many variations in how quality of life in patients with SCI is studied and how it is measured can be more about the researchers than the patients with SCI being studied. Attempts have been made to determine exactly what the published qualitative research literature contributed to patients' QoL after an SCI (Hammell, 2007). Shockingly, healthcare professionals were found to frequently hold misconceptions about life with an SCI and conveyed them to patients. Secondly, survivors with SCI needed accurate information from people who were already living with the disability (Hammell, 2007). Meta-synthesis identified issues of: "pain, pressure sores, spasticity, inadequate income, boredom, reduced mobility,

dissatisfaction with occupations and perceptions of having reduced control over life" were stated as low areas related to life satisfaction (pg. 134). Conversely, autonomy, or the ability to live in a community, to be able to do their own care, and be independent was what the subjects really lived for in their daily lives (Hammell, 2007).

In a Norwegian study from 2008, following 165 patients with SCI who were more than 20 years post injury; health related QoL was decreased, specifically in patients who had co-morbidities. In addition, if subjects were employed and/or had the absence of comorbidities, they had better health related QoL (Lidal et al., 2008).

## **Summary of Gaps in Literature**

A review of the extant literature finds:

1. The variation in how studies rehabilitate patients with SCI around function and quality of life is extensive.

2. A plethora of factors impact patient's with SCI overall quality of health, including, but not limited to: age at injury, age at entry into study, gender, marital status at injury, marital status at entry into study, level of education, and level of spinal cord injury, which the majority of these factors are unable to be controlled by the patient.

3. Healthcare professionals, specifically nurses and their understanding of what happens to the spinal circuits at the time of an SCI; how nurses can initially maximize their assistance to the patient with a SCI and make an enormous difference in the patient's future around functional recovery and overall quality of life.

4. Patients' with SCI needs vary on a long continuum and are dependent on what level of recovery has been achieved and whether or not patients have been able to redefine themselves.

5. The degree of modesty around the understanding of what functional recovery means to a patient with SCI and if a multi-modal activity-based training program will positively affect them in the long run.

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## CHAPTER III

## METHODS

This chapter presents the methods to be used to achieve the specific aims of the study, including: description of the research design, sample, data collection, data analysis, and human subject's concerns. The parent study, which the data for this study was derived, is described, along with descriptions of instruments used in the original study.

## **Specific Aims**

The specific aims of this secondary analysis correlational study are to:

Examine the effects of a multi-modal activity-based therapy program on quality of life
 (QoL) outcomes (SWLS and EuroQol) in individuals with chronic spinal cord injury.

1.a Compare between-group (experimental vs. control group) differences in QoL outcomes (SWLS and EuroQol).

1.b For individuals in the experimental group, examine the relationship between functional recovery (e.g., improvements in ISNSCI motor scores) and QoL outcomes (SWLS and EuroQol).

2) Examine the relationship between the intensity of exercise (level of participation) and QoL outcomes (SWLS and EuroQol).

3) Examine the relationship between injury (level of injury) and personal characteristics (age, gender), and intensity of exercise.

#### **Research Design**

The proposed study uses data collected in a parent study. Harness, Yozbatiran, and Cramer conducted the original study in 2006-2007 and published it in 2008. Harness and his research team have graciously made this database available to this researcher, for the purpose of exploring some previously unexamined relationships in the study database. A correlational design will be used to perform a secondary analysis of the pre-existing data. Secondary analysis refers to the analysis of data, which has been collected already by another researcher and will be re-analyzed by a new researcher to answer new questions (Hulley et al., 2001; Polit & Beck, 2008).

Correlational designs are used to search variables and the interrelationships among them without intervention from a researcher (Fain, 2013; Polit & Beck, 2008). This type of descriptive, correlational design is appropriate for the current study whose overall purpose is to examine the relationships between relevant personal factors (age, gender, and level of spinal cord injury), participation in a multi-modal activity-based training program, level of functional recovery, and overall quality of life in adults following a spinal cord injury.

## **Description of the Parent Study**

Harness and co-authors (2008) performed the original study at a private outpatient clinic for patients with SCI in Southern California, using a "non-blinded, non-randomized controlled design". The parent study data set consists of data from 31cases (28 men, 3 women), initiated the original study. Of this group, 22 cases were already clients at PW to the multi-modal activity-based training program, while nine were in the control group. One case from each group was unable to return for the six-month retest therefore, the total in the study was 29.

The following inclusion criteria was used in the parent study: an SCI of more than two months (whether motor complete or incomplete); a neurological lesion level higher than L1; a primary neurologic insult due to trauma or ischemia; absence of pressure ulcers; non-ventilator dependent; no major psychiatric illnesses; and no co-existing neurological disorders (Parkinson's, stroke, epilepsy, or server peripheral neuropathy). Exclusion criteria included not meeting one or more of the above inclusion criteria.

Following informed consent, the cases were required to complete a baseline questionnaire. The following baseline data was collected on the study cases: age at injury, age at entry into study, gender, marital status at injury, marital status at entry into study, level of education, and level of SCI injury, and an initial administration of the neurological examination using ASIA. Three instruments were evaluated including: the ASIA scale specifically looked at the sensory and motor scores (see Appendix A), EuroQoL, and SWLS.

The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) is now used to complete the ASIA Impairment Scale (AIS), a measure of neurologic function. This scale is described as internationally recognized "gold standard", for measuring any changes in patients with SCI and is thought to detect positive movements on the scale in relation to someone's functional recovery as well (Curt, Schwab, & Dietz, 2004; Steeves et al., 2007). In addition, it is further described as the instrument most often utilized and acceptable for measuring impairments (Marino, 2007).

In this scale, the amount of sensory and motor function is measured at different levels in patients with SCI. In addition to the level and severity of the injury, SCI's are further broken down into complete versus incomplete. The ASIA Scale defines complete

as absolutely no sensory or motor function and incomplete as having partial sensory and motor function (Young, 2014). For example, Level A is usually indicative of patients without any motor or sensory function and as the scale progresses to Level E, patients usually exhibit sensory and motor functions being intact and properly functioning (Young, 2014).

Cases were not assigned, rather experimental cases were individuals who were already enrolled in Project Walk and the control cases were recruited from local advertisements. This intervention program consisted of a set of structured, supervised psychophysical activities designed to enhance muscle strength and promote optimal physical abilities. The set of six activities for the parent study included:

1) Active assistive, for cases with little to no voluntary movement, helping cases through several ranges of motion while providing some resistance. Even though cases could not assist, they were asked to visualize actively assisting or some movement against the resistance.

2) Resistance training, for cases with voluntary motor control, whether concentric or eccentric, or some resistance greater than gravity.

3) Load bearing, for cases with motor function at all levels, with body weight supporting extremities (in some percentage).

4) Cycle Ergometry, for all cases whether during cool down or warm up periods at the beginning and end of their sessions. An arm crank ergometry was utilized for exercise of the upper body and a stationary bike for exercise of the lower body.

5) Gait-training or supported ambulation, for 20 clients with several forms of gaittraining included: a) partial body weight-supported treadmill training and mechanized

elliptical training. Assistance was provided from zero to four specialists, dependent on the case's functional ability of the upper and lower body. If clients did not require support they were advanced to overground walking with a walker.

6) Vibration training, for all cases that showed muscle contractions voluntarily at which time contact was made with a platform a vertical vibration up to 40Hz, ultimately initiated contractions of their muscles.

This set of activities was performed an average of 7.3 hours per week across a sixmonth period at a private outpatient clinic for patients with SCI in Southern California, also known as the intervention group in the parent study.

At the end of the six-month period, all cases again were assessed for any advancement in functional recovery, and completed the ASIA (motor and sensory), EuroQoL, and SWLS instruments. Other data collected in the parent study that are not part of the proposed study include scores on the Developmental Activity Scale, Muscle Testing Form, Muscle Testing Evaluation Scoring Form, and Spinal Cord Independence Measure (Catz, 2002).

## Sample and Sampling

The proposed study will utilize data collected for the parent study.

## **Power Analysis**

A power analysis was completed to estimate sample size necessary for this proposed study, to avoid type 2 errors, to ensure a large enough effect size and strengthen statistical conclusions. To identify and restrict the number of study covariates to a small number normally has the effect of increasing power and decreasing necessary study

(Steeves et al., 2007, pg 211). For the parent study and this study, an n = 29 or n/2 = approximately 15 in each group, power size of 1.05, with a power of 80%, Confidence Interval (CI) of 95% and a p of < 0.05 would be considered statistically significant and providing valuable data for clinical significance (Polit, 2011, Appendix B.1). However, since a sample size of 167 is necessary for this study to be considered statistically significant, this study is therefore underpowered.

A larger sample size would be needed to draw conclusions with the same degree of confidence. However, in the proposed descriptive correlational study of pre-existing data, appropriate non-parametric statistics can provide an initial approach to analyzing the data set for trending relationships between the variables.

#### Variables

# Table 1

Independent Variables	Dependent Variables:
Participation in a Multi-Modal Activity-Based Training Program	Overall Quality of Life (SWLS and EuroQol)
Selected personal factors (age, gender, and level of SCI)	ASIA motor scores and Level of Functional Recovery
Experimental and Control Groups	Overall Quality of Life (SWLS and EuroQol)
Time	Overall Quality of Life (SWLS and EuroQol)

## Variables Described

## Independent

The first independent variable in this study is participation in the multi-modal

activity-based training program, consisting of a set of structured, supervised

psychophysical activities designed to enhance muscle strength and promote optimal

physical abilities. In addition, the relationship was examined between the level of

participation (intensity of exercise) and whether QoL outcomes were improved.

Additional independent variables include relevant personal factor data (age, gender, and level of spinal cord injury). Age, gender, and level of spinal cord injury were recorded in the parent study's baseline survey. Relationships were examined for participation in a multi-modal activity-based program with level of spinal cord injury and the above-mentioned personal factors. In addition, between groups and time were compared with the overall quality of life (SWLS and EuroQol).

# Dependent

Dependent variables for the proposed study include: changes in ASIA motor scores (Upper Extremity Motor [UEM]), level of functional recovery and overall quality of life data.

Level of Functional Recovery or Neurological Function. The level of neurological function was assessed using the ISNSCI (pre and post intervention). Specifically, individuals in the experimental group were examined for any relationships between functional recovery (changes in ASIA total motor scores [or UEM and LEM motor scores combined]) and Qol.

Overall Quality of Life. Although the parent study collected the original data, for the proposed study, overall quality of life will consist of the two scores SWLS and EuroQol (initial and six months). EuroQoL, which indexes health-related quality life, and the SWLS, which indexes a global perception of satisfaction with one's quality of life, were analyzed for the change in means against the intervention (after it was performed) and changes in ASIA UEM and LEM motor scores.

Table 2 Variables and Measures

Variable	Measure
Participation in the Multi-modal Activity- Based Training program (categorical)	An intense exercise program, based on functional ability as tested via manual muscle testing and the developmental activity scale
Relevant Personal Factors (continuous and nominal/categorical)	Age, gender, and level of SCI
Level of Functional Recovery (nominal/categorical)	Changes in ASIA motor scores
Overall Quality of Life (nominal/categorical)	Changes in Individual EuroQol and SWLS scores

## **Data Collection**

Data will be obtained from the original researcher. All data have been cleansed of any personal identifiers. Specifically, the variables of age, gender, and SCI level, pre- and post-study ASIA UEM and LEM motor scores, EuroQoL, and SWLS scores will be downloaded and analyzed.

## **Data Analysis**

Data analysis will be conducted to achieve each of the specific aims as follows:

1) Examine the effects of a multi-modal activity-based therapy program on quality of life

(QoL) outcomes (SWLS and EuroQol) in individuals with chronic spinal cord injury.

1.a Compare between-group (experimental vs. control group) differences in QoL outcomes (SWLS and EuroQol).

1.b For individuals in the experimental group, examine the relationship between functional recovery (e.g., improvements in ISNSCI motor scores) and QoL outcomes (SWLS and EuroQol). A Mixed ANOVA will be run for between-group differences and within-group differences. Correlations will be run looking at change scores for all the variables. Appropriate non-parametric statistics will be used. Relationships will be examined for direction and significance.

2) Examine the relationship between the intensity of exercise (level of participation) and QoL outcomes (SWLS and EuroQol). Correlations will be run looking at the differences in scores.

3) Examine the relationship between injury (level of injury) and personal characteristics (age, gender), and intensity of exercise. Mixed ANOVA and cross tabs will be run. Appropriate non-parametric statistics will be used to test the differences between the intervention and original control groups across variables. Measures of central tendency (mean, mode, median) and variability (range, standard deviation) will be calculated and data analyzed using SPSS statistical software, version 22.

## Limitations of the study

The findings of this study should be viewed within the contexts of its limitations. The size of the sample under investigation was previously collected and small, thus making it not possible to generalize the findings of this study (Astorino et al., 2008).

The researcher will access pre-existing data from a parent database. There are a number of limitations when using existing data. One such limitation deals with motivation of participation in interventional studies. Specifically in this study, it might be posited that ASIA UEM and LEM scores and functional recovery could have been better or higher in cases who were more motivated to do well in the multi-modal activity-based training program or had been participating in extensive exercise prior to the study date.

Such confounding factors must be taken into account when analyzing the implications of the findings for future research (Steeves et al., 2007).

## Human Subjects Protection

The parent study was conducted in compliance with the Code of Federal Regulations pertaining to human subjects research. Cases' privacy in the original study was protected in accordance with the Health Insurance Portability and Accountability Act (HIPAA). For the proposed study, data to be downloaded will be cleansed of all personal identifiers. An application to the University of San Diego Institutional Review Board (IRB) seeking exempt oversight status for the proposed study will be made. Data will be kept in a locked, password-protected file for a minimum of five years before being destroyed.

#### CHAPTER IV

#### RESULTS

The overall purpose of this study was to utilize a secondary analysis to explore the relationships between relevant personal factors, participation in a multi-modal activitybased training program, and the program's impact on an individual's level of functional recovery, and overall quality of life in adults with SCI. The study proposes the participation in a multi-modal activity-based training program will lead patients with SCI to greater functional recovery, less dependency on other people, fewer costly secondary diagnoses and overall an improved quality of life. Lack of a multi-modal activity-based training program in patients with SCI places them at risk for, but not limited to: permanently being in a wheelchair, life threatening secondary diagnoses, depending on others for their ADL's and eliminating a chance at an improved overall quality of life. First a descriptive profile of the Experimental Group, including: age, gender and level of SCI are presented, followed by the results for the specific research questions.

## **Sample Profile**

## **Demographics**

In the parent study, a total of 29 cases were examined at a private outpatient clinic for patients with SCI in Southern California, using a "non-blinded, non-randomized controlled design" over a 6-month period. These 29 cases were not evenly distributed, the experiment or treatment group, (project walk) had more cases (n = 21) than the control group (n = 8). Additionally, in the Experimental Group there were more men (n = 18) than women (n = 3)(Table 1) and more than three-fourths of the cases was accounted for

in the Cervical cases (n = 19 and approximately 90% of the cases) compared to Thoracic cases (n = 2 and approximately 10% of the cases)(Table 1). Further breaking down the level of SCI, Cervical cases were slightly older ( $\mu$  = 35.74, sd = 14.13) compared to Thoracic cases ( $\mu$  = 24.50, sd = 4.95)(Table 1).

# Specific Aim #1

Examine the effects of a multi-modal activity-based therapy program on quality of life (QoL) outcomes in individuals with chronic spinal cord injury. 1.a.) Compare between-group (experimental vs. control group) differences in QoL outcomes. 1.b.) For individuals in the experimental group, examine the relationship between functional recovery (e.g., improvements in ISNSCI motor scores) and QoL outcomes.

# **Research Question #1**

Does participation in a multi-modal activity-based therapy program result in improvements in patient-reported quality of life (SWLS and EuroQol) and are these improvements associated with the degree of functional recovery observed?

A mixed ANOVA was run to examine the effects of the independent variable (Experimental group and Control group with time) on the dependent variables (SWLS and EuroQol). In addition, inferential statistics and correlational analysis were applied to examine the relationships of all the change scores between ASIA UEM and LEM scores and SWLS and EuroQol scores.

# Table 1

Sample Characteristics in the Experimental Group

	Cervical (N=19)	Thoracic (N=2)	
	μ (sd)	μ (sd)	
Age	35.74(14.13)	24.50(4.95)	
Gender	3(F); 16(M)	0(F); 2(M)	

# **Functional Recovery**

In the treatment group, ASIA UEM and LEM scores means ranged from ( $\mu$ 's = 39.76 – 44.48, sd 16.06 – 17.85; Table 2); SWLS mean scores ranged from ( $\mu$ 's = 17.48 – 18.29, sd 7.47 – 8.02; Table 2); and EuroQol score means ranged from ( $\mu$ 's = 65.14 – 79.14, sd 20.16 – 18.68; Table 2), initially and at 6 months, respectively (Table 2). In the Control group, ASIA UEM and LEM scores means ranged from ( $\mu$ 's = 39.25 – 39.13, sd 12.94 – 12.76; Table 2); SWLS mean scores ranged from ( $\mu$ 's = 18.63 – 20.00, sd 7.39 – 6.46; Table 2); and EuroQol score means ranged from ( $\mu$ 's = 67.13 – 70.00, sd 19.75 – 19.79; Table 2), initially and at 6 months, respectively (Table 2).

# ASIA

# Table 2 (1.a.)

Descriptive Statistics For All Mixed ANOVA's (ASIA Bilateral Motor, SWLS, and EuroQol)

	Control Group	Treatment Group
	N=8	N=21
ASIA Bilateral Motor (initial)	39.25(12.94)	39.76(16.06)
ASIA Bilateral Motor (post)	39.13(12.76)	44.48(17.85)
SWLS (pre)	18.63(7.39)	17.48(7.47)
SWLS (post)	20.00(6.46)	18.29(8.02)
EuroQol (pre)	67.13(19.75)	65.14(20.16)
EuroQol (post)	70.00(19.79)	79.14(18.68)

Table 3

Analyses of Variance (ANOVA) for Effects of Experimental Program and Time

on 2 Dependent Variables

Variable and source	Sum of Squares (SS)	df	Mean of Squares (MS)	F	Р	η²
ASIA Motor Scores						
Between groups	61.01	1	61.01	8.09	.008	.231
Within groups	67.83	1	67.83	9.00	.006	.250
SWLS						
Between groups	13.82	1	13.82	1.42	.244	.050
Within groups	.926	1	.926	0.10	.760	.004
EuroQol						
Between groups	824.84	1	824.84	3.29	.081	.108
Within groups	358.49	1	358.49	1.43	.243	.050

# Experimental Group and Control Group ASIA

The analysis of variance was conducted to investigate differences in experimental and control groups across time in adults with spinal cord injuries. ANOVA results, presented in Table 3, show a significant main effect for time, F(1, 27) = 8.09, p = .008, partial  $\eta^2 = .231$ . Interaction between factors was significant F(1, 27) = 9.00, p = .006, partial  $\eta^2 = .250$ . The calculated effect size indicates a small proportion of experimental group variance is accounted for by time.

Since the sample sizes were uneven, Box M test was used to assess the homogeneity of the variance-covariance matrix. The Box M test is 9.265, which is transformed to an F value (2.738) that is significant (p = .042), therefore the assumption of homogeneity has been violated.

The parametric Levene's test verified the equality of variances in the sample (homogeneity of variance) (p > .05). Accept the null and assume equality of the variances.

# Quality of Life SWLS

The analysis of variance was conducted to investigate differences in experimental and control groups in SWLS across time in adults with spinal cord injuries. ANOVA results, presented in Table 3, show a nonsignificant main effect for time, F(1, 27) = 1.42, p = .244, partial  $\eta^2 = .050$ . Interaction between factors was nonsignificant F(1, 27) =0.10, p = .760, partial  $\eta^2 = .004$ . The calculated effect size indicates a small proportion of experimental group variance is accounted for by time. Since the sample sizes were uneven, Box M test was used to assess the homogeneity of the variance-covariance matrix. The Box M test is .784, which is transformed to an F value (.232) that is nonsignificant (p = .874), therefore the assumption of homogeneity has not been violated.

The parametric Levene's test verified the equality of variances in the sample (homogeneity of variance) (p > .05). Accept the null and assume equality of the variances.

# EuroQol

The analysis of variance was conducted to investigate differences in experimental and control groups in EuroQol across time in adults with spinal cord injuries. ANOVA results, presented in Table 3, show a main effect trending toward significance for time, F(1, 27) = 3.29, p = .081, partial  $\eta^2 = .108$ . Interaction between factors was nonsignificant F(1, 27) = 1.43, p = .243, partial  $\eta^2 = .050$ . The calculated effect size indicates a small proportion of experimental group variance is accounted for by time.

Since the sample sizes were uneven, Box M test was used to assess the homogeneity of the variance-covariance matrix. The Box M test is 3.712, which is transformed to an F value (1.097) that is nonsignificant (p = .349), therefore the assumption of homogeneity has not been violated.

The parametric Levene's test verified the equality of variances in the sample (homogeneity of variance) (p > .05). Accept the null and assume equality of the variances.

# Functional Recovery and QoL measures for the Experimental Group

Table 4 (1.b.)

Correlations in the Experimental Group of ASIA Motor Change Scores (Pre and Post scores) with the dependent variables (SWLS and EuroQol)

	SWLS Total	SWLS Total	EuroQol	EuroQol
	(pre)	(post)	Total (pre)	Total (post)
	Pearsons r	Pearsons $r$	Pearsons r	Pearsons r
	(p)	( $p$ )	(p)	(p)
ASIA Bilateral Motor_diff ASIA Bilateral Motor change scores	.246(.28)	.291(.20)	.213(.35)	.335(.14)

Although no statistically significant correlations were noted in the experimental group when looking at the differences in ASIA UEM and LEM scores and SWLS (pre and post) or EuroQol (pre and post) scores, both SWLS and EuroQol post scores had a stronger (moderate) relationship when compared to the SWLS and EuroQol pre scores (Table 4).

# Table 5

Correlations in the Experimental Group Change Scores of the dependent variables (SWLS and EuroQol) and ASIA Motor

	SWLS_diff SWLS change score	EuroQol_diff EuroQol change score
	Pearson's r (p)	Pearson's r ( <i>p</i> )
ASIA Motor_diff ASIA Motor change score	.112(.63)	.079(.73)

Although no statistically significant correlations were noted in the experimental group when looking at the differences in ASIA UEM and LEM change scores and the differences in SWLS (post minus pre) or EuroQol (post minus pre) scores, SWLS score changes were slightly more positive than EuroQol score changes (Table 5).

# Specific Aim #2

Examine the relationship between the intensity of exercise (level of participation) and QoL outcomes (SWLS and EuroQol).

# **Research Question #2**

Is there a positive association between level of participation (intensity of exercise) and improvements in QoL outcomes (SWLS and EuroQol)?

Inferential statistics and correlational analysis were applied to examine the strength and direction of any potential relationships between (or differences in change scores) the independent variables (level of participation or Experimental group) and the dependent variables of this study (SWLS and EuroQol).

# Table 6

Correlations in Experimental Group of the difference in change scores differences between ASIA Motor and SWLS/EuroQol

	SWLS (pre) Pearson's r (p)	SWLS (post) Pearson's r (p)	EuroQol (pre) Pearson's r (p)	EuroQol (post) Pearson's r (p)	SWLS diff SWLS change score Pearson's r (p)	EuroQol diff EuroQol change score Pearson's r (p)
ASIA Motor (pre)	.324(.15)	.152(.51)	.350(.12)	.261(.25)	272(.23)	088(.71)
ASIA Motor (post)	.353(.12)	.209(.36)	.368(.10)	.318(.16)	217(.34)	060(.80)

No statistically significant correlations were noted in the experimental group when looking at the differences in ASIA UEM and LEM change scores and SWLS (pre and post) or EuroQol (pre and post) scores (Table 6). When considering the SWLS and EuroQol change scores with ASIA Motor (pre and post), SWLS had a change of (r = -.272, p = .23) to (r = -.217, p = .34) and EuroQol had a change of (r = -.088, p = .71) to (r = -.060, p = .80) (Table 6). Change scores tend to be negative with pre test, therefore the lower the pre test, the higher the change.

# Specific Aim #3

Examine the relationship between injury (level of injury) and personal characteristics (age, gender), and intensity of exercise.

# **Research Question #3**

Is the level of participation in an activity-based therapy program related to injury

(level of injury) or personal (age and gender) characteristics?

A mixed ANOVA and inferential statistics were run to examine the effects of the independent variable (Level of injury) and personal characteristics (age, gender).

# Table 7SCI and Gender Crosstabs

			Gender		
			F	М	Total
SCI_dich	.00 cervical	Count	3	16	19
		Expected Count	2.7	16.3	19.0
		% within SCI_dich	15.8%	84.2%	100.0%
		% within Gender	100.0%	88.9%	90.5%
		% of Total	14.3%	76.2%	90.5%
	1.00 thoracic	Count	0	2	2
		Expected Count	.3	1.7	2.0
		% within SCI_dich	0.0%	100.0%	100.0%
		% within Gender	0.0%	11.1%	9.5%
		% of Total	0.0%	9.5%	9.5%
Total		Count	3	18	21
		Expected Count	3.0	18.0	21.0
		% within SCI_dich	14.3%	85.7%	100.0%
		% within Gender	100.0%	100.0%	100.0%
		% of Total	14.3%	85.7%	100.0%

A Chi-square test of independence was run to test whether proportions were different in each group with a = .05 as criterion for significance. Assessing for strength in the assumption  $\chi^2 = .368$ , df(1), the probability of obtaining this value is (p = .544) .544 which is not statistically significant. To determine the existence of a relationship, Phi coefficient = 0.132, shows a weak relationship between SCI and gender. The assumption is however, to be considered violated if the percentage in the cells exist > 20% and it is noted here to be = 75%, it has therefore been violated. Because there is a small sample size and the cells were less than 5, Fisher's exact test was noted to be 1.000.

When looking at the analysis of the variance (ANOVA) although not statistically significant, the Age means were similar to each other regardless of the level of injury. For Sum of Squares Between groups (SSB) F(1, 19) = 1.199, p = .287,  $\eta^2 = .059$ . Therefore when  $\eta^2 = .059$ , only 5.9% of the variance is explained by the treatment group

## CHAPTER V

## DISCUSSION OF FINDINGS

The overall purpose of this study was to utilize a secondary analysis to explore the relationships between relevant personal factors, participation in a multi-modal activitybased training program, level of functional recovery, and overall quality of life in adults with SCI. The study proposed that participation in a multi-modal activity-based training program would be associated with greater functional recovery, less dependency on others for ADLs, fewer costly secondary diagnoses, and an improved quality of life. This study was undertaken to explore a relatively under-studied area. Intuitively, the absence of a multi-modal activity-based training program in SCI patients places them at risk for such negative outcomes as permanently being in a wheelchair, life threatening secondary diagnoses, depending on others for their ADL's, and a decreased quality of life.

Thus, this study had as its conceptual model the World Health Organization (WHO) International Classification of Functioning, Disability, and Health Model of Functioning (ICF) as a basis for undertaking this initial attempt at examining the relationships between relevant personal factors, participation in a multi-modal activity-based training program, level of functional recovery, and overall quality of life in adults with SCI. In this chapter, a discussion of the findings and implications for nursing practice, education, and research are presented.

#### **Study Summary**

A descriptive, correlational design was performed on a secondary analysis dataset to conduct this study. Inferential statistics were performed with mixed ANOVA's on

measures of ASIA UEM and LEM scores, EuroQol, and SWLS to compare their means.

## **Demographics**

In the parent study a total of 29 cases were examined at a private outpatient clinic for patients with SCI in Southern California using a non-blinded, non-randomized controlled design over a six-month period. These 29 cases were not evenly distributed, with the experimental group who participated in the multi-modal activity-based program having more cases (n = 21) than the control group (n = 8). Additionally, in the experimental group there were more men (n = 18) than women (n = 3) (Table 1). Within the experimental group, more than three-fourths constituted cervical site injury cases (n = 19) compared to thoracic site injury cases (n = 2) (Table 1). Further breaking down the level of SCI, participants with cervical site injuries were slightly older ( $\mu$  = 35.74, sd = 14.13) compared to participants with thoracic site injuries ( $\mu$  = 24.50, sd = 4.95)(Table 1).

Given the small overall sample size, the skewed number of participants in the experimental group prevents any meaningful examination of group differences. In addition, 20 of the 31 participants were ASIA A and ASIA B, which may have impacted the results, given that SCI cases typically are without ASIA motor scores. Only 11 of the 31 participants were ASIA C and ASIA D, where ASIA motor scores should be present. Additionally, the control group had more chronic injuries compared to the experimental group who participated in the multi-modal activity-based program, rendering comparisons difficult.

This study failed to find any significant relationships between key variables. A

major limitation of this study is its small size and underpowered nature; thus, no generalizations from these findings are possible. However, this study constitutes a starting point on which to build other research in this area. The documentation that 21 participants were able to complete a multi-modal activity-based program constitutes a datum that the implementation of such programs is feasible in this population. Future studies with larger, more diverse groups may yield meaningful results regarding the association between the key variables of relevant personal factors, participation in a multi-modal activity-based training program, level of functional recovery, and overall quality of life in adults with SCI.

Future studies with larger participant groups may also utilize time series or longitudinal designs, thus building a knowledge base regarding the trajectory of patients who do participate in multi-modal programs. Examination of other relevant personal factors within larger populations, including recent SCI, gender, and marital status may also be useful in more clearly defining those factors which impact level of functional recovery and overall quality of life in adults with SCI.

## Importance to Advancement of Knowledge

While limited in scope and hampered by the inability to provide any significant findings in such a small population, nevertheless this study constitutes an initial attempt to examine those factors affecting the efficacy of the relatively-new multi-modal activitybased program for the SCI population. As the implementation of such programs increases, future research opportunities will provide a more nuanced examination of the relationships between these factors in a meaningful way.

#### **Conclusion and Implications for Nursing**

The World Health Organization (WHO) International Classification of Functioning, Disability, and Health Model of Functioning was the conceptual framework guiding this study (Figure 1). It was deemed appropriate for this study as this model places an emphasis on the environment in which patients exist, and proposes that such environments may have a long-term influence on patient outcomes (Fougeyrollas, Noreau & Boschen, 2002). In 1980, the WHO recognized the environment as a significant factor affecting the health and overall well-being of people who have disabilities, (Fougeyrollas et al., 2002; Lollar, 2002), an important advance in the understanding of this area. Subsequently, the International Classification of Impairments, Disabilities, and Handicaps (ICIDH, 2013), a manual of classification relating to the consequences of disease, was developed.

In 2001, WHO was further motivated to revise the ICIDH model and create a more systemic approach using a new name, International Classification of Impairments, Activities and Participation (ICIDH-2) (Ditunno et al., 2000). As a more complex understanding of this study area develops, future research investigating the centrality of environments in enhancing patient outcomes will become essential. As future, larger studies document the posited positive outcomes of such environmental interventions as the multi-modal program, it can be anticipated that more persons with SCI will have the necessary resources early after the spinal cord injury to maximize functional recovery and overall quality of life.

## **Implications for Nursing Practice**

In the context of the Affordable Care Act, advanced practice nurses will continue to play an increasing role as patient advocates and providers of rehabilitation resources to patients with SCI as early as possible. While the limitations of this study prevent any statement of direct practice implications, future research in this area described below will provide advanced practice nurses with data to design interventions that enhance functional recovery, reduce secondary diagnoses, increase productivity in the workforce, and ultimately impact the overall quality of life.

### **Implications for Nursing Education**

Given the increasing SCI population, it is incumbent on nurse educators to provide a well-rounded, theory-based approach in teaching advanced practice nurses to care for the SCI population. The utilization of the WHO model in this study constitutes a starting point for designing both curricula and future research, which involves an emphasis on the environment as an important element of care in the SCI population.

#### **Implications for Nursing Research**

Future studies with larger participant groups, which utilize time series or longitudinal designs will provide valuable information regarding the trajectory of patients who do participate in multi-modal activity-based programs versus those who do not. In addition, research is needed to identify those barriers, which may prevent patients with SCI from participating early in multi-modal activity-based training programs. The use of qualitative methods in exploring both barriers and facilitators of participation in such programs might be useful in creating therapeutic environments in which a wider participation in these programs is possible. In addition, further exploration of the WHO model in examining the factors affecting functional recovery, secondary diagnoses,

productivity in the workforce, and quality of life in this population may yield a more insightful view of the complex relationships between these variables in this population.

In conclusion, this study constitutes a starting point. While the data yielded no significant results, this area of research represents a rich area for further exploration. Meaning multi-modal activity-based programs in the SCI population are not only feasible, but also worthy of future study as an important element for future researchers to consider.

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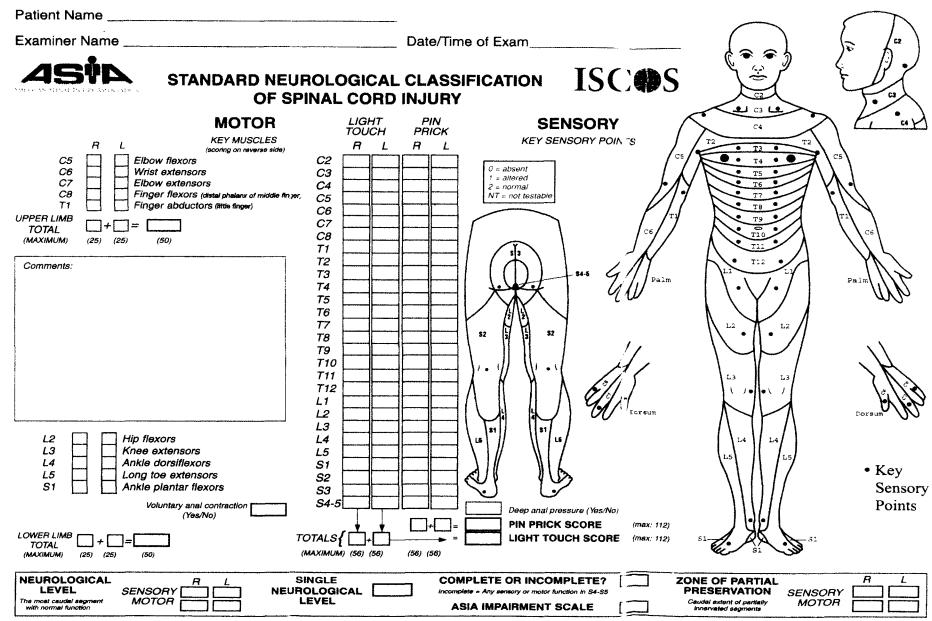
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# APPENDIX A

# AMERICAN SPINAL INJURY ASSOCIATION IMPAIRMENT SCALE (ASIA)



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