Physical Performance and

Health-Related Quality of Life Post-Stroke

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ABSTRACT

Reduced levels of health-related quality of life (HRQL) post-stroke are an important issue to address in rehabilitation. Despite improvement in function over time, HRQL remains poor for many stroke survivors. This longitudinal study is aimed at estimating the extent to which physical performance, social, and psychological functioning influence HRQL.

Forty-three community-living persons with stroke were recruited to participate in a six-week intervention preceded and followed by a performance- and interview-based evaluation assessing different levels of disability and functioning. HRQL was measured by the VAS of the EQ-5D.

Regression models generated cross-sectionally demonstrated that physical performance, social, and psychological functioning explained up to 90% of the variation in HRQL. A GEE model revealed that, over time, only upper extremity functioning had a significant relationship with HRQL.

Much attention has already been focused on increasing physical performance in rehabilitation. However, clinicians should consider other components that affect HRQL directly or indirectly through physical performance. Only by treating the different components of functioning at various levels can HRQL be ultimately increased.

Abrégé

Une réduction au niveau de la qualité de vie des personnes ayant subi un accident vasculaire cérébral (AVC) est un problème important à adresser en réadaptation. Avec le temps, malgré des améliorations dans le fonctionnement d'une personne, sa qualité de vie demeure mauvaise. L'objectif de cette étude est d'estimer à quel degré le fonctionnement physique, social, et psychologique influencent la qualité de vie.

Quarante-trois personnes ayant subi un AVC et vivant dans la communauté ont participé à un programme de réadaptation de six semaines. Une évaluation qui mesure les différents niveaux d'incapacité et de fonctionnement a été conduite avant et après le traitement. La qualité de vie a été mesurée à l'aide de l'échelle visuelle analogue (EVA) de «l'EQ-5D».

Les modèles de régression transversale ont démontré que le fonctionnement physique, social, et psychologique ont expliqué 90% de la variation de la qualité de vie. Un modèle «GEE» a établi qu'avec le temps, l'association entre le fonctionnement des membres supérieurs et la qualité de vie est statistiquement significative.

Déjà beaucoup d'emphase est mise sur l'amélioration du fonctionnement physique en réadaptation. Par contre, les cliniciens devraient considérer les autres facteurs qui influencent la qualité de vie directement ou indirectement par le biais de fonctionnement physique. Seul le traitement des différents facteurs de fonctionnement à divers niveaux peut améliorer la qualité de vie.

ACKNOWLEDGMENTS

First and foremost, I would like to thank my supervisor, Dr. Nancy Mayo, for encouraging me to take on this Masters project. Her ongoing support and encouragement through various obstacles have been remarkable - for which I will never forget. Her love and dedication to research in the area of stroke and quality of life served as an excellent source of motivation for me.

I would also like to thank my supervisory committee, Dr. Sharon Wood-Dauphinee and Dr. Jim Hanley for their expertise and valuable input to this project. Their continued support despite my leave of absence was very much appreciated.

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A much deserved thank you to my family - Mom, Dad, Nicole, Réal, and Marie Josée, for putting up with me for the past few years. Thank you for believing in me and supporting me through this no matter what. *Mom & Dad, this is the beginning of many good things to come.*

I cannot even put into words how much I appreciate all that my husband, Eric, has done for me. His love, patience, understanding, and support have made this journey unforgettable. *Now, on to another crazy venture...together.*

Finally, I am grateful for the participation of all the patients and their families. Although they were going through a difficult period in their lives, they found time to take part in this study, each with remarkable a story to tell. Without them, this project would not have been possible.

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PREFACE

The decision to carry out a Master's thesis in the area of stroke and rehabilitation was one not taken lightly. With a Bachelor's degree in Exercise Science and work experience in Occupational Health and Safety, I felt like I was heading into uncharted territory. However, at the time I was working as a research coordinator with Dr. Nancy Mayo who believed that higher education is crucial, in any field of work. So with her guidance and support, I embarked on a challenging and most memorable journey.

Following my year of course work, I was offered a position in the Department of Occupational Health and Safety for the McGill University Health Centre. I did not feel that taking on these two endeavors would be feasible, therefore, I had requested a leave of absence from the Faculty of Graduate Studies and Research for one semester.

In September 2000, I returned as a full-time student and began data collection while continuing to work. Evaluating persons post-stroke, although scary at first, was an enlightening experience. As I was accustomed to working with persons who suffered work-related accidents, I was meeting a different group of individuals who were living with a chronic disease and yet most were able to maintain a positive attitude throughout their uphill battle in rehabilitation to resume some of their regular activities. They helped me to appreciate the things that really matter in life.

A year later, I finally began writing my thesis. There were many times that I felt overwhelmed and questioned whether or not I would ever finish. Many people (including myself) wondered why I wanted to complete this thesis as the topic is unrelated to my field of work. After thinking about this, I came to the realization that the purpose of learning is not always to apply new-found knowledge in some way but sometimes we need to learn more for the simple reason of wanting to know more.

The past three years have taught me so much about topics ranging from quality of life, persons with stroke, and statistics to multi-tasking, perseverance, and relationships. This has truly been an unforgettable experience.

CHAPTER 1

INTRODUCTION

As stroke affects an increasing number of people in our society, the consequences of this disease have become a great concern. The sequelae of stroke ranges from impairments in speech, perception, cognition, fine and gross motor skills to disabilities in walking, negotiating stairs, and the capacity to carry out basic and/or instrumental activities of daily living.

The inability to resume usual activities can lead to a reduction in the health-related quality of life (HRQL) of persons post-stroke. As the ultimate goal of clinicians is to improve HRQL, this concept itself cannot be modifiable by rehabilitation. Therefore, it is the physical performance factors making up HRQL that are the targets of treatment. In order for therapy to be effective, it is important to establish the association between functioning and disability to HRQL.

Chapter 2 consists of a detailed literature review of the prevalence of stroke in society, the sequelae of this disease, and the recovery of persons post-stroke. The evolution of the concept of HRQL is also discussed beginning with early models of disablement to recent models of (health-related) quality of life. Next, the components having the greatest influence on HRQL are identified and their relationship to each other and to HRQL are examined. Finally, a summary and the results of previous studies conducted in the area of physical performance and HRQL is presented.

Chapter 3 outlines the specific objectives of the research study.

Chapter 4 describes the methodology used to address each objective. The study design, study population, and data collection process are discussed. All the measures used to assess the variables are outlined. In addition, the statistical analyses carried out to treat the data are explained.

Chapter 5 highlights the findings at various stages of the analyses proceeding to the final results. This includes descriptive statistics on the study population as well as univariate and multivariate associations between the variables.

Finally, *Chapter 6* provides an overview and an interpretation of the results. The study limitations and their possible effects on the findings are discussed. In conclusion, the contributions of this study are summarized with directions for future research.

CHAPTER 2

LITERATURE REVIEW

2.1. Stroke and Its Consequences

Stroke is a leading cause of disability in society. According to the Health and Stroke Foundation of Canada, there are approximately 50,000 new strokes occurring each year, resulting in almost 300,000 stroke survivors (http://www.heartandstroke.ca). Although stroke is a major cause of death in this country, the number of fatalities has decreased by approximately 50% over the past 20 years (Petrasovits, Nair, 1994; Mayo, 1996). Close to 80% of stroke survivors eventually return home (Bonita, 1992) and more than 50% of them are still alive five years post-stroke (Dombovy et al., 1987). These statistics demonstrate an increase of the number of persons living with the sequelae of stroke which impact on virtually all of an individual's functions: gross and fine motor ability, ambulation, capacity to carry out basic and instrumental activities of daily living, mood, language, perception, and cognition.

Stroke can have a devastating impact on individuals who are employed full-time since only a minority of them is able to return to work. Hop et al. (1998) reported that less than 30% were able to return to their previous jobs at four months post-stroke (only on a part-time basis) and this percentage remained similar at one year post-stroke.

2.2. Recovery after Stroke

The consequences of this disease are not surprising considering the clinical patterns of recovery post-stroke. Although most persons will experience some recovery of the affected lower extremity allowing the person to walk independently, their gait may not be normal in pattern or velocity (Duncan et al., 1994; Von Schroeder et al., 1995). Secondary effects of stroke are manifested by reduced strength in the non-affected leg and this is compounded by reduced activity (Sinkjaer, Magnusson, 1994; Davies et al., 1996). Of patients three-months post-stroke who had returned to the community, 85% demonstrated reduced gait speed, 68% had decreased physical mobility, and 29% were balance impaired (Mayo et al., 1999). Almost 50% were unable to climb up and down stairs independently (Shah et al., 1991; Linacre et al., 1994; Wilkinson et al., 1997; Mayo et al., 1999).

This pattern of decreased mobility persists well into the chronic stages of stroke. Even at five years post-stroke, 24% were unable to walk independently and 52% were unable or needed assistance to negotiate stairs (Wilkinson et al., 1997). Those who were able to walk and climb stairs at discharge from the primary care institution continued to have safety issues, required some kind of mechanical aid, or needed more time in rehabilitation (Thorngren et al., 1990; Stineman et al., 1998). In the population-based Frenchay Health District Study, 27% of the patients were mobile within one week of their stroke. Although at six months post-stroke 85% of them were independent in mobility, only 25% had regained their normal speed of ambulation (Wade, Hewer, 1987).

The recovery process of the upper extremity follows a similar pattern. Use of the arms is vital to carry out activities of daily living. Nakayama et al. (1994) assessed arm and hand functioning of acute stroke patients weekly until discharge. They found that it had improved in 39% of the patients but it was the unaffected side that performed most of the task. Mayo et al. (1999) concluded that at three months post-stroke, 78% had not reached age-specific norms for upper extremity functioning. As in the lower extremity, the unaffected upper extremity should not be considered as normal. Desrosiers et al. (1996) compared the unaffected arm and hand to that of a control group without upper extremity deficits. They concluded that the persons with stroke performed lower in tests measuring gross and fine manual dexterity, global performance, motor coordination, and thumb kinesthesia.

The resumption of basic activities of daily living (eating, personal hygiene, bathing, dressing, continence, transfers) often plateaus after the first three months post-stroke (Gray et al., 1990; Nakayama et al., 1994; Jorgensen et al., 1995; Jorgensen et al., 1995), with most of the improvement occurring within the first month (Mayo et al., 1999). Once discharged from rehabilitation, persons with stroke can accomplish basic functional activities independently, but high-level tasks needed for community-living (instrumental activities of daily living), often remain problematic. The inability to perform these tasks is mainly due to not having complete use of their lower and/or upper extremities but because they are considered "functional", no further rehabilitation is provided. Being discharged home too soon without additional treatment has resulted in patients becoming dependent on others and experiencing a great degree of perceived difficulty in performing high-level activities (Grimby et al., 1998).

2.3. Health-Related Quality of Life Post-Stroke

Due to the impact that the sequelae of stroke have on an individual, it should not be surprising that the health-related quality of life (HRQL) of persons with stroke would be lower than that of healthy individuals of the same age. HRQL is a concept representing individual responses to the physical, mental, and social effects of illness on daily living which influence the extent to which personal satisfaction with life circumstances can be achieved (Bowling, 1994).

Although a person's HRQL would be expected to increase as his/her impairments and disabilities decrease, studies show that this is not the case. After a stroke, there is a reduction in the level of HRQL. This is most apparent at three months post-stroke, but even after one year, levels of HRQL remain low. In a study conducted by Åström et al. (1992), 50 patients at three months post-stroke were asked to rate their lives as being "poor", "fair" or "good". Only 32% of patients reported it as being "good". At one year post-stroke, this proportion increased to 52% but did not change significantly thereafter. The long-term prognosis of HRQL for persons with stroke does not look promising (Hindfelt, Nilsson, 1992). It remains severely reduced as late as two years (Ahlsio et al., 1984), three years (Lawrence, Christie, 1979), four years (Niemi et al., 1988), five years (Viitanen et al., 1988), even up to 14 years (Tuomilehto et al., 1995) post-stroke.

The HRQL of individuals from 6 to 20 months post-stroke were found to be lower when compared to healthy controls matched on age using the Medical Outcomes Study 36-item Short Form Questionnaire (Ware et al., 1992; Ware et al., 1994). Decreased scores were particularly apparent in the subscales of *Physical Functioning, Role Physical*, *General Health*, and *Vitality*. Psychological domain scores were also lower. The only subscale where a statistically significant difference was not noted between persons with stroke and controls was in *Bodily Pain* (Duncan et al., 1997; Mayo et al., 2001) (Table 2.3).

Unfortunately, this pattern of reduced HRQL also exists for those who experience mild strokes. Studies by Anderson et al. (1995) and Duncan et al. (1997) found that patients who had mild strokes and were independent in their basic activities of daily living (BADLs) still reported lower levels of HRQL than healthy controls. In the latter study, almost 70% of the stroke patients scored 100 on the Barthel Index (Mahoney, Barthel, 1965) indicating complete independence in BADLs yet an average score of only 61 out of 100 points on the *General Health* sub-scale was obtained. Therefore, this reduction in HRQL is an important issue to address considering that the majority of individuals who survive a stroke have minimal to moderate neurological deficits (Jorgensen et al., 1995; Jorgensen et al., 1995; Duncan et al., 1997).

Table 2.3. SF-36 Scores for Persons with Stroke in Comparison to Healthy Controls

MOS SF-36 Subscales	Duncan et al., 1997		Mayo et al., 2001	
	Stroke (n=304) Mean (SD) 20 mo. post-stroke	Control (n=654) Mean (SD)	Stroke (n=434) Mean (SD) 6 mo. post-stroke	Control (n=486) Mean (SD)
Physical Functioning	59.3 (31.0)	77.6 (22.8)	63.4 (29.9)	85.0 (21.0)
Role Physical	55.0 (41.4)	74.5 (36.1)	53.0 (45.0)	84.7 (33.1)
Bodily Pain	73.8 (27.9)	75.0 (24.3)	66.6 (38.8)	68.0 (35.5)
General Health	54.2 (24.4)	62.8 (22.1)	68.9 (20.5)	80.4 (18.2)
Vitality	50.3 (26.8)	60.8 (21.3)	50.2 (23.5)	68.1 (21.8)
Social Functioning	76.6 (29.1)	88.0 (21.3)	75.4 (27.6)	84.8 (21.9)
Role Emotional	73.4 (38.4)	85.0 (29.4)	61.2 (46.2)	85.6 (33.1)
Mental Health	73.7 (23.0)	80.2 (17.0)	69.0 (22.6)	78.0 (19.1)

Tracking the HRQL for persons with stroke over time is methodologically challenging because of the tendency for individuals with the lowest HRQL to drop out of the study due to death, institutionalization, or illness. These types of losses to follow-up create a systematic bias inflating the value of HRQL over time.

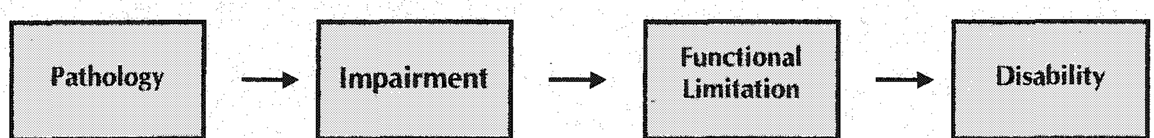
2.4. Measuring the Outcome of Stroke

Given the outcome of this disease, it has become increasingly important for researchers and clinicians to measure the consequences of stroke. This can be achieved by using models as a guide.

2.4.1. Models of Disablement

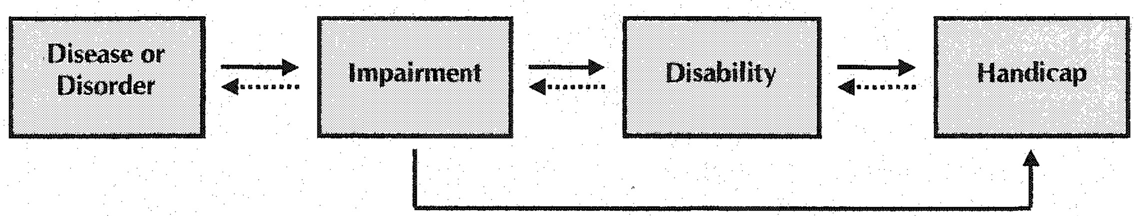
The first model developed was based on the disablement process (Figure 2.4.1a). This was conceptualized by Nagi (1969) to distinguish between pathology, impairment, limitation in functional performance, and disability. He stressed that rehabilitation should focus on the latter two components rather than just pathology and cure.

Figure 2.4.1a. Model of the Disablement Process - Nagi, 1969



In 1980, the World Health Organization proposed the International Classification of Impairments, Disabilities, and Handicaps (ICIDH). It included a model with a bi-directional relationship at each conceptual level (Figure 2.4.1b). A disease and/or injury may lead to an impairment – *any loss or abnormality of psychological, physiological, or anatomical structure or function.* This may result in a disability – *any restriction or lack of ability, resulting from an impairment, to perform an activity in the manner or within the range considered normal.* Finally, this may generate a handicap – *a disadvantage for a given individual, resulting from an impairment or disability, that limits or prevents the fulfillment of a role that is considered normal.* The bi-directionality depicted in broken arrows refers to secondary consequences of a primary impairment, disability, or handicap. For example, an impairment of one extremity may lead to a new disorder as the unaffected extremity over-compensates for the impairment.

Figure 2.4.1b. International Classification of Impairments, Disabilities, Handicaps - WHO, 1980



These early models assessed an individual's health simply through the absence of disease or disability. They did not reflect the World Health Organization's definition of health as *a state of complete physical, mental, and social well-being and not merely the absence of disease and infirmity* (WHO, 1948). However, more optimistic models of health needed to be developed using a more positive definition of this concept moving beyond disablement.

The WHO's broader view of health was assessed mainly through an individual's functional performance defined as *the function of an individual in personal and/or societal roles reflecting any impairment and/or disability one may have* (Jette, 1984). However, functional performance only focused on the physical component of a person's status including such tasks as the ability to eat, dress, bathe, walk, negotiate stairs, etc. The subjective factors that may influence one's physical performance were not considered.

By the mid 80's, other components of functional performance were introduced and became important to measure such as *mental performance* (cognition, awareness, memory), *emotional performance* (ability to cope, anxiety, happiness), and *social performance* (interactions with family/friends, roles, responsibilities) (Jette, 1984). At this time, all four aspects of functional performance (or any combination of these factors) were believed to be inter-related. Therefore, a new concept was developed to consider the interaction of all these components termed *health-related quality of life – HRQL* (Berzon et al., 1993; Bowling, 1994).

2.4.2. Defining Health-Related Quality of Life

There are many definitions of HRQL but one of the most complete comes from Patrick and Erickson (1993). They define it as:

> *...the value assigned to the duration of life as modified by the impairments, functional states, perceptions and social opportunities that are influenced by disease, injury, treatment or policy.*

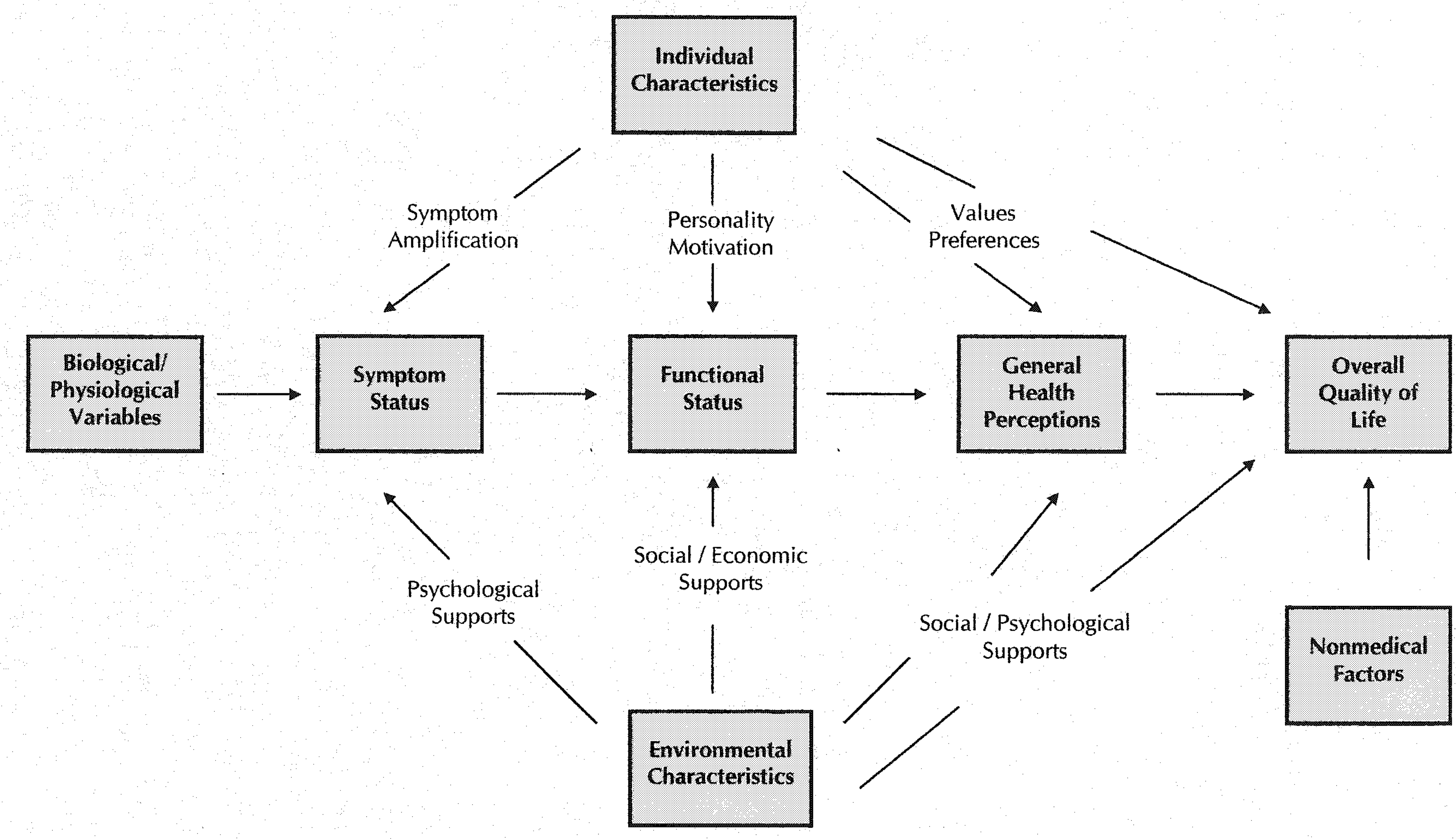
This definition stresses the multi-dimensional nature of HRQL and highlights the relationship between quality and quantity of life. No single definition of HRQL has been universally accepted but generic measures of this concept take into account levels of physical, mental, social, and role functioning and include abilities, perceptions of health, life satisfaction, and well-being (Berzon et al., 1993; Bowling, 1994). HRQL, as opposed to quality of life, is more specific and appropriate for researchers and clinicians assessing those aspects of a person's experience which are affected primarily by health and health care interventions (Berzon, 1998).

2.4.3. Models of Quality of Life

With the introduction of (health-related) quality of life, new models were developed to include it as an endpoint, encompassing a more general definition of health.

The following models suggest that the measurement of HRQL include both objective and subjective components. The first model by Wilson and Cleary (1995) used the WHO's classification of impairments, disabilities, and handicaps as its theoretical framework in which measures of health can be thought of as existing on a continuum of increasing biological, social, and psychological complexity (Figure 2.4.3a). At the left end of the model are biological and physiological measures. It then increases in complexity as the continuum shifts to the right integrating measures of physical functioning, general health perceptions, then finally, quality of life. Individual as well as environmental characteristics are also considered.

Figure 2.4.3a. Model of Quality of Life - Wilson, Cleary, 1995



The second model proposed by Duncan (1994) illustrates the relationship between impairment, functional performance, disability, and quality of life (Figure 2.4.3b). Psychosocial, etiology/pathology, and environmental factors can have an influence at any of these levels. Assessing the consequences of stroke should capture the perceptions of a person's physical, emotional, mental, and social functions and the ease with which these activities are performed by the individual. This model makes a distinction between functional performance that is observed and functional performance that is self-reported. In rehabilitation settings where conditions are usually ideal, the person is able to perform the task, whereas the ability to do so in the environment can be reduced.

The third model comes from the International Classification of Functioning, Disability, and Health (ICF) (WHO, 2001), a revision of the ICIDH. The ICF is comprised of two main parts: Functioning/Disability and Contextual Factors, which in turn, is further divided into various components and constructs.

1) Functioning and Disability
    i) body functions and structures
    ii) activities and participation

2) Contextual Factors
    i) environmental factors
    ii) personal factors

The *body* component is grouped into functions of body systems and functions of body structures. The *activities and participation* component encompasses all domains affecting functioning from an individual and societal perspective. It can be further divided into two constructs: capacity and performance. Finally, the *environmental factors* component impacts on all aspects of functioning ranging from an individual's most immediate environment to the general environment. Although *personal factors* are also considered in Contextual Factors, they are not classified in the ICF due to their large social and cultural diversity.

The ICF model classifies the "components of health" rather than the "consequences of disease" to provide a more positive basis for understanding health, health-related states, outcomes, and determinants. A person's functioning and disability is interpreted as a dynamic interaction between health conditions (diseases, disorders, injuries, traumas, etc.) and contextual factors where the environment either facilitates or hinders the features of the physical, social, and attitudinal world (Figure 2.4.3c).

For the purposes of this thesis, the terminology of the ICF will be used when referring to the various impacts of stroke.

Figure 2.4.3b. Model of Physical Disablement in Stroke - Duncan, 1994

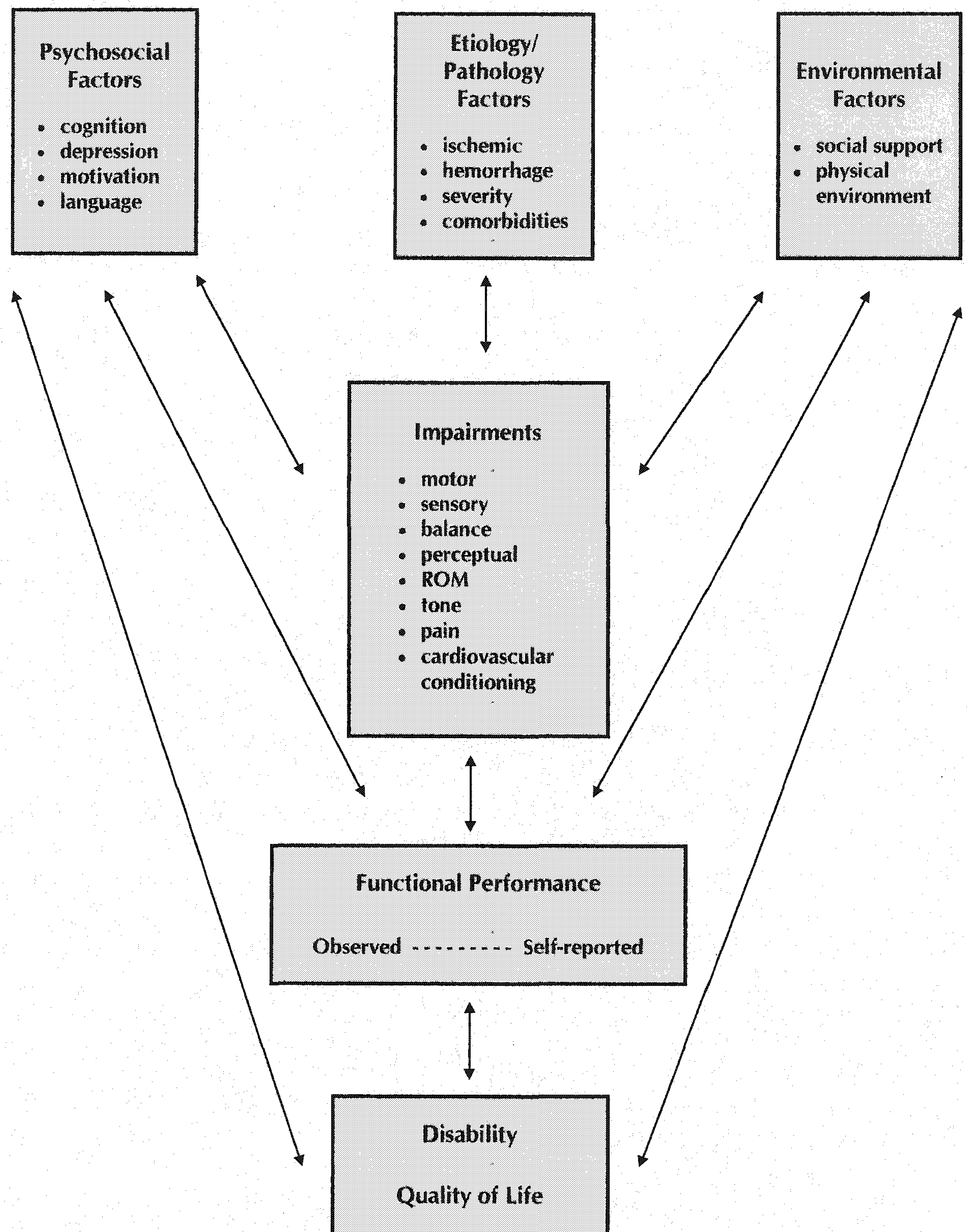
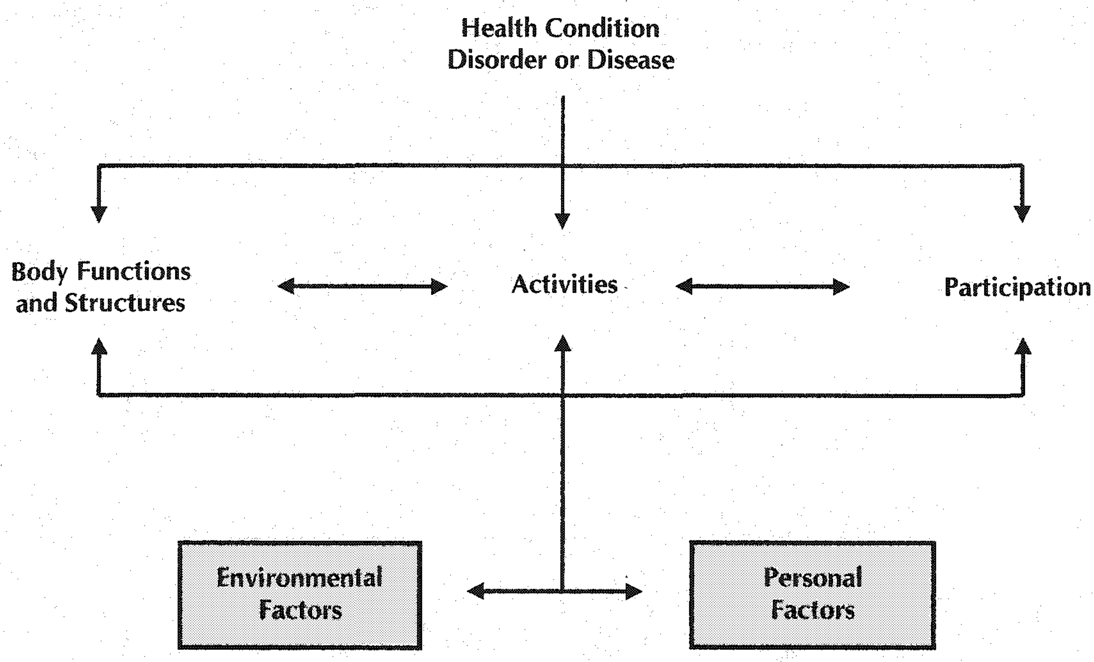
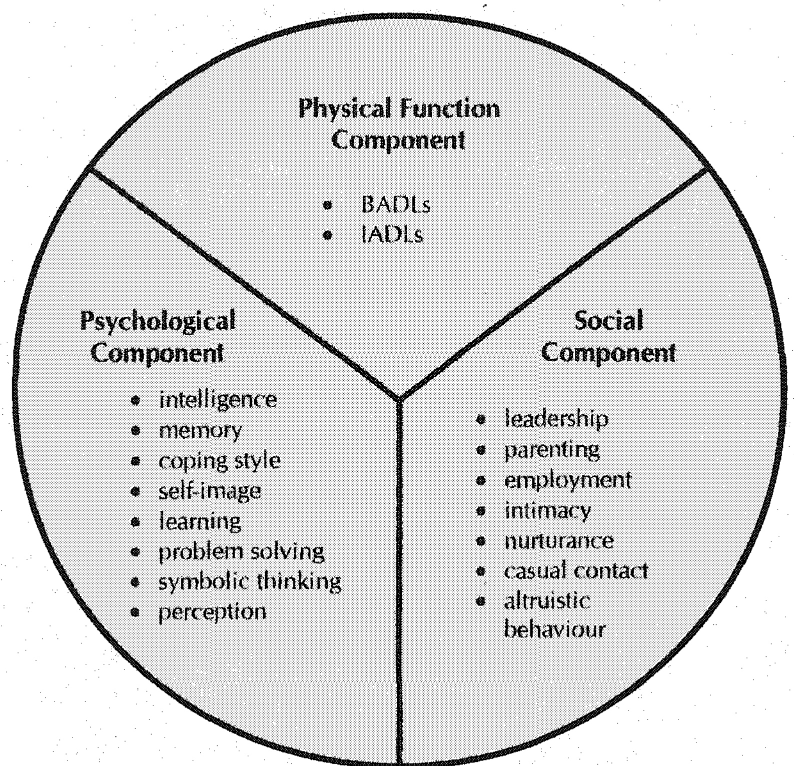


Figure 2.4.3c. Interactions Between Components of the ICF - WHO, 2001



One final model by Engel (1982), describes a person's health as a composition of various physical, psychological, and social capabilities. This concept is merely a simplified version of Duncan's (1994) and Wilson and Cleary's (1995) models where the additional factors that the latter two models have highlighted can fall into one of Engel's broader components. Unlike the previous linear models, all three components in this framework can interact with the other where a change in one component can affect the others.

Figure 2.4.3d. The Biopsychosocial Framework for HRQL - Engel, 1982



2.5. Physical Performance and HRQL

Although the ultimate goal of clinicians is to improve the patient's overall HRQL, this construct itself cannot be treated. The various models serve as a starting point for identifying the modifiable components that affect HRQL. However, the theories behind the models must be tested, the concepts refined, and tested again (Hunt, 1997).

One aspect of HRQL that is highly relevant in the field of rehabilitation is the extent to which performance on physical tasks impact on HRQL. Rehabilitation focuses on improving an individual's capacity and performance on these tasks that are crucial for basic and instrumental ADLs as well as for participation in family, social, and community life. Understanding how capacity and performance affects HRQL is important for identifying areas where interventions would yield the greatest impact on HRQL.

There are many aspects of physical performance that are theoretically linked to HRQL. There are also a variety of measures that can be used to assess functioning and disability. In this thesis, physical performance measures will refer to those that use viewed-performance to rate individuals. Interview-based measures are those evaluated through questionnaires, where the person is asked to rate their own perceived performance.

Measuring HRQL is a more difficult task. Hunt (1997) noted that the lack of its conceptual clarity due to its varying components and to the fact that there is no gold standard measure has led to a plethora of measures evaluating related constructs. There are many examples of questionnaires asking about basic, instrumental, and community ADLs.

2.6. Summary of Background Material

Table 2.6 provides an overview of the various studies that have examined the relationship between physical performance and HRQL. Cross sectional analyses reveal that HRQL is impacted upon by stroke (Duncan et al., 1997; Wyller et al., 1997; Hackett et al., 2000) even among persons with relatively good functional outcome (Hop et al., 1998). The construct groupings associated with HRQL have been functional status, social support, and mental health (King, 1996; Wyller et al., 1998; Kim et al., 1999).

There have been few longitudinal studies (Duncan et al., 1998; Jonkman et al., 1998; Kauhanen et al., 2000) demonstrating that a rehabilitation intervention improved HRQL. Although functional status has shown to be associated with HRQL, the strength of its various components has never been examined over time.

Table 2.6. Summary of Recent Studies Examining Physical Performance and HRQL

Author(s)	Design	Outcome (Measures)	Construct(s) (Measure)	Results
King, 1996	Cross-sec.	HRQL (QLI)	Functional status (FIM)	Functional status, social support, and depression explained 38% of QoL.
Duncan, 1997*	Cross-sec.	Health status (SF-36)	Functional status (BI)	Health status was lowest for persons with stroke compared to controls and TIA.
Wyller, 1997*	Cross-sec.	Well-being (GHQ-20)	Not assessed	Subjective well-being for persons with stroke is lower than controls at 1 year post-stroke mainly due to arm impairments.
Hop, 1998*	Cross-sec.	HRQL (SIP, SF-36, VAS)	Functional status (Rankin Scale)	Having good functional outcomes still resulted in lower levels of QoL.
Wyller, 1998*	Cross-sec.	Well-being	Functional status, sociodem. characteristics	Women, older age, good general/mental health, social support were asso. with high levels of subjective well-being.
Kim, 1999*	Cross-sec.	HRQL (QLI)	Functional status (FIM, FAI), social support (SSI-PAD), depression (CES-D)	Depression, marital status, social support, and functional status were the most important variables associated with QoL.
Hackett, 2000*	Cross-sec.	HRQL (SF-36)	Not assessed	Persons with stroke, especially women, older persons, and those living in institutions, had lower levels of QoL when compared to healthy controls.

Table 2.6. Summary of Recent Studies Examining Physical Performance and HRQL (cont'd)

Author(s)	Design	Outcome (Measure)	Construct(s) (Measure)	Results
Duncan, 1998*	Longitudinal	HRQL (SF-36)	Functional status (BI, Lawton IADL, 10-m Walk, 6-min Walk, Berg Balance, Jebsen Test of Hand Func.)	The intervention increased walking speed and distance, balance, and QoL.
Jonkman,1998*	Longitudinal	HRQL (SIP)	Cognition (WAIS) mood, neurological deficit	QoL improved slightly between 3 to 12 months. The decrease in QoL was only correlated to depression.
Kauhanen, 2000*	Longitudinal	HRQL (RAND-36)	Functional status (BI), handicap (Rankin Scale), cognition (MMSE)	Only the domains of PF and RP of the SF-36 improved after one year.

Legend and Abbreviations:

*	Multiple authors
BI	Barthel Index
CES-D	Center for Epidemiologic Studies Depression Scale
CNS	Canadian Neurological Scale
FAI	Frenchay Activities Index
FIM	Functional Independence Measure
GHQ	General Health Questionnaire - 20 Questions
MMSE	Mini-Mental State Examination
QLI	Ferrans & Powers Quality of Life Index
RAND-36	RAND 36-Item Health Survey
RNLI	Reintegration to Normal Living Index
SIP	Sickness Impact Profile
SF-36	MOS 36-Item Short-Form Health Survey
SSI-PAD	Social Support Inventory for Stroke Survivors
VAS	Visual Analogue Scale
WAIS	Wechsler Adult Intelligence Scale

CHAPTER 3

RATIONALE AND RESEARCH OBJECTIVES

Improving an individual's health-related quality of life (HRQL) may be considered as the ultimate outcome of rehabilitation, however HRQL itself cannot be treated. Rather, the functions and disabilities making up this concept are the targets of treatment. Therefore, it is important to understand the relative contribution of these functions and disabilities to HRQL.

The purpose of this study is to address the following objectives:

1a. ***To estimate the extent to which physical performance is associated with HRQL post-stroke.***

An increase in a person's physical performance will increase the ability to participate in physical and social activities ultimately increasing HRQL. Therefore, it is hypothesized that a significant relationship does exist between physical performance and HRQL.

1b. ***To identify the additional impact of psychosocial variables on HRQL post-stroke.***

In addition to physical performance, it is hypothesized that social functioning and psychological functioning will affect HRQL. However, physical performance will be the strongest determinant of HRQL.

2. ***To estimate whether the relationship between HRQL and those factors modifiable by rehabilitation differ over time.***

Chapter 4

Methods

4.1. Research Design

This study was situated within a randomized clinical trial: *The Effectiveness of Rehabilitation Therapy in Stroke* (Mayo et al., 1999). The patients were randomized to either an ***Arm Use*** or a ***Walking Competency*** rehabilitation program and were followed longitudinally for a period of six weeks.

4.2. Study Population

The participants for this study come from subjects in a clinical trial. Because this is an observational study, their representativeness to all possible eligible subjects is an issue. Therefore, the characteristics of the participants and non-participants were collected and compared. Those who participated in this trial had completed formal post-stroke rehabilitation and had consented to be randomized to either the *Arm Use* or *Walking Competency* program (Appendix 4.2.1). In addition, they had to meet the following:

Inclusion Criteria:

1. first time stroke defined as *the sudden onset of a focal neurologic deficit due to a presumed local disturbance in the blood supply to the brain* (WHO, 1971)
2. discharged home by three months post-stroke
3. independent in mobility (no wheelchairs)

Exclusion Criteria:

1. stroke secondary to metastatic disease
2. severe cognitive deficits as evaluated by the telephone version of the Mini-Mental State Examination (Folstein et al., 1975)
3. severe co-morbid conditions that interfered with the patient's ability to participate in the intervention or evaluations

Patients were not excluded on the basis of their age, as age should not affect the outcome of physical rehabilitation (Olney, 1994; Salbach, 1997) or on language as long as the patients were accompanied by a family member or friend who spoke either English or French. The trial received ethical approval from the McGill University Health Centre Institutional Review Board (Appendix 4.2.2).

4.3. Data Collection

The baseline evaluation was conducted prior to randomization. Following the initial evaluation, the six-week intervention was provided, and then the post-intervention evaluation was performed. Details of the intervention are found in Appendix 4.3. Each evaluation consisted of both viewed-performance tests and interview-based measures conducted at the Richardson Hospital Centre. For the purposes of this study, both groups were combined.[1]

[1] The circumstances of the trial prohibit interim analyses by group.

4.4. Measurement of Study Variables

Three types of variables were considered in this study. The outcome variables were measures of HRQL. The explanatory variables were measures of functioning and disability. Finally, the confounding variables were medical and socio-demographic information. A detailed description of the measures is provided in Appendix 4.4.

4.4.1. Outcome Variables (HRQL)

The primary outcome measure to assess HRQL was the visual analogue scale (VAS) of the EuroQol-5D (EQ-5D) (Kind, 1995). A secondary measure was the Medical Outcomes Study 36-item Short Form Questionnaire (SF-36) (Ware, Sherbourne, 1992). Although the EQ-5D and the SF-36 are generic measures of HRQL and health status, they have been validated for the stroke population (Anderson et al., 1996; Dorman et al., 1997). Both these measures were administered during the baseline and post-intervention evaluations.

EuroQol-5D *(EQ-5D):* This measure is composed of two parts. The first part evaluates health status providing a description of health in five dimensions (*mobility*, *self-care*, *usual activities*, *pain/discomfort*, and *anxiety/depression*). Each dimension has three ordinal levels of severity. Patients classify their health states by choosing one level of severity in each dimension so that their overall health state is defined as a five-digit number. There are 243 possible health states (3^5). The second part consists of a 20 cm vertical visual analogue scale with endpoints from 0 (the worst imaginable health state) to 100 (the best imaginable health state). The patients were asked to rate their HRQL on the day that the questionnaire was administered. The EQ-5D has been tested to be valid (concurrent and discriminant) for the stroke population (Dorman et al., 1997), has substantial test-retest reliability (*k* statistic from 0.6 to 0.8) (Dorman et al., 1998), and can also be used with proxies (ICC=0.5) (Dorman et al., 1997). The EQ-5D takes approximately five minutes to complete and has been translated into a French-Canadian version (Mayo et al., 1997).

Medical Outcomes Study 36-item Short Form Questionnaire *(SF-36):* This is a measure of HRQL which comprises of eight subscales: *Physical Functioning, Role Limitations (physical), Bodily Pain, General Health, Vitality, Social Functioning, Role Limitations (emotional)*, and *Mental Health*. Each question is scored ordinally then transformed on a scale of 0 to 100 with higher scores representing better health. Two summary scores, *Physical Composite Score* (PCS) and *Mental Composite Score* (MCS), can also be obtained by grouping the subscales which result in a mean of 50 ± 10 for the healthy US population (Ware et al., 1994). Canadian norms have also been recently published (Hopman et al., 2000). The SF-36 has been tested to be sensitive, reliable, and valid when administered in person or over the telephone (Anderson et al., 1996; Brazier et al., 1996; Watson et al., 1996; Dorman et al., 1998). Moderate agreement was found when administered with a proxy (ICCs from 0.4 to 0.6) (Dorman et al., 1997). It takes approximately ten minutes to complete and has also been translated into a French-Canadian version (Wood-Dauphinee et al., 1997).

4.4.2. Explanatory Variables

Various constructs of physical performance were assessed using I) performance-based measures and II) interview-based measures.

I) Performance-Based Measures

a) Body Functions and Structures / Impairment

The Stroke Rehabilitation Assessment of Movement (STREAM): evaluates voluntary motor ability and basic mobility of the affected upper and lower extremity in comparison to the unaffected side. The STREAM is comprised of 10 items for the upper extremity and 20 items for the lower extremity combined to produce a total score from 0 to 70. Inter-rater and intra-rater reliability were found to be above 0.9 for the total and subscale scores. Internal consistency was demonstrated by Cronbach alphas of greater than 0.9 (Daley et al., 1999). Both validity and responsiveness have also been tested (Ahmed, 1998). For the purposes of this study, the items of the STREAM assessing the upper and lower extremity were separated and analyzed as two different measures.

Grip Strength Test: measures the strength of the affected hand (kg of force) using the Jamar™ dynamometre. Inter-rater reliability was found to be greater than 0.9 and test-retest reliability proved to be over 0.8 (Mathiowetz et al., 1984). Three trials were administered and the average score was taken.

b) Activity / Activity Limitations

The Box & Block Test: evaluates gross manual dexterity of the affected hand by recording the number of equal-sized blocks (2.5 cm) moved from one compartment to another in 60 seconds. Test-retest reliability and construct validity were reported to be above 0.9 (Cromwell, 1976; Mathiowetz et al., 1985; Desrosiers et al., 1994).

The Nine-Hole Peg Test: assesses fine manual dexterity using the time (seconds) required to place nine pegs (0.6 cm in diametre and 3.2 cm in length) onto a board with nine holes (spaced 3.2 cm apart), then removing them. Inter-rater reliability was found to be between above 0.9 for both hands and test-retest reliability was 0.4 for the right hand and 0.7 for the left hand (Mathiowetz et al., 1985). These properties were established using a relatively small sample size.

«Test d'Évaluation des Membres Supérieur des Personnes Agées» (TEMPA): measures upper extremity sensorimotor skills while performing nine everyday tasks (unilateral and bilateral) (Desrosiers et al., 1991). Each task is evaluated on the speed of execution and quality of movement on a four-point ordinal scale. The overall score ranges from -207 to 0 (the time required to complete the task is not reflected in the total score). Concurrent validity was between 0.7 and 0.9, construct validity from 0.5 and 0.7 (Desrosiers et al., 1995), and test-retest reliability was above 0.9 for unilateral tasks while it was less than 0.7 for most bilateral tasks (Richards et al., 2001).

The Berg Balance Scale: assesses balance while executing 14 single tasks that one may be required to perform on a daily basis. Each task is scored on a five-point ordinal scale for an overall score ranging from 0 to 56. An ICC of 1.0 was reported for the total score and 0.7 to 1.0 for the individual items (Berg et al., 1992). Construct validity and responsiveness have also been tested in the stroke population (Berg et al., 1992; Berg et al., 1995).

Gait Speed Tests: measures the time (seconds) required to walk a distance of five metres at both a comfortable pace and a maximum pace (Holden et al., 1984; Wade et al., 1987). Test-retest and inter-rater reliability ranged from 0.9 to 1.0.

Stair Climbing: evaluates the ability to negotiate a full flight of stairs (10 steps). The time required to climb up and down were recorded separately and averaged into one time (seconds). The test protocol is similar to that of Olney (1979).

The Timed "Up & Go" Test: assesses mobility by measuring the time (seconds) to rise from a chair, walk a distance of three metres, return to the chair, and sit back down (Podsiadlo, Richardson, 1991). Inter-rater and intra-rater reliability were found to be above 0.9 (Venturini et al., 1995).

The Community Balance & Mobility Scale: evaluates both balance and mobility through 13 tasks (unilateral and bilateral), each rated on a six-point ordinal scale for an overall score ranging from 0 to 96. Psychometric properties are currently being developed for this measure.

The Six-Minute Walk Test: assesses walking endurance (distance in metres) adapted from the 12-minute walk test developed by Cooper (1968). Validity and reliability have been demonstrated in persons with chronic heart failure and chronic lung disease (Guyatt et al., 1985, Guyatt et al., 1985).

II) Interview-Based Measures

a) Activity / Activity Limitations

The Barthel Index: evaluates functional independence in ten basic activities of daily living (Mahoney, Barthel, 1965). Each item has three ordinal levels and the overall score ranges from 0 to 100. Predictive validity, concurrent validity, and reliability have been demonstrated (Roy et al, 1988; Wade et al., 1983).

The Older American Resource Scale (OARS): assesses the ability to perform instrumental activities of daily living through seven items scored on a three-point ordinal scale with the final score ranging from 0 to 14. Test-retest reliability between 0.7 and 0.8 and inter-rater reliability of 0.9 have been reported (Kane, Kane, 1991; McDowell, Newell, 1996).

b) Participation / Participation Restrictions

The Reintegration to Normal Living (RNL) Index: evaluates participation in family, social, recreational, and community activities through 11 items scored on a three-point ordinal scale. The overall score ranges from 22 to 0 with lower scores indicating better participation. Internal consistency was found to be above 0.9 with an inter-rater reliability of 0.6 (Wood-Dauphinee et al., 1988).

4.4.3. Confounding Variables

Data on potential confounders that may have influenced the patient's HRQL and physical performance were also collected. This included medical information (co-morbid conditions, type and side of stroke, extremity most affected) and socio-demographic information (age, gender, language, education, living arrangement).

Table 4.4. Summary of Study Variables

Constructs	Measures
<u>Outcome Variable</u>	
HRQL	EQ-5D - Visual Analogue Scale (scored 0 to 100)
	EQ-5D - Health Dimensions (3-level ordinal scale, 5 scores combined for 5-digit total score)
	SF-36 - PSC, MCS (scored 0 to 100)
<u>Explanatory Variables</u>	
Performance-Based Measures	
Upper Extremity	
Movement	STREAM - UE (scored 0 to 20)
Strength	Grip Strength - affected hand (kg of force)
Manual dexterity	Box & Block - affected hand (no. of blocks - 0 to 150)
	Nine-Hole Peg - affected hand (time in sec)
Function	TEMPA (scored -207 to 0)
Lower Extremity	
Mobility	STREAM - LE (scored 0 to 50)
	Stair Climbing (time in sec for 10 steps)
	Timed "Up & Go" (time in sec)
Balance	Berg Balance Scale (scored 0 to 56)
	CB&M Scale (scored 0 to 96)
Gait speed	Com. & Max. Gait Speeds (time in sec to walk 5 m)
Cardiovascular endurance	Six-Minute Walk (distance walked in m)
Interview-Based Measures	
Basic ADL's	Barthel Index (scored 0 to 100)
Instrumental ADL's	OARS (scored 0 to 14)
Participation	RNL Index (scored 22 to 0)

4.5. Statistical Analyses

Prior to proceeding with the analyses to address the two research objectives, the characteristics of the participants were described and compared to the non-participants. Chi-square tests and t-tests were used to compare socio-demographic and stroke-related information. Means, medians, standard deviations, and ranges of the HRQL variables, physical performance measures, and potential confounders were calculated at baseline and at post-intervention.

Pearson's correlation co-efficients were calculated at both points in time to describe the relationship among all variables measured on a continuous scale. Because most confounders were categorical, an Analysis of Variance (ANOVA) was used to assess their relationship with the HRQL variables and the physical performance measures.

The statistical analyses used to address each objective are described below.

Objective 1:

To estimate the extent to which physical performance is associated with HRQL post-stroke and to identify the additional impact of psychosocial variables.

Univariate associations between the outcome variables, VAS, PCS, MCS, and the physical performance variables were assessed using simple linear regression at baseline and at post-intervention. Because the physical performance variables were all measured on different scales, the parameter estimates from these univariate models were not comparable as to their separate impacts on the outcome. Therefore, to create a unified scale, the parameter estimates were standardized by multiplying each β with the standard deviation (SD) of the study sample. The standardized parameter is interpreted in the following way: groups that differ by one SD on the explanatory variable will differ by "x" standardized β units on the outcome. Ninety-five percent confidence intervals and R-squared values were also calculated for each univariate model.

The relative effects of the physical performance variables were assessed using multiple linear regression at both points in time. For these analyses, only the VAS was used as the outcome variable. The parameters of interest were the amount of variability in the VAS explained by the physical performance measures. Total R-squared values were obtained for the models as well as semi-partial correlation co-efficients for each physical performance measure.

In this type of analysis, the R-squared parameter depends upon the order in which the variables are entered. Therefore, a hierarchical sequence of the components of functioning and disability had to be established. The upper and lower extremity functioning tests were entered first as they assessed single constructs that are related to the more complex constructs of basic ADLs, instrumental ADLs, and participation (see Table 4.4). As the impact of the potential confounders was negligible, they were excluded from the analyses. Psychosocial variables were entered in the model last. These variables were derived from subscales of the SF-36 (Social Functioning, Bodily Pain, Vitality, and Mental Health).[2]

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[2] The need to consider psychosocial variables as explanatory was the principle reason why components of the SF-36 (PCS, MCS) were no longer used as outcome variables.

Residual plots were generated for the outcome with each physical performance measure, while adjusting for those variables already in the model, to ensure that the assumptions for regression (normality, linearity, homoscedacity) were met. Regression diagnostics were used to assess the extent of collinearity and the influence of potential outliers in the data. This was achieved by examining the Variance Inflation Factor of each variable and the Cook's Distance of each observation.

To aid in the interpretation of the R-squared and semi-partial R-squared values of the physical performance variables to HRQL, the results were depicted with a pie graph. The total amount of area to be explained by the semi-partial R-squared of the different components was that amount of variation explainable by all the measures at baseline and post-intervention.

Objective 2:

To estimate whether the relationship between HRQL and those factors modifiable by rehabilitation differ over time.

To assess the impact of time on the physical performance and psychosocial functioning variables, models based on Generalized Estimating Equations (GEEs) were used. This analysis is similar to a repeated measures analysis of variance (ANOVA). One difference is that the correlation between the measures at both points in time is considered in the analysis. The regression parameters indicate the strength of the association between the independent variable and the dependent variable adjusted for time.

Because the number of variables with respect to total sample size was large, the measures were grouped into common constructs.[3] A confirmatory factor analysis was used to verify that all the variables could be grouped as follows: upper extremity functioning, lower extremity functioning, BADLs, IADLs, participation, and psychosocial functioning. Next, in order to sum up all the measures in their respective group, the score of each measure was standardized using the z-statistic.

A diagrammatic representation of all the steps for the analyses is presented in Appendix 4.5. All analyses were performed using the Statistical Analysis System (SAS) for Windows Version 6.12.

Sample Size Estimation

The sample size required for this study was estimated using Kramer and Thiemann's (1987) calculations for linear regression. With a critical effect size of 0.40 and using a correlation coefficient of 0.6 as the maximum value between two predictor variables, a sample size of 36 patients is required. However, this number must be adjusted to account for multiple predictor variables using the formula $n = v + p + 1$ where v is the number of patients calculated for simple regression and p is the additional number of predictor variables. Therefore, a total of 47 patients was planned to obtain 80% power in identifying important predictors.

[3] Each specific measure represented an important construct in the context of rehabilitation and was therefore worthy of consideration in influencing HRQL.

Chapter 5

Results

5.1. Description of Study Sample

From July 2000 to September 2001, 142 persons with stroke were identified as being eligible for the clinical trial and basic socio-demographic as well as stroke-related information were collected. Of those eligible, 46 patients agreed to participate. Table 5.1 summarizes the characteristics of all the participants and the non-participants indicating that no significant differences existed between the two groups with respect to age, gender, language, living arrangement, and side of stroke ($p > 0.10$). For two variables, number of co-morbid conditions and type of stroke, there were some differences. It is noteworthy that the non-participants had a tendency to have greater co-morbidity than the participants ($p = 0.07$). One of the main reasons that individuals declined to participate in the trial was related to the reduction in their health status due to other medical conditions. Type of stroke was also significantly different ($p = 0.02$), however, this may have been due to the amount of missing data on the non-participants (27%).

Of the 46 patients recruited into the study, three patients were unable to participate in the post-intervention evaluation. Within those who participated in both evaluations, three did not perform the Six-Minute Walk Test, one did not perform the Stair Climbing Test, and one did not perform the Grip Strength Test. In these instances, a score for the missing measure was imputed using the mean of different scores from a comparable group of patients. Therefore, complete data were available for 43 patients.

There was a predominance of men compared to women (65% versus 35%) and English speaking participants compared to French speaking (74% versus 19%). Seven percent of the patients did not speak either English or French, therefore, a family member was present at the evaluations to translate the instructions for the performance-based tests and the questionnaires. The mean age of the participants was 72±10 years ranging from 46 to 88 years. Sixteen percent of them lived alone, 68% lived with their spouses, and 16% lived with other family members. In addition to their stroke, 46% had less than three co-morbid medical conditions, 42% had from three to four, and 12% had five or more. The majority of patients suffered ischemic strokes (79%) while less had hemorrhagic strokes (14%). The lesion was on the left side for 49%, the right side for 49%, and a bilateral lesion occurred for 2%. The apparent disability was noted in the upper extremity for 30% of the patients, in the lower extremity for 35%, and in both or neither extremity for 35%.

5.2. Description of Study Sample on Outcome Variables

The correlation co-efficients between the three outcome measures, VAS, PCS, and MCS, were examined to determine if they were measuring similar constructs of HRQL.

At baseline, the correlation co-efficient was 0.4 between the VAS and PCS, 0.3 between the VAS and MCS, and -0.2 between the PCS and MCS. At post-intervention, they were 0.6, 0.2, and -0.2 respectively. The association between the VAS and the PCS at both evaluations was statistically significant ($p < 0.05$) suggesting that they assessed similar components of HRQL while the MCS was capturing slightly different constructs.

Although the health dimensions of the EQ-5D were assessed for all patients, the scores were not included in the analyses due to their significant associations ($p < 0.05$) with the similar constructs of the SF-36 (Appendices 5.2a and 5.2b). The *Physical Functioning* subscale of the SF-36 was correlated with *Mobility*, *Self-Care*, and *Usual Activities* of the EQ-5D (Spearman's correlation co-efficients ranging from 0.4 to 0.7). *Bodily Pain* of the SF-36 correlated with *Pain* of the EQ-5D ($r = 0.6$ at baseline and $r = 0.4$ at post-intervention). Finally, the association between *Mental Health* of the SF-36 and *Anxiety/Depression* of the EQ-5D correlated at $r = 0.5$ for both evaluations. A study conducted by Dorman et al. (1999), demonstrating similar results, concluded that both measures assess similar aspects of HRQL despite differences in background, structure, and content.

Table 5.2 provides the means, standard deviations, medians, and ranges for the VAS of the EQ-5D as well as the PCS and MCS of the SF-36 including all of its eight subscales. The mean scores for the VAS, PCS, and MCS changed very little form baseline to post-intervention. The only statistically significant change ($p < 0.05$) between the two evaluations was in the *Physical Functioning* subscale, increasing from 39.1 to 52.4.

5.3. Description of Study Sample on Physical Performance Measures

A summary of the mean scores, standard deviations, medians, and ranges for both evaluations is presented in Table 5.3. The only measures in which the scores increased significantly ($p < 0.05$) were the Box & Block, the TEMPA, and the Barthel Index. Slight decreases (increases in time) were noted in Maximum Gait Speed (from 11.1 sec to 12.0 sec), Stair Climbing (from 20.9 sec to 21.1 sec), and the Timed "Up & Go" (from 25.2 sec to 25.3 sec), however, none of these differences were statistically significant.

5.4. Correlations Between HRQL and Physical Performance Measures

The correlation co-efficients between the VAS and PCS with the physical performance measures at baseline ranged from $r = 0.1$ (VAS with Nine-Hole Peg) to $r = 0.5$ (VAS with Six-Minute Walk). At post-intervention, the correlations were stronger for most measures with $r = 0.2$ (PCS with TEMPA) to $r = 0.5$ (VAS with Timed "Up & Go", PCS with Six-Minute Walk). When examining the associations by extremity, only Grip Strength was consistently significant in the upper extremity measures whereas all the lower extremity measures were significant with the VAS and PCS at both evaluations ($p < 0.05$) (Appendix 5.4.a).

The correlation co-efficients for the MCS with the physical performance measures ranged from $r < 0.1$ to 0.1 at baseline and from $r = -0.1$ to -0.3 at post-intervention

(Appendix 5.4.a). In general, the correlations were quite low demonstrating that the association between mental health and physical performance is weak. The negative values indicated that the MCS decreased although the performance on that particular measure improved.

To further examine the strength of association between HRQL and physical performance, the values on five measures, Grip Strength, Timed "Up & Go", Six Minute Walk Test, Barthel Index, and the RNL Index, were categorized into quartiles[4] and regressed against the VAS. The mean value of the VAS was calculated for each quartile and the strength of the linear relationship was assessed using the visualization of scatter plots (Appendix 5.4.b) and simple linear regression (Table 5.4). There was a statistically significant linear relationship between the VAS and the Timed "Up & Go" (post-intervention), Six-Minute Walk (baseline), and RNL Index (both points in time). For the other measures, there was a clear separation between the Quartile 1 and 4 but the separation between Quartile 2 and 3 was less distinct.

5.5. Associations Between Variables and Potential Confounders

The mean scores for the VAS, PCS, and MCS were compared with respect to differences in socio-demographic and stroke-related information using ANOVAs (Tables 5.5.a and 5.5.b). Significant differences ($p < 0.05$) were found in the scores of the VAS according to age, side of stroke, and extremity affected. The PCS was only influenced

[4] A quartile is when the distribution is divided into four equal parts with each part comprising 25% of the sample.

by whether the patient lived alone or with someone else (spouse or others). No associations were found with the MCS.

When the relationship between the physical performance and the confounding variables was assessed, no significant differences were found at either point in time. Therefore, the confounders were not used for further analyses.

5.6. Univariate Associations Between HRQL and Physical Performance

At baseline, univariate models of each explanatory variable with the VAS were significant for all the lower extremity measures as well as the Barthel Index and the RNL Index ($p<0.05$). The upper extremity tests were not significant producing lower standardized parameter estimates with the 95% confidence intervals crossing "0" ($p>0.05$). At post-intervention, all the models were significant. The standardized βs ranged from 7.6 to 11.8 indicating that groups of individuals who differed by one standard deviation change in the score of that measure resulted in an 8 to 12-point change in the VAS (Appendices 5.6a and 5.6b).

For the PCS, all the lower extremity measures were significant at both evaluations except for the Six-Minute Walk at baseline. The standardized βs for the upper extremity tests were comparable to those of the lower extremity, however, only Grip Strength was statistically significant at both evaluations (Appendices 5.6c and 5.6d). Finally, none of the physical performance measures were associated with the MCS.

5.7. Multivariate Associations Between HRQL and Physical Performance

5.7.1. Multiple Linear Regression

Two models of HRQL were generated, one at baseline and one at post-intervention. Type I regression analyses, where the variables in the model were defined *a priori*, were used. Upper extremity functioning was entered first, followed by lower extremity functioning, the Barthel Index, the OARS, and the RNL Index. The final model demonstrated that the OARS did not contribute in explaining any of the variance in either model. The addition of this variable did not increase the total R-squared value and its semi-partial correlation co-efficient was below 0.01. Therefore, the OARS was not considered as having an important association with HRQL and was not included in the models.

Using the raw R-squared of the models, 68% of the variance of HRQL at baseline and 80% at post-intervention was explained by the physical performance variables including the Barthel Index and the RNL Index. The semi-partial R-squared values of each variable were added together to demonstrate the contribution of the main constructs of physical performance to HRQL. At baseline, upper extremity functioning explained 28% of the variance, lower extremity functioning - 36%, the Barthel Index - 1%, and the RNL Index - 3%. At post-intervention, upper extremity functioning contributed 41%, lower extremity functioning - 26%, the Barthel Index – 2%, and the RNL Index - 11%.

The above regression models were re-run with lower extremity functioning entered first, followed by upper extremity functioning, then the other variables in the same order (as described on the previous page) to see if a difference existed in the amount of their contribution when the order of the first two constructs was reversed. At baseline, the R-squared value of lower extremity functioning increased slightly (from 30% to 39%) when entered first because it has not been adjusted for any other variable. Whereas, upper extremity functioning was adjusted for lower extremity functioning (already in the model) therefore decreased from 24% to 15%. However, their total contribution remained unchanged at 54% for both models. Similar results were found at post-intervention.

In order to account for the proportion of HRQL that was not explained by physical performance, subscales from the SF-36 describing psychosocial functioning (*Social Functioning, Bodily Pain, Vitality, and Mental Health,*) were included as final variables to the existing models. The addition of these subscales resulted in a raw R-squared of 0.7 at baseline and 0.9 at post-intervention with psychosocial functioning contributing 18% and 13% respectively (Figures 5.7.1a and 5.7.1b).

The question remains to whether the physical performance measures contributed anything over and above self-reported measures. The correlation co-efficients (Appendix 5.7.1a) and parameter estimates (Appendix 5.7.1b) between the VAS and SF-36 subscales were calculated. As well, the proportional contribution of the subscales to the VAS was examined (Table 5.7.1).

Table 5.7.1. Total Variance of VAS Explained by Physical Performance Measures Versus SF-36 Subscales

Variables	Number of Measures	Total R^2 - Pre		Total R^2 - Post	
		Raw	Adj.	Raw	Adj.
Physical Performance	*13*				
Activities (Barthel Index)	*1*				
Participation (RNL Index)	*1*				
*Psychosocial Functioning**	*4*				
ALL	19	0.72	0.34	0.90	0.78
SF-36 Subscales	8	0.42	0.26	0.62	0.51

* Consisted of four subscales from the SF-36 (*Social Functioning, Bodily Pain, Vitality, Mental Health*)

Because there is a concern that the number of measures was greater when using the physical performance variables, and this in itself would increase the amount of variability explained, both the raw and adjusted R-squared are presented. As can be seen, the amount of variability explained was greater when performance measures were included, particularly at post-intervention, and this trend remained even after adjusting for the number of variables in the model.

5.7.2. Verification of Assumptions for Regression

Residual plots of the final two models were generated to ensure normality, linearity, and homoscedacity. Performing this analysis once the models were developed allows for each variable to be adjusted for the others already in the model. There were no violations of the assumptions mentioned.

5.7.3. Regression Diagnostics

The variables that were measuring the same constructs of physical performance were identified using correlations and collinearity diagnostics. Strong associations (co-efficients above 0.8) at both evaluations were detected between Comfortable with Maximum Gait Speed, Timed "Up & Go" with both Gait Speeds, and Box & Block with the TEMPA. When the variance inflation factor and the variance of proportion between the measures were examined, the same variables were shown to be problematic.

Jackknife residuals, leverages, and Cook's Distance were analyzed to detect possible outliers. Although four observations surpassed the critical values for leverages, their Cook's Distances (which is a measure of the influence that these possible outliers may have on the model, as it combines both residuals and leverages) were below the critical value. Therefore, these observations were not excluded from the analyses.

5.8. Reduction of Variables

The correlations co-efficients between the two sets of scores (at baseline and post-intervention) were all above 0.8 indicating that they were highly correlated. However, a change did occur in the total and semi-partial R-squared values between the two models suggesting that an interaction with time may have occurred. In order to examine this possibility, first, the number of variables in the model was reduced to accommodate the sample size and to eliminate collinear variables. This was achieved by grouping them to produce a summary score representing i) upper extremity functioning, ii) lower extremity functioning, iii) BADLs (Barthel Index), iv) participation

(RNL Index), v) psychosocial functioning (*Social Functioning, Bodily Pain, Vitality, and Mental Health*).

5.8.1. Factor Analysis

Next, rotational confirmatory factor analysis (orthogonal factors) was used to ensure that all the measures in each group were assessing one common construct and, therefore, could be combined together. When both the upper and lower extremity measures were analyzed together, two distinct factors were produced with the upper extremity measures loading on one (0.6 to 0.9) and the lower extremity measures loading on the other (0.6 to 0.8). The only discrepancy found was with the STREAM - LE that loaded on the upper extremity factor with a value 0.7. However, due to the small sample size (n=43), random error may have occurred, therefore, this variable remained grouped with the other lower extremity measures (0.5). When all five groups were analyzed together, four main factors resulted - upper extremity (0.6 to 0.9), lower extremity (0.6 to 0.8), participation (0.8), and psychosocial functioning (0.6 to 0.8). BADLs (Barthel Index) loaded on both the lower extremity (0.6) and the participation (0.5) factors. However, this measure assesses a different construct and was kept as a separate factor (Appendix 5.8.1).

5.8.2. Transformation of Scores

Finally, in order to sum up all the measures in their respective group, the scores were transformed into a standardized value using the following z-statistic then added together (Appendices 5.8.2a and 5.8.2b):

$$\frac{\textbf{score} - \textbf{mean}}{(\delta \,/\, \textbf{sq.rt. n})}$$

5.9. Generalized Estimating Equations

The strength of the associations between the physical performance and psychosocial functioning variables using GEEs are presented in Table 5.9. Lower extremity functioning, BADLs (Barthel Index), participation (RNL Index), and psychosocial functioning were all statistically significant ($p < 0.05$) as demonstrated by all previous analyses. The only variable that changed significantly over time was upper extremity functioning as indicated by a significant interaction term (upper extremity functioning * time).

5.9.1. Final Regression Models of HRQL

The final regression models were as follows:

At baseline:

HRQL = 66.3 **- 0.1 (UE Func.)** + 0.5 (LE Func.) +6.9 (Barthel Index) + 2.9 (RNL Index) + 10.5 (Psychsocial Func.)

At post-intervention:

HRQL = 66.3 **+ 0.1 (UE Func.)** + 0.5 (LE Func.) +6.9 (Barthel Index) + 2.9 (RNL Index) + 10.5 (Pychosocial Func.) **+ 4.4 (time)**

Table 5.1. Comparison of Characteristics for Participants vs. Non-Participants

Characteristics	Participants (n=43)	Non-Participants (n=96)	*p*-value
Gender*			
Men	65% (28)	55% (53)	0.27
Women	35% (15)	45% (43)	
Language*			
English	74% (32)	55% (53)	0.10
French	19% (8)	33% (32)	
Other	7% (3)	12% (11)	
Age†	71.7 (10.0)	72.8 (12.7)	0.56
Living arrangement*			
Alone	16% (7)	16% (15)	0.36
Spouse	68% (29)	54% (52)	
Other	16% (7)	26% (25)	
Not noted	0	4% (4)	
No. Comorbid Conditions*			
<3	46% (20)	32% (31)	0.07
3-4	42% (18)	40% (38)	
>4	12% (5)	28% (27)	
Level of Education*			
None / Primary	40% (17)	N/A	—
Secondary	40% (17)	N/A	
College / University	20% (9)	N/A	
Type of stroke*			
Ischemic	79% (34)	66% (63)	0.02
Hemorrhagic	14% (6)	7% (7)	
Not noted	7% (3)	27% (26)	
Side of stroke*			
Left	49% (21)	45% (43)	0.25
Right	49% (21)	43% (41)	
Bilateral	2% (1)	5% (5)	
Not noted	0	7% (7)	
Affected Extremity*			
Upper extremity	30% (13)	N/A	—
Lower extremity	35% (15)	N/A	
Both	35% (15)	N/A	
Treatment Group*			
Upper Extremity	47% (20)	—	—
Lower Extremity	53% (23)	—	

* proportion (number) N/A variable not assessed
† mean (standard deviation)

Table 5.2. Overview of Outcome Variables
Baseline and Post-Intervention (n = 43)

Outcome Measures (0-100)	Mean (SD)		Lowest		Median		Highest	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
EQ-5D								
VAS	61.8 (22.9)	67.0 (20.4)	0	20	70	70	100	100
SF-36 Composite Scores								
PCS	34.9 (8.7)	36.0 (9.9)	16	21	35	36	54	58
MCS	50.5 (9.5)	51.8 (10.9)	33	24	52	53	69	66
SF-36 Subscales								
Physical Functioning	39.1 (23.4)*	52.4 (25.1)*	5	0	40	50	85	95
Role Physical	33.3 (37.7)	25.0 (33.4)	0	0	25	0	100	100
Bodily Pain	69.7 (25.7)	66.8 (27.2)	20	0	72	62	100	100
General Health	54.6 (19.5)	62.5 (21.7)	17	10	55	62	87	100
Vitality	52.2 (17.7)	48.3 (21.2)	15	0	50	50	95	85
Social Functioning	64.1 (28.1)	68.6 (27.5)	0	0	63	63	100	100
Role Emotional	70.9 (42.0)	80.3 (38.8)	0	0	100	100	100	100
Mental Health	69.3 (16.1)	72.7 (17.8)	44	40	68	76	100	100

* statistically significant change ($p < 0.05$)

Table 5.3. **Overview of Physical Performance Variables Baseline and Post-Intervention (n=43)**

Physical Performance Variables	Mean (SD)		Lowest Scores		Median		Highest Scores	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
STREAM - UE (scored 0 to 20)	14.8 (6.7)	15.3 (6.5)	0	0	17	19	20	20
Grip Strength (kg of force)	16.0 (12.2)	17.1 (12.8)	0	0	13	15	59	43
Box & Block (no. of blocks)	25.3 (18.4)*	28.3 (19.1)*	0	0	28	32	52	56
Nine-Hole Peg† (time in sec)	117.0 (93.4)	88.9 (60.7)	243.4	172.7	59.0	64.7	22.7	19.8
TEMPA (scored -207 to 0)	-34.3 (34.3)*	-29.6 (34.3)*	-120	-101	-24	-17	0	0
STREAM - LE (scored 0 to 50)	36.6 (10.0)	39.3 (10.3)	13	11	40	44	49	50
Berg Balance (scored 0 to 56)	41.3 (11.1)	42.9 (11.7)	16	10	44	44	56	56
Com. Gait Speed† (time in sec)	13.3 (14.3)	12.7 (17.4)	62.5	96.3	7.7	6.2	3.9	3.2
Max. Gait Speed† (time in sec)	11.1 (13.4)	12.0 (19.1)	62.6	106.3	6.6	5.9	2.1	2.1
Stair Climbing† (time in sec)	20.9 (15.9)	21.1 (27.3)	67.7	125.0	15.2	13.5	4.3	3.6
Timed "Up & Go"† (time in sec)	25.2 (22.2)	25.3 (26.8)	100.0	154.4	17.3	16.1	7.0	7.1
CB&M (scored 0 to 96)	16.9 (17.5)	19.1 (18.6)	0	0	13	14	66	64
Six-Min. Walk (distance in m)	215.6 (135.8)	231.3 (140.2)	31	20	208	240	594	550
Barthel Index (scored 0 to 100)	89.4 (12.0)*	93.2 (11.9)*	60	45	95	100	100	100
OARS (scored 0 to 14)	9.5 (2.0)	10.1 (3.1)	3	4	10	11	14	14
RNL Index† (scored 22 to 0)	7.6 (4.3)	5.7 (4.8)	19	17	7	6	0	0

* statistically significant change ($p < 0.05$)
† the lower the score/time, the better the performance

Table 5.4. Mean VAS Scores by Quartile for Specific Physical Performance Measures (0-100) (n=43)

Quartiles	Grip Strength		Timed "Up & Go"		Six Min. Walk		Barthel Index		RNL Index	
	VAS Pre	VAS Post	VAS Pre	VAS Post	VAS Pre	VAS Post	VAS Pre	VAS Post	VAS Pre	VAS Post
Quartile 4	73	81	69	81	75	77	69	76	78	78
Quartile 3	64	69	67	71	69	68	60	68	57	63
Quartile 2	65	71	62	63	57	70	63	54	57	59
Quartile 1	53	55	47	43	47	49	54	45	35	45
Parameter Est.*	5.9	7.6	7.1	12.2	9.6	8.2	4.2	10.7	12.9	10.3
Standard Error*	1.7	2.3	2.1	1.9	0.8	3.1	1.7	0.8	3.0	1.5
p-value	0.07	0.08	0.08	0.02	0.01	0.1	0.1	0.01	0.05	0.02

* ratio, parameter estimate/standard error, is equivalent to a t-test

Table 5.5a. Associations Between Outcome Variables and Confounders Baseline (n = 43)

Characteristics	VAS Mean (SD)	PCS Mean (SD)	MCS Mean (SD)
Gender			
Men (n = 28)	64.1 (24.5)	36.2 (8.1)	52.4 (9.8)
Women (n = 15)	57.6 (20.1)	32.8 (9.5)	47.2 (8.1)
Language			
English (n = 32)	64.2 (23.8)	32.7 (9.1)	52.1 (10.1)
French (n = 8)	52.9 (20.6)	37.7 (7.0)	46.3 (6.2)
Other (n = 3)	59.3 (20.0)	30.7 (9.3)	45.0 (5.2)
Age			
< 65 (n = 10)	47.2 (31.9)*	33.7 (6.2)	50.4 (9.0)
65-75 (n = 16)	72.7 (12.2)*	33.2 (7.8)	49.6 (8.7)
> 75 (n = 17)	62.7 (18.5)	36.9 (10.4)	51.2 (10.7)
Living arrangement			
Alone (n = 7)	61.9 (19.8)	41.9 (5.5)*	47.0 (10.9)
Spouse (n = 29)	60.0 (24.6)	34.3 (8.5)*	51.0 (8.5)
Other (n = 7)	69.7 (20.2)	29.5 (8.8)*	52.7 (12.7)
No. Comorbid Conditions			
< 3 (n = 20)	58.6 (28.1)	35.8 (8.7)	49.6 (7.4)
3-4 (n = 18)	66.8 (19.0)	35.1 (9.0)	51.9 (12.0)
> 4 (n = 5)	55.0 (10.0)	30.7 (8.1)	49.2 (6.8)
Type of stroke†			
Ischemic (n = 34)	59.1 (23.2)	35.8 (7.9)	50.1 (9.0)
Hemorrhagic (n = 6)	68.0 (19.6)	37.7 (11.8)	50.5 (11.1)
Side of stroke			
Right (n = 21)	53.4 (24.8)	32.7 (7.9)	48.7 (8.2)
Left (n = 21)	69.9 (15.0)	37.5 (9.4)	51.6 (10.1)
Bilateral (n = 1)	100 (0)	39 (0)	69 (0)
Extremity Affected			
Upper extremity (n = 13)	64.8 (19.9)	33.5 (9.1)	51.0 (11.0)
Lower extremity (n = 15)	63.0 (21.6)	38.6 (8.7)	50.9 (10.8)
Both (n = 15)	53.5 (27.0)	33.3 (8.9)	47.7 (9.0)

* statistically significant difference ($p < 0.05$)

† type of stroke for 4 participants was not noted

Table 5.5b. Associations Between Outcome Variables and Confounders Post-Intervention (n=43)

Characteristics	VAS Mean (SD)	PCS Mean (SD)	MCS Mean (SD)
Gender			
Men (n=28)	71.4 (18.8)	38.0 (8.6)	51.5 (11.6)
Women (n=15)	59.1 (21.2)	32.6 (11.4)	52.2 (9.6)
Language			
English (n=32)	68.2 (20.6)	36.3 (10.4)	52.1 (10.1)
French (n=8)	67.9 (18.2)	38.7 (7.5)	47.6 (13.4)
Other (n=3)	53.3 (25.2)	27.3 (5.5)	58.7 (10.2)
Age			
<65 (n=10)	59.5 (26.3)	32.4 (8.7)	51.9 (12.3)
65-75 (n=16)	64.6 (22.3)	39.0 (10.8)	49.9 (12.6)
>75 (n=17)	73.1 (13.2)	36.2 (9.7)	53.0 (8.8)
Living arrangement			
Alone (n=87)	75.0 (20.2)	45.9 (9.1)*	46.7 (15.5)
Spouse (n=29)	65.6 (19.6)	35.3 (8.6)*	52.3 (9.4)
Other (n=7)	63.3 (25.0)	28.2 (8.0)*	55.5 (10.2)
No. Comorbid Conditions			
<3 (n=20)	63.1 (24.3)	37.4 (10.1)	53.3 (10.3)
3-4 (n=18)	70.7 (17.0)	35.5 (9.6)	51.0 (11.7)
>4 (n=5)	68.7 (13.1)	32.5 (11.9)	48.2 (10.8)
Type of stroke†			
Ischemic (n=34)	66.5 (19.5)	36.2 (10.0)	51.9 (10.9)
Hemorrhagic (n=6)	66.7 (24.2)	36.7 (9.4)	52.5 (12.1)
Side of stroke			
Right (n=21)	60.2 (21.6)*	33.9 (9.3)	50.4 (10.8)
Left (n=21)	73.3 (15.1)*	38.3 (10.5)	53.2 (11.2)
Bilateral (n=1)	100 (0)	42 (0)	55 (0)
Extremity Affected			
Upper extremity (n=13)	59.8 (22.9)*	34.1 (9.8)	51.8 (11.0)
Lower extremity (n=15)	79.5 (12.3)*	39.8 (12.2)	50.9 (10.8)
Both (n=15)	61.5 (19.9)*	34.4 (9.1)	51.0 (12.3)

* statistically significant difference ($p<0.05$)
† type of stroke for 4 participants was not noted

Figure 5.7.1a. Contribution of Components to HRQL - Baseline
R-squared = 0.72

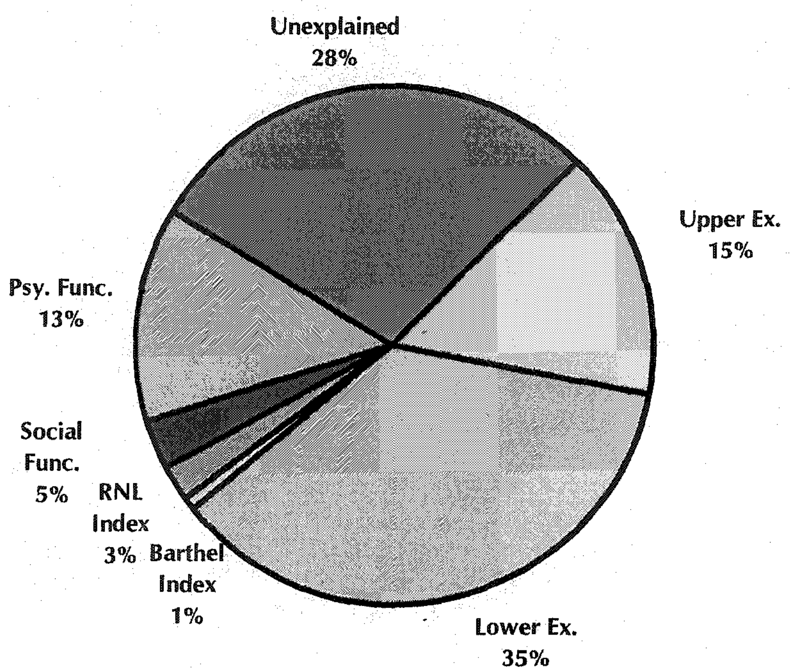


Figure 5.7.1b. Contribution of Components to HRQL - Post-Intervention
R-squared = 0.90

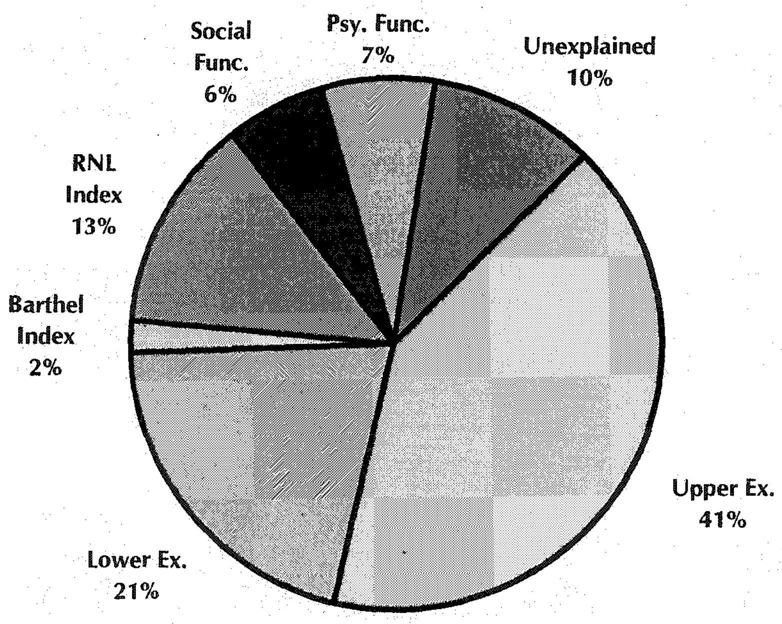


Table 5.9. Parameter Estimates for Final Model Using Grouped Z-Scores (n = 43)

Constructs	Parameter Estimate (β)	Standard Error (S_E)	*p*-value
Time (Pre) ref.	0	0	—
Time (Post)	4.4	2.9	0.13
Upper Extremity	-0.1	0.1	0.12
Lower Extremity	0.5*	0.1	< 0.01
Barthel Index	6.9	7.8	0.38
RNL Index	2.9*	1.3	0.03
Psychosocial Func.	10.5*	2.3	< 0.01
Upper Extremity and Time	0.2*	0.1	< 0.01

* statistically significant association ($p < 0.05$)

Chapter 6

Discussion

6.1. HRQL and its Determinants

The results of this study showed that the physical performance of persons post-stroke had an important impact on how they rated their HRQL. To arrive at this conclusion, we examined the proportion of variability in HRQL, as measured by the VAS of the EQ-5D, explained by the different constructs that were measured. The results of this type of analyses depend on the order in which the variables are entered (see Statistical Analyses, p. 34). Thus, it was important to have a strong theoretical model to drive the analysis. Such a model exists in rehabilitation, the WHO ICF model (see p. 17). This model suggests a strong hierarchical relationship between impairments of body structures and functions, limitations in activities, and restrictions in participation although it is recognized that alterations in capacity or performance at a higher level of functioning (e.g. participation) will affect a lower level of functioning (e.g. activities). For example, if a person does not go out in the community, the ability to walk long distances may be lost.

These theoretical relationships are supported by decades of clinical observations. Therefore, to "build" our statistical model, we began with the building blocks to activity and participation, namely capacity and performance in upper and lower extremity functioning.

Once the foundation of the model had been laid, capacity and performance in basic and instrumental activities of daily living were added, followed by participation in family, social and community life. The model was then reinforced by considering the impact of psychosocial factors such as social functioning, bodily pain, vitality, and mental health (see Statistical Analyses, p. 34).

Using this theoretical and empirical hierarchy, measures of basic and instrumental activities of daily living and of participation contributed relatively less than the building blocks of upper and lower extremity functioning. Psychosocial functioning had a greater influence on HRQL than activities and participation at baseline, however, physical performance remained the strongest determinant of HRQL at both points in time.

A summary of the results is presented in Table 6.1 where the raw R-squared was calculated to represent the total amount of variation explained by the physical and psychosocial factors. The use of this value is believed to be inflated, as it will increase as the number of variables added to the model increases. It is generally recommended that the adjusted R-squared be used to take into consideration the number of variables included in the model. This value is calculated as follows:

$$\textbf{Adjusted R-squared} = 1-[((n-1)(1-\text{R-squared}))/(n-p)]$$

where n represents the number of subjects and p represents the number of parameters. However, due to our small sample size, a change in the number of parameters will have a large effect on the adjusted R-squared. It was not reasonable to decrease the number of parameters (measures) because the model consisted of only those constructs critical to describing functioning and disability. The impact of the number of measures would be reduced if the sample size became very large. As we wish to generalize to the stroke population in general, we felt that presenting the raw R-squared was reasonable.

Table 6.1. Contribution of Construct Groupings to HRQL

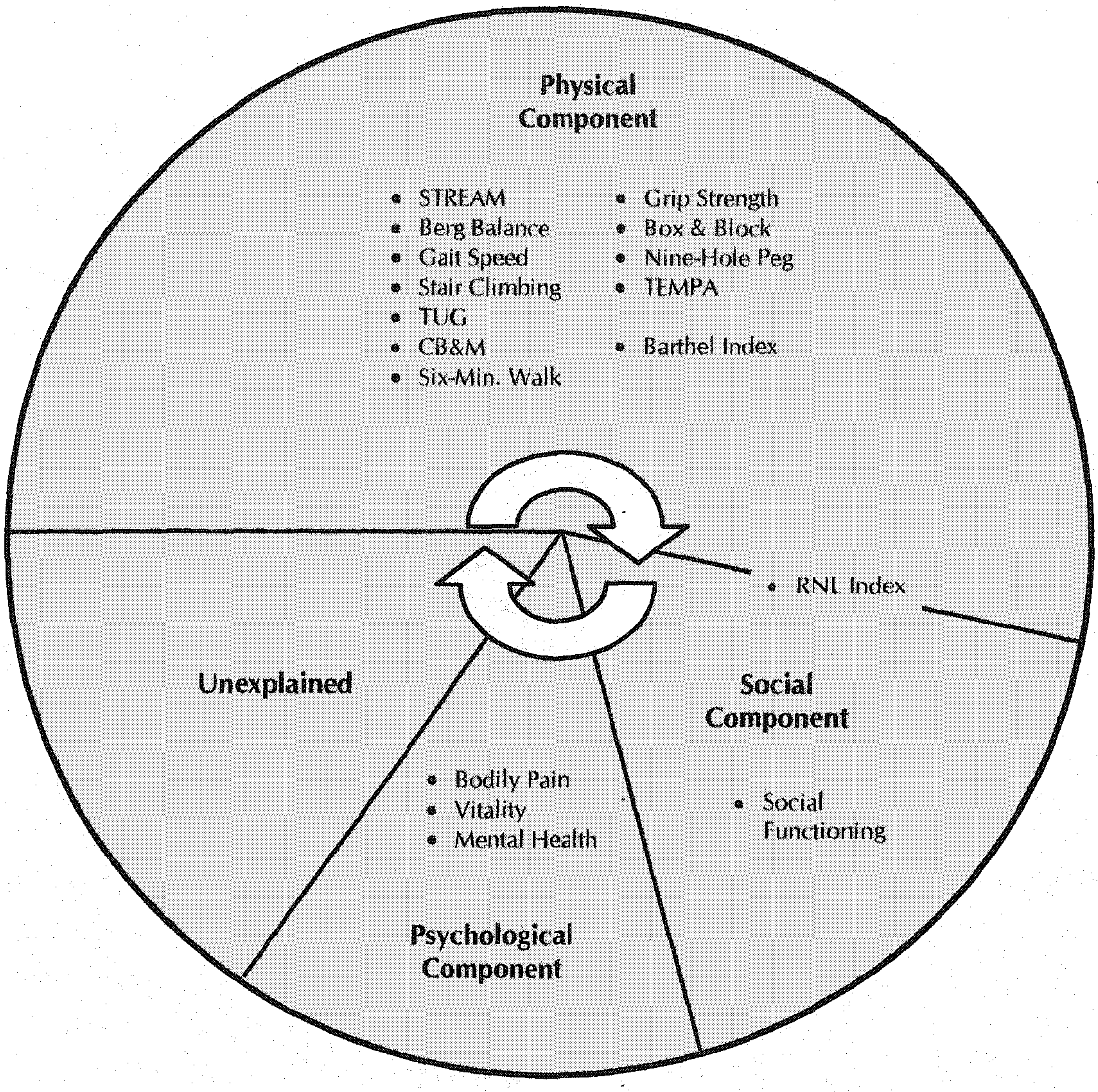
Constructs	Baseline	Post-Intervention
Upper Extremity Functioning	15%	41%
Lower Extremity Functioning	35%	21%
Basic ADLs (Barthel Index)	1%	2%
Participation (RNL Index)	3%	13%
Social Functioning	5%	6%
Psychological Functioning	13%	7%
Total	72%	90%
Unexplained	28%	10%

The ramifications of these findings are important for the practice of rehabilitation. The results imply that it is crucial to increase capacity and performance in such areas as strength, dexterity, speed, and endurance in order for a person to realize the highest HRQL possible.

The combination of physical, social, and psychological functioning to explain HRQL supports Engel's biopsychosocial framework (Figure 2.4.3d). Unlike the linear models of HRQL, all three components can have a direct influence on HRQL or an indirect influence through the other two components. In the case of social functioning, an example of a direct association would be persons who view their relationships with family and friends as positive and are able to participate in social and community activities tend to have higher levels of HRQL (King, 1996; Wyller et al., 1998; Kim et al., 1999). Therefore, a strong social support network for persons with stroke, ranging from their immediate home environment to the community, will have a great influence on their HRQL. An example of an indirect relationship would be when persons with stroke do not have family or friends to drive them or if adapted transport is not available to take them to therapy, reduced physical performance could result from their inability to access rehabilitation and affect their HRQL (Bélanger et al., 1988). In addition, a lack of socialization can lead to depressive symptoms and ultimately impact on HRQL (Åström et al., 1992).

Based on these analyses, Engel's model can be modified to reflect that these three components have varying strengths in terms of their individual relationships to HRQL and do not influence HRQL equally. A graphic representation of the theoretical relative contributions of the different components is depicted in Figure 6.1.

Figure 6.1. Theoretical Model of HRQL



The relative size of the components has been estimated from our data and while there may be some variability across different samples of subjects, this can serve as a working model. The measures that were used are listed, and while not exhaustive, cover the constructs in the respective groups. The proportion of this pie graph that represents the physical component of HRQL is substantial. The Barthel Index (measuring BADLs) is listed but not the OARS (measuring IADLs) because it did not contribute to HRQL once the physical performance measures and the Barthel Index were included. The RNL Index is situated at the junction of the physical and social components as this measure has features of both. A small proportion of HRQL remains unexplained and perhaps can only be individually determined.

6.2. Inferring Causation from Association

The overriding wish in studies of relationships between and among variables is to identify those variables that are causally related to the outcome of interest. This study is no different. As far back as the 1930's, criteria to infer causality from observational studies have been proposed (Hill, Bradford, 1977). The first criterion is a *strong relationship*. While the correlations here could not be considered "strong", there are moderate correlations between the VAS and the physical performance measures. The correlations ranged from 0.1 to 0.5 (see Appendix 5.4.a).

Another important criterion is demonstrated by a *logical gradient*. In our study, evidence that persons with higher levels of functioning should have higher levels of HRQL was partially demonstrated (see Table 5.4). However, the value of HRQL for people in each quartile was not always linear. The value of HRQL between Quartile 2 and Quartile 3 did not differ although physical performance did[5]. One explanation may be because small changes in performance may not be enough to translate into increase activity. For example, in the case of individuals who wish to return to playing cards with friends, small increases in manual dexterity may still not enable them to hold the cards. Their performance in hand functioning may need to exceed a certain level before they can carry out the activity.

Another point worth noting is that HRQL decreased after six weeks for individuals in the lowest quartiles for the Barthel Index. As this measure assesses very basic activities of daily living, the realization that one is unable to accomplish these may lead to a reduction in HRQL over time.

In interpreting the results of the secondary analysis, we are aware that our sample size was not sufficient. It was calculated to answer the primary objective only. In a larger sample, the power to detect changes across quartiles would be increased.

Another criterion for causality is that the "exposure" (performance) must precede the "outcome" (HRQL) and not arise as a consequence of the outcome, *temporality*. Even with a longitudinal study, it is challenging to infer temporality among constructs that are hierarchically linked, not without measurement error, and human interpretation. Thus, it would be virtually impossible to completely isolate whether the changes in physical performance preceded the changes in HRQL.

[5] See Appendix 6.2a for the values of the performance measures at the 25^{th}, 50^{th}, 75^{th}, percentiles.

The relationship between HRQL and the physical performance measures considering time was estimated using a statistical approach, namely GEE (see Statistical Analyses, p. 35). The results presented in Table 5.9 demonstrated that the estimated change in the VAS (4.4 points) was not statistically significant over time, however, lower extremity functioning, participation (RNL Index), and psychosocial functioning were significant contributors to HRQL, averaged over time.

The one variable that demonstrated a statistically significant association over time with HRQL was upper extremity functioning. This suggests the upper extremity functioning becomes more important to individuals later on post-stroke perhaps because, early on, there is a greater emphasis on walking (Jorgensen et al., 1995).

A simplistic way of examining changes in one variable with changes in another is to correlate change scores. This analysis was carried out and the results are presented in Appendix 6.2b. The correlation between change scores is not a satisfactory parameter to support temporality because the calculation of change considerably reduces the variation in all variables making it difficult to detect meaningful relationships.

The quantitative paradigm is limited for understanding this complex relationship. Therefore, to sort out whether changes in physical performance contributed to changes in HRQL, qualitative information would be required.

6.3. True Change or Reconceptualization

The major finding from this study was that the proportion of variability in HRQL explained by physical performance increased over time particularly with respect to upper extremity functioning. In Engel's biopsychosocial framework, it was believed that the importance of the various elements within the physical, social, and psychological components differed among individuals and within individuals over time. His theory has been supported by recent studies examining "response shift", a fairly new concept in the area of HRQL (Padilla et al., 1992; Allison et al., 1997; Sprangers, Schwartz, 1999; Wilson, 1999). Response shift can be defined as:

> *a change in one's evaluation of a target construct as a result of i) a change in the respondent's internal standards of measurement, ii) a change in the respondent's values, iii) a redefinition or reconceptualization of the target construct* (Sprangers, Schwartz, 1999).

In simple terms, the value that an individual places on the components that can affect HRQL will vary over time (between and within individuals) depending on a number of personal factors such as adaptation (Heyink, 1993), coping (Folkman, 1980), and social comparison (Festinger, 1954). As HRQL is a subjective evaluation of how persons view their own ability to function, these personal factors are important to consider.

One mechanism of response shift is the *reconceptualization* of the construct and this may have occurred in our study. Reconceptualization could account for the differences in the variation of the components explaining HRQL between the two evaluations. For example, at baseline, all the construct groupings combined explained 72% of HRQL while at post-intervention they explained 90%. The contribution for all the components increased at the second evaluation, except for psychological functioning where it decreased slightly. Response shift is more likely to occur in subjective measures (RNL Index, Social Functioning, Bodily Pain, Vitality, Mental Health) rather than the objective ones (performance-based tests, Barthel Index). The results of this study indicated that the total contribution of all the constructs (objective and subjective) increased from baseline to post-intervention. However, for the most part, there were no significant changes in the values of the measures assessing physical performance, social, and psychological functioning. The only exception was in upper extremity functioning which improved over time. Therefore, other personal factors most likely played a role in modifying the importance of each component between the two evaluations.

6.4. Study Limitations

The first factor that may affect the results of this study is the small sample size (n=43). Although the number of subjects was sufficient to address our primary objective, the study lacked power to make inferences from the secondary analyses.

Also, it would have been interesting to measure HRQL at later time following the intervention as the benefits of increased physical performance are not immediately translated into increases in HRQL. It is only when individuals realize that the improvements in functioning has allowed them to perform more independently within their home or their community that a corresponding level of HRQL can be achieved. However, due to the time constraints of this study, a later assessment could not be conducted. The ongoing data collection that comprises the larger study will help to answer this question.

There is the possibility that Type I or alpha error occurred. When a relationship is presumed between the study variables, the association may have resulted purely by chance.

Another limiting factor was that the study population consisted of individuals recruited to participate in a clinical trial. Therefore, they were a convenient sample rather than a random sample of the stroke population. As the clinical trial was offering additional rehabilitation, individuals agreeing to take part in this study were looking to increase their physical performance. For this reason, any small increase in physical performance may have resulted in an increase in HRQL. It was also noted that the participants in this study were in better health (as measured by the number of co-morbid health conditions) than those who refused (see Table 5.1). As a result, the findings may only be applicable to persons with relatively good health and want to achieve better functioning.

The differences in the variation of the HRQL models between baseline and post-intervention were attributed to the possibility of response shift occurring. In order to compare HRQL levels between individuals, or within an individual at different times, the importance placed on the components affecting HRQL must be similar. As personal factors may alter the value one places on these components, HRQL scores will be difficult to interpret as the change in physical performance could not explain the apparent response shift.

The small sample size in this study decreased the precision of the estimated relationships. However, it was the number of subjects that was reasonable for a Master's thesis. A larger sample size would have reduced imprecision as well as permitted complex analyses of relationships and inter-relationships between and among groups of variables. With the number of subjects in the several hundreds, Structural Equation Modeling (SEM) would be an attractive analytical option. SEM permits the identification of latent variables that may represent the underlying construct better than the individual measures considered separately or additively. However, this analysis will not sort out directionality (physical performance $\rightleftarrows$ HRQL) which has to be inferred from a strong theoretical framework.

6.5. Conclusions and Future Research Directions

This study demonstrated that physical performance remains an important component for clinicians to optimize when targeting the HRQL of individuals post-stroke. Interventions should be aimed at treating the basic factors of physical performance that will build up to higher level activities enabling them to function more independently at home and in the community.

However, in order for the intervention to be effective and improve HRQL, a causal relationship must be established between physical performance and HRQL. This was demonstrated by a moderately strong association between HRQL and physical performance, a dose-response effect as HRQL increased when physical performance increased, and a biologically plausible association that is coherent with the knowledge of the relationship between HRQL and physical performance. The possibility that a change in physical performance resulted in a change in HRQL was also examined, however, requires further evidence.

In addition to physical performance, social and psychological functioning should be addressed in rehabilitation as they not only play significant roles in determining HRQL, but they may interfere with the improvement of physical performance if not remediated. Therefore, the interaction between these three components, as well as their individual associations to HRQL, need to be examined further to support the continued application of a multidisciplinary approach to rehabilitation aimed at the various components of functioning, treating persons with stroke and their environment as a whole.

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Appendix 4.2a. Patient Consent Form for Clinical Trial

Neurology Department
Royal Victoria Hospital
McGill University Health Centre

TITLE OF THE STUDY: THE EFFECTIVENESS OF REHABILITATION THERAPY IN STROKE

Clinical Contact Person: **Dr. Allen Huang (514-842-1231 ext. 4678 or 5704)**

Introduction: Researchers at this hospital and at McGill University are conducting a study to evaluate two rehabilitation programs that are specially designed for persons following a stroke. One program aims to improve arm and hand function, while the other aims to improve walking ability. The therapy provided in each of these two programs is a special type of therapy that focuses on the performance of functional tasks. This therapy is not provided in a standard fashion by rehabilitation professionals as its effectiveness has not yet been demonstrated in research. This is the goal of the study we are inviting you to enter. We realize that you may be involved in other studies. Your participation in this study will not affect your involvement in the other studies.

Time of Entry into the Study: We are asking if you would like to participate in this study. If you agree, then you would enter the study once you have completed formal rehabilitation therapy. For example, the situation described below that applies to you indicates when you would begin to participate:

1) If you have been discharged home from an acute-care hospital and you *are not receiving* physical or occupational therapy, then you would begin participation in this study three to four weeks after arriving home.

2) If you have been discharged home and you *are receiving* physical or occupational therapy as an out-patient, then you would begin participation in this study on completion of your therapy.

3) If you have been discharged to an in-patient rehabilitation centre where you *are receiving* physical or occupational therapy, then you would begin participation in this study on completion of your therapy.

Schedule of Evaluations: On entry into the study, you will undergo a baseline evaluation. The evaluations will be performed by a trained health professional who will assess your balance, how well you move your arms and legs, and how well you can do activities like walking, and climbing stairs. We will also ask you questions about how you feel about your health, and what you are able to do at home. Following this baseline evaluation, you will participate in one of the rehabilitation programs for six weeks. You will be re-evaluated on completion of this program, and then again six months later. The evaluations will be performed at the Richardson Hospital Centre.

In addition to these evaluations, we need to obtain some basic information about your medical history and your stroke from your medical chart.

Description of the Rehabilitation Programs: After your baseline evaluation, you will be assigned to one of the two rehabilitation programs by a random procedure (like flipping a coin). In other words, you will have a 50% chance of being assigned to one program or the other. If you are assigned to program A, you will perform functional, challenging, and creative tasks that involve coordination and strength of the arms and hands. You will also learn to perform activities on a computer. If you are assigned to program B, you will perform mobility tasks such as standing up from chairs of different heights, walking forwards, backwards, over obstacles, and up and down ramps and stairs. You will also participate in endurance training. In both programs, the exercises will be tailored to the level of ability of the individual.

As a participant in the rehabilitation program you will attend three sessions of exercise a week at the Richardson Hospital Centre. Each exercise session will last approximately one hour and a half. The therapist who designs your rehabilitation program may need to perform a few additional tests during your initial visits.

Transportation and Parking: The Richardson Hospital Centre is located at 5425 Bessborough Avenue in Montreal near the corner of Côte-St-Luc Road and Cavendish Road. Free visitors parking is available at the centre as well as on the quiet surrounding streets. While we cannot directly pay for transportation, we will make arrangements for car-pooling, adapted transport, or taxi services as needed.

Participation and Confidentiality: Participation is voluntary. You may refuse to participate or withdraw from the study at any time without this having an effect on your health care. All of the information that we obtain from you will be kept strictly confidential. The data will be kept in a locked filing cabinet in the investigator's office. You will be assigned a study number and this will be the only identifying mark that will appear on your results. The results of the study will be published in scientific journals but your data will appear as numbers in statistical summaries.

Risks: We do not envision that the therapy provided through this study will cause you any harm. There may be a potential risk of falling for participants in the program that focuses on walking-related tasks. For this reason, you will be provided with physical assistance to walk when necessary to ensure your physical safety. The exercises that you will undertake will be performed at your own pace. All activities will be supervised so that if you do not feel well, or if you are anxious about your health, the appropriate action will be taken.

Benefits: The study offers you the opportunity to receive further rehabilitation therapy at a time when such services are no longer being provided by the public health care system. The results of this study will help us to identify which rehabilitation programs are most effective in improving physical function in persons who have been discharged home and who are no longer receiving therapy after stroke.

Contact Numbers: If you have any questions about the research, please contact Dr. Nancy Mayo, the principal investigator, or Nancy Salbach, the study coordinator, at (514) 842-1231 ext. 6906. If you have any questions concerning your rights as a participant in this study, you may contact the Ombudsman at (514) 842-1231 ext. 5655.

In signing this consent form, you recognize that the study has been explained to you and that you understand the study. You also agree that you have had the opportunity to ask questions, and that you are satisfied with the responses.

Declaration of the Participant: I understand what is expected of me and I freely and voluntarily agree to participate in this study entitled "The Effectiveness of Rehabilitation Therapy in Stroke".

A copy of this consent form has been given to the participant named below.

Name of Participant	***Signature of Participant***	***Date***
Name of Researcher	***Signature of Researcher***	***Date***

McGill

Faculty of Medicine
3655 Drummond Street
Montreal, QC H3G 1Y6
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August 8, 2000

Dr. Nancy Mayo
Division of Clinical Epidemiology
Royal Victoria Hospital
687 Pine Avenue
Montreal, Quebec
H3A 1A1

Dear Dr. Mayo:

We are writing in response to the request for Institutional Review Board continuing review, as well as review of an amendment to the study A06-M10-99 entitled **"The Effectiveness of Rehabilitation in Stroke"**.

We have reviewed the progress report and are pleased to inform you that re-approval for the study was provided by the Board on August 7, 2000, valid until June 2001. The certification approval document has been enclosed.

We are also pleased to inform you that approval for the amendment (correspondence dated July 10, 2000) and revised consent form (version 2, July 10, 2000), was provided by the Board on August 7, 2000.

We ask you to take note of the investigator's responsibility to assure that the current protocol, study amendments and consent document are deposited, on an annual basis, with the Research Ethics Boards of each hospital where patient enrollment or data collection is carried out. Should any study modification or unanticipated development occur prior to the next review, please advise the IRB promptly.

Yours sincerely,

J. Lawrence Hutchison, M.D.
Chair
Institutional Review Board

Encl.

cc: Ms. F. Cantini
Ms. E. Boyle
Dr. R. Pokrupa
Ms. L. Fateen
Ms. A. Collins
A06-M10-99
REB Files JGH/MGH/MNI/RVH/SMH

The Effectiveness of Rehabilitation Therapy in Stroke

Principal Investigator:
Nancy E. Mayo, PhD

Intervention

Schedule: Each rehabilitation intervention will run for a six-week period. Therapy sessions will last approximately 1.5 hours and they will be given three times per week. Subjects in different experimental groups will practice separately to minimize crossing-over. Depending on the rate of recruitment, two Walking Competency groups will participate in the morning and two Arm Use groups in the afternoon.

Evaluation of Outcome: Performance on the Six-Minute Walk Test, as well as on all other measures, will be assessed at the baseline evaluation, at the end of the six-week intervention, and at six months and one year following the date of the stroke. The first evaluation will take place prior to randomization. The remaining evaluations will be conducted by independent evaluators who are unaware of the details of the study and of the treatment group to which the subjects have been assigned.

Treatment Planning: At the baseline evaluation, each subject assigned to the Walking Competency intervention will be asked to list five tasks related to walking and changing positions that they find the most difficult to perform at home and would like to improve. A similar question related to the performance of fine and gross motor tasks involving the arm and hand will be posed to the subjects in the Arm Use group. The study physical therapist (N. Salbach) will conduct any additional clinical tests of the subjects in the Walking Competency group and Arm Use group during the first few exercise sessions. She will then design an individual treatment program using the results of the baseline and clinical evaluation, and the list of the tasks provided by the subject. The program will comprise both of impairment- and task-specific exercises appropriate to the individual's level of ability. Impairment-related exercises will be given as part of a home program. The sessions at the rehabilitation centre will be reserved primarily for challenging task-specific exercises arranged in workstations as described by Dean and associates (forthcoming). Table 1 highlights some potential workstations for each intervention. All therapy sessions will be preceded by a warm-up period similar to that reported by Duncan and associates.

Potential Workstations for Walking Competency and Arm Use Interventions

Walking Competency Intervention	Arm Use Intervention
1. Sit to stand from various chair heights, within a confined space (as from a car) 2. Walking to a beat 3. Treadmill walking on a level surface and with inclination 4. Stepping over obstacles 5. Walking forwards, backwards and sideways on the floor and balance beam 6. Walking on ramps, on surfaces slanted laterally, and on uneven surfaces 7. Walking while carrying objects 8. Step-ups 9. Climbing stairs 10. Walking out of doors along a paved pathway 11. Kicking and receiving a ball	1. Unilateral tasks: handling coins, picking up paper clips, playing Chinese checkers, completing a puzzle, turning pages in a book, using a zipper, opening / closing doors 2. Bilateral tasks: dealing cards, pouring water, using a rolling pin, dial a phone, writing, cutting paper with scissors, opening jars, hammering a nail 3. Bilateral tasks (continues): buttoning a vest that you are wearing, putting on jewellery, pulling on a pair of pants in sitting, taking money out of a wallet, opening envelopes with a letter opener 4. Tasks requiring speed: intercepting moving objects, computer games 5. Tasks with greater cognitive involvement: learning to type on the computer, playing solitaire or hearts on the computer

Please indicate which statement best describes your own health state today. Do not tick more than one box in each group.

Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

Self-Care

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain / Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

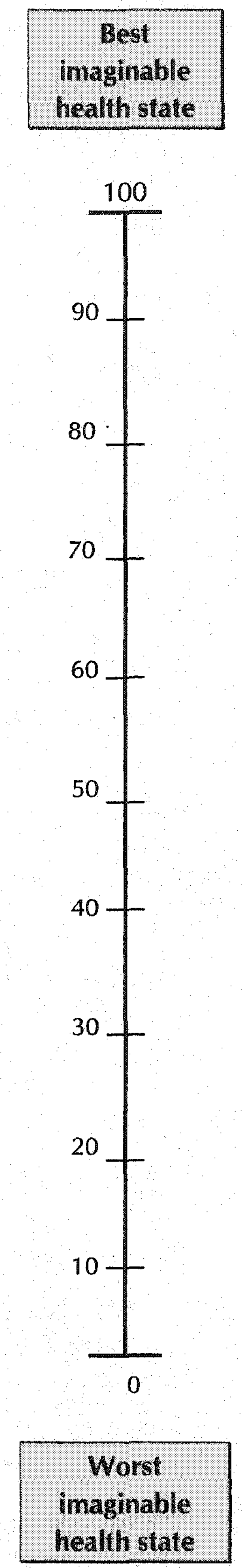
Anxiety / Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale how good or bad is your own health today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.

Your own health state today



INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

	(circle one)
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

	(circle one)
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same as one year ago	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a kilometre**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?

(circle one)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

11. How **TRUE** or **FALSE** is each of the following statements for you?

(circle one number on each line)

	Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

SCORE	SUPINE
/2	**1. Protracts scapula in supine** *"Lift your shoulder blade so that your hand moves towards the ceiling."* Note: therapist stabilizes arm with shoulder 90° flexed and elbow extended
/2	**2. Extends elbow in supine** (starting with elbow fully flexed) *"Lift your hands toward the ceiling, straightening your elbow as much as you can."* Note: therapist stabilizes arm with shoulder 90° flexed, strong associated shoulder extension and/or abduction = marked deviation (score 1a or 1c)
/2	**3. Flexes hip and knee in supine** (attains half crook lying) *"Bend your hip and knee so that your foot rests flat on the bed."*
/3	**4. Rolls onto side** (starting from supine) *"Roll onto your side."* Note: may roll onto either side; pulling with arms to turn over = aid (score 2)
/3	**5. Raises hips off bed in crook lying position** (bridging) *"Lift your hips as high as you can."* Note: therapist must stabilize foot, but if knee pushes strongly enough into extension with bridging = marked deviation (score 1a or 1c); if requires aid (external or from therapist) to maintain knees in midline = aid (score 2)
/3	**6. Moves from lying supine to sitting** (with feet on the floor) *"Sit up and place your feet on the floor."* Note: may sit up to either side using any functional and safe method; longer than 20 seconds = marked deviation (score 1a or 1c); pulling up using bed rail or edge of plinth = aid (score 2)
/2	SITTING (feet supported; hands resting on pillow on lap for items 7-14) **7. Shrugs shoulders** (scapular elevation) *"Shrug your shoulders as high as you can."* Note: both shoulders are shrugged simultaneously
/2	**8. Raises hand to touch top of head** *"Raise your hand to touch the top of your head."*
/2	**9. Places hand on sacrum** *"Reach behind your back and as far across toward the other side as you can."*
/2	**10. Raises arm overhead to fullest elevation** *"Reach your hand as high as you can towards the ceiling."*
/2	**11. Supinates and pronates forearm** (elbow flexed at 90°) "Keeping your elbow bent and close to your side, turn your forearm over so that your palm faces up, then turn your forearm over so that your palm faces down." Note: movement in one direction only = partial movement (score 1a or 1b)
/2	**12. Closes hand from fully opened position** "Make a fist, keeping your thumb on the outside." Note: must extend wrist slightly (wrist cocked) to obtain full marks
/2	**13. Opens hand from fully closed position** *"Now open your hand all the way."*
/2	**14. Opposes thumb to index finger** (tip to tip) *"Make a circle with your thumb and index finger."*

/2	**15. Flexes hip in sitting** *"Lift your knee as high as you can."*
/2	**16. Extends knee in sitting** "Straighten your knee by lifting your foot up."
/2	**17. Flexes knee in sitting** "Slide your foot back as far as you can." Note: start with affected foot forward (heel in line with toes of other foot)
/2	**18. Dorsiflexes ankle in sitting** *"Keep your heel on the ground and lift your toes off the floor as far as you can."*
/2	**19. Plantarflexes ankle in sitting** *"Keep your toes on the ground and lift your heel off the floor as far as you can."*
/2	**20. Extends knee and dorsiflexes ankle in sitting** "Straighten your knee as you bring your toes towards you." Note: extension of the knee without dorsiflexion of ankle = partial movement (score 1a or 1b)
/3	**21. Rises to standing from sitting** "Stand up; try to take equal weight on both legs." Note: pushing up with hand(s) to stand = aid (score 2); asymmetry such as trunk lean, trendelenburg, hip retraction, or excessive flexion or extension of the affected knee = marked deviation (score 1a or 1c)
/3	STANDING **22. Maintains standing for 20 counts** *"Stand on the spot while I count to 20."*
/2	STANDING (holding onto a stable support to assist balance for items 23-25) **23. Abducts affected hip with knee extended** *"Keep your knee straight and your hips level, and raise your leg to the side."*
/2	**24. Flexes affected knee with hip extended** *"Keep your hip straight, bend your knee back and bring your heel towards your bottom."*
/2	**25. Dorsiflexes affected ankle with knee extended** *"Keep your heel on the ground and lift your toes off the floor as far as you can."*
/3	STANDING AND WALKING ACTIVITIES **26. Places affected foot onto first step** (or stool 18 cm high) "Lift your foot and place it onto the first step (or stool) in front of you." Note: returning the foot to the ground is not scored; use of handrail = aid (score 2)
/3	**27. Takes 3 steps backwards** (one and a half gait cycles) *"Take 3 average sized steps backwards, placing one foot behind the other."*
/3	**28. Takes 3 steps sideways to affected side** *"Take 3 average sized steps sideways towards your weak side."*
/3	**29. Walks 10 meters indoors** (on smooth, obstacle free surface) "Walk in a straight line over to ... (a specified point 10 meters away)." Note: orthotic = aid (score 2); longer than 20 seconds = marked deviation (score 1c)
/3	**30. Walks down 3 stairs alternating feet** "Walk down 3 stairs; place only one foot at a time on each step if you can." Note: handrail = aid (score 2); non-alternating feet = marked deviation (score 1a or 1c)

I. Voluntary Movements of the Limbs (/2)

0 unable to perform the test movement through any appreciable range (includes flicker or slight movement)

1a able to perform only part of the movement and with marked deviation from normal pattern
b able to perform only part of the movement, but in a manner that is comparable to the unaffected side
c able to complete the movement, but only with marked deviation from normal pattern

2 able to complete the movement in a manner that is comparable to the unaffected side

X activity not tested (specify why: ROM, Pain, Other – reason)

II. Basic Mobility (/3)

0 unable to perform the test movement through any appreciable range (ie. minimal active participation)

1a able to perform only part of the activity independently (requires partial assistance or stabilization to complete), with or without an aid, and with marked deviation from normal pattern
b able to perform only part of the activity (requires partial assistance or stabilization to complete), with or without an aid, but with a grossly normal movement pattern
c able to complete the activity independently, with or without an aid, but only with marked deviation from normal pattern

2 able to complete the activity independently with a grossly normal movement pattern but requires an aid

3 able to complete the activity independently with a grossly normal movement pattern without an aid

X activity not tested (specify why: ROM, Pain, Other – reason)

		AMPLITUDE OF ACTIVE MOVEMENT		
		None	Partial	Complete
MOVEMENT QUALITY	Marked Deviation	0	1a	1c
	Grossly Normal	0	1b	2 (3)

Clientele

This evaluation instrument is developed specifically for individuals aged 60 and over who present with disabilities in the upper extremities. It was designed for a variety of neuro-sensorimotor deficits, not for a clientele presenting specific pathologies such as arthritis or hemiplegia/paresis. This instrument could also be used to evaluate individuals presenting exclusively perceptual, psychosocial or emotional disorders in order to determine the effects of these conditions on daily life in the absence of sensorimotor deficits, but the studies that were conducted did not examine this clientele.

Therapist-Subject Positioning

The person being evaluated sits on a chair or armchair of standard height (44cm ± 2.5cm) or in her own wheelchair facing a table of regular height (76cm ± 2.5), representing a normal, everyday situation. The therapist, with the score sheet and stopwatch in hand, sits beside the table at an angle of 90° to the subject. The equipment to be used is within reach.

Before each task, the subject puts her hands on the edge of the table waiting until the therapist gives the signal to begin. The stopwatch is started as soon as the subject's hands leave the table.

Required Equipment

Shelves

Arrangement of two shelves of different heights and dimensions joined by an articulated system such that they can be folded together and closed to facilitate storing and carrying the test material. All the test material is placed in precise, predetermined positions designed to ensure a high level of standardization in the tasks. All the tasks are performed within the area encompassed by the shelves.

Task Scoring System

During or immediately upon completion of each task, the therapist scores the performance obtained according to three measurement criteria: speed of execution, functional rating and task analysis.

Speed of Execution

Each task is timed with a stopwatch to the nearest tenth of a second, beginning as soon as the subject's hands leave the table and ending the moment the task is completed.

Functional Rating

The functional rating refers to the subject's independence in each of the tasks; it is measured using a four-level scale:

Score	Scale
0	The task is successfully completed, without hesitation or difficulty, as instructed or demonstrated.
-1	The task is executed completely, but with some hesitation or difficulty.
-2	The task is partially executed (more than 25%) or certain steps are executed with major difficulties necessitating repeated efforts. Part of the task may have had to be modified or needed assistance to make it achievable.
-3	The task cannot be performed to more than 25%.

Task Analysis

This section identifies and quantifies the difficulties experienced by the subject on each of the tasks. It is composed of five dimensions directly related to the main sensorimotor abilities of the upper extremities: active range of motion, strength, precision of gross motor movements, prehension and precision of fine motor movements.

When the nine tasks are completed and scored, the therapist adds vertically the scores on the functional rating as follows: all the scores obtained on the right unilateral tasks (0 to -12), left unilateral tasks (0 to -12) and bilateral tasks (0 to -15) and then the total of the scores on all the tasks (unilateral right + unilateral left + bilateral) (0 to -39). In a similar manner, the same additions are done for the five dimensions in the Task Analysis section.

Interpretation

The scores were not correlated with the level of impairment of the subject's upper extremities and, as is true with the majority of measurement instruments, two people may obtain the same score without having the same profile of capacities and limitations. Thus a score of -10 certainly demonstrates some difficulty with upper extremity function but at present this score cannot be related to a precise level of difficulty (eg. minor, moderate or major impairment). Furthermore, because of the limits of ordinal scales, it would not be wise to compare the scores obtained from two different subjects. However, the scores obtained over time by the same person can be compared in order to follow the evolution of upper extremity performance.

Active Range of Motion

The subject's ability to reach the material and execute the movements required by the task; the quality of the movement is not taken into consideration.

Score	Scale
0	All the ranges required by the task are present.
-1	Certain parts of the task are difficult or compensated for because of a partial limitation in the active range of motion.
-2	Certain ranges of motions are very limited making it impossible to reach the material or execute part of the task.
-3	The majority of ranges are necessary to perform the task are very restricted, substantially compromising the accomplishment of the task.

Strength

The subject's ability to use the "task heavy" material (offering resistance other than gravity) without compensatory movements.

Score	Scale
0	The strength of the upper extremity(ies) is sufficient to do the task as described (at least against gravity and the resistance of the object).
-1	The strength of the upper extremity(ies) is diminished, contributing to the emergence of some compensatory movements.
-2	The strength of the upper extremity(ies) is greatly diminished and the loss cannot be easily compensated for by substitution movements.
-3	The strength of the upper extremity(ies) is too diminished to lift the material making the task impossible to execute or impossible to evaluate because it proved impossible to handle the material.

Precision of Gross Motor Movements

The subject's ability to execute precise, rapid and appropriate movements with the whole of the upper limb, excluding the hand.

Score	Scale
0	The unilateral or bilateral gross movements are precise, rapid and appropriate to the task.
-1	The gross motor movements are slightly uncoordinated or done slowly.
-2	The gross motor movements are imprecise, poorly directed or very slow.
-3	No precision in the gross motor movements in terms of achieving the task objectives.
	Cannot be evaluated

Prehension

The subject's ability to take different objects, small or large, with the hand or fingers using grasping and pinching actions appropriately.

Score	Scale
0	All the prehension patterns (grasps and pinches) required to perform the task are executed without apparent difficulty.
-1	All the objects can be grasped in spite of some prehension difficulties.
-2	Certain prehensions are impossible or very difficult and require several attempts.
-3	No prehension is possible in the activity.
	Cannot be evaluated.

Precision of Fine Motor Movements

The subject's ability to use both hands and fingers to execute precise, rapid movements that are well directed towards accomplishing the task.

Score	Scale
0	The movements of the hands and fingers are very precise and goal-directed. Manipulation of the objects is done normally.
-1	The precision of the fine motor movements is diminished or the movements are slow. Manipulation may be difficult but possible. There may be some slight trembling.
-2	Distal movements significantly lack precision. Objects are often dropped. There may be some substantial trembling.
-3	The fine motor movements are very imprecise or are impossible to accomplish. It becomes impossible to perform the fine motor movements desired, which are necessary to do the activity.
	Cannot be evaluated.

Scoring – Specific Cases

1. If the task **is completed**, with or without difficulty, as instructed or demonstrated, the speed of execution is recorded and each of the other measurement criteria is scored according to performance.

2. If a **part of the task cannot be done** because of some limitation, whatever its nature, the therapist may give physical help or reduce the degree of difficulty of the task in such a way as to be able to observe a maximum number of dimensions. The subject can thus proceed with the task in spite of difficulties. However, the speed of execution cannot be counted in this instance. The subject will obtain a score of -2 on the functional rating and the task analysis dimensions will be scored according to the pre-established scale for each task.

Examples of help given or modifications

- steadying the material
- reducing the weight of an object (eg. taking some water out of the pitcher)
- reducing the height (eg. putting the material on the lower shelf instead of the upper shelf)

3. If there is **unequal functioning** of the upper extremities during bilateral tasks (unilateral paresis), the bilateral tasks are scored according to the functional global performance of the upper extremities. This type of task normally requires that the less functional or non dominant upper limb stabilize the material (asymmetrical tasks), except in the case of task no. 5 (tying a scarf) which is a symmetrical bilateral task.

   If the subject uses only one upper extremity in a bilateral task, a maximum score of -1 on the functional rating is obtained because the task presents some difficulty, however slight. Regarding the scoring of the dimensions in the Task Analysis section, you score what you see, namely, the performance of the active upper limb (the better side). In the left or right corner of the appropriate box, you can put a check mark to indicate that a single upper limb performed the task. The unilateral tasks should make it possible to quantify the dimensions for each upper limb individually, thus showing the non-performance of one of the upper limbs, if such is the case.

4. You may give verbal assistance throughout the task.

5. If the subject obtains -3 on the functional rating, it is often impossible to measure the dimensions in the Task Analysis section. In such cases, you score -3 on these dimensions.

6. If the subject is apraxic and performs movements irrelevant to the task, a maximum of -1 on the functional rating will be obtained.

7. Write all pertinent comments in the section provided for this purpose.

Description of the Tasks

The TEMPA includes five bilateral tasks and four unilateral tasks that are performed in an order that is similar to the activities accomplished during a day. The detailed procedure for administering each of the tasks, together with its description, its instructions and its scoring are given. In addition, the precise positioning of the material is indicated in the illustrations following the description of each task. Finally, in order to locate the exact position of the material, small numbers that correspond to the numbers of the tasks are indicated directly on the shelves. These reference points ensure that a high level of standardization in the tasks is achieved.

1. **Pick up and move a jar** (unilateral task)

   A jar of coffee is placed on the upper shelf in the designated location, opposite to the upper extremity being evaluated. The subject picks up the jar of coffee and puts it down in the middle of the lower shelf.

2. **Open a jar and remove a spoonful of coffee** (bilateral task)

   A jar of coffee and a cup are placed in the designated location on the lower shelf. The lid of the jar is moderately tightened. A spoon is placed in the cup, its handle oriented towards the subject's body. The cup handle is to the left. The subject picks up the jar of coffee, removes a spoonful of coffee from the jar, puts it in the cup, closes the jar and puts it back in the original location. The cup is not picked up.
   <u>Note:</u> After the task is completed, the therapist puts the coffee back in the jar.

3. **Pick up a pitcher and pour water into a glass** (unilateral task)

   A pitcher containing 400ml of water is placed in the middle of the upper shelf, its handle towards the right for the right hand performance and towards the left for the left hand performance. The glass is located on the side of the performing hand. The subject picks up the pitcher, lifts it to the lower shelf and fills the glass three-quarters full. The pitcher is then put down and using the same hand, the glass is brought up to touch the chin and then put down on the table.
   The task is repeated using the other hand.

4. **Unlock a lock and open a pill container** (bilateral task)

   A key is placed in the middle of the ledge at the back of the lower shelf. The head of the key is pointing forward. The key notches are oriented to the same side as the dominant hand, this facilitates handling the key and opening the lock. A cabinet, with a lock, is situated on the upper shelf. The subject picks up the key and unlocks the cabinet by turning the key a quarter turn to the right or left. (The therapist requests that the key be grasped with a lateral pinch, thumb on top.) Leaving the key in the lock, the subject removes the pill container from the cabinet, opens it, removes two pills, closes it and puts everything on the table.

Note: The cabinet on the upper shelf is removable. So if the subject cannot reach it for any reason, the therapist can pull the cabinet out of its space and move it to the level of the lower shelf. This allows other aspects of the task to be evaluated. However, the subject will obtain a -2 on the functional rating.

5. **Write on an envelope and stick a stamp on it** (bilateral task)

   An envelope, stamp and ballpoint pen are placed on the lower shelf. A model envelope with 'Bell Canada' and a stamp on it is placed at the back of the lower shelf. The subject writes the words 'Bell Canada' in the middle of the envelope and sticks the stamp in the upper right-hand corner of the envelope. The subject may move the envelope to be more comfortable while writing. If the subject is illiterate, substitute his/her name for 'Bell Canada'.

6. **Tie a scarf around one's neck** (bilateral task)

   A dark blue scarf is folded in eight and centered on the lower shelf with the fringe on the left. The subject picks it up, unfolds it, wraps it around the neck and ties a simple knot. The neck must not bend during the task. The objective is that the task be performed using both upper limbs as symmetrically as possible.

7. **Shuffle and deal playing cards** (bilateral task)

   A deck of cards held together with a simple rubber band is placed in the middle and at the back of the lower shelf. The subject picks up the deck of cards, removes the rubber band, shuffles three times, then proceeds to lay out five cards one beside the other on the lower shelf. The deck is put down and then the subject picks up the cards one by one sliding them to the edge of the table (as is normally done when playing cards).

8. **Handle coins** (unilateral tasks)

   The coins are stacked from the smallest to the largest (the largest on top) on the lower shelf in the identified location. The subject inserts them one by one in the slot designed for this purpose located in the cabinet on the upper shelf. The task is repeated with the other hand.
   Note: As explained in task no.4, the cabinet in the upper shelf is removable. Therefore, if the subject cannot reach the slot to insert the coins, the therapist may remove the cabinet.

9. **Pick up and move small objects** (unilateral tasks)

   Five small objects are placed on the lower shelf on a piece of non-slip material to stabilize them. The outlines of the objects are sketched on the piece of material. The subject picks the objects up one at a time and puts them in the glass dish located in the back corner of the side being evaluated.

THE BERG BALANCE SCALE

Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgement will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 5, 12 and 25 centimetres. Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item 12.

1. Sitting to standing

Instructions: Please stand up. Try not to use your hands for support.

( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. Standing unsupported

Instructions: Please stand for two minutes without holding.

( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item 4.

3. Sitting with back unsupported but feet supported on floor or on a stool

Instructions: Please sit with arms folded for 2 minutes.

( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. Standing to sitting

Instructions: Please sit down.

( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. Transfers

Instructions: Arrange chair(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely with definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervision to be safe

6. Standing unsupported with eyes closed

Instructions: Please close your eyes and stand still for 10 seconds.

( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. **Standing unsupported with feet together**

Instructions: Place your feet together and stand without holding.

( ) 4 able to place feet together independently
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. **Reaching forward with outstretched arm while standing**

Instructions: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger can reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently < 25 cm (10 inches)
( ) 3 can reach forward > 12 cm safely (5 inches)
( ) 2 can reach forward > 5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. **Pick up object from the floor from a standing position**

Instructions: Pick up the shoe/slipper which is placed in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assistance to keep from losing balance or falling

10. **Turning to look behind left and right shoulders while standing**

Instructions: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( ) 4 looks behind from both sides and shifts weight well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. Turn 360 degrees

Instructions: Turn completely around in a full circle. Pause, then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. Placing alternative foot on step or stool while standing unsupported

Instructions: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps but needs minimal assistance
( ) 0 needs assistance to keep from falling/unable to try

13. Standing unsupported one foot in front

Instructions: (Demonstrate to subject) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. Standing on one leg

Instructions: Stand on one leg as long as you can without holding.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5 - 10 seconds
( ) 2 able to lift leg independently and hold = or > 3 seconds
( ) 1 tried to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assistance to prevent fall

TOTAL: _____/56

GAIT SPEED

Comfortable and maximum walking speed are determined over distances of 5 and 10 metres (m). Gait speed is measured in a quiet section of the hospital corridor, of the rehabilitation department, or of the subject's home, using tape to mark the distances on the floor. Acceleration and deceleration distances, each of 2 m, are marked. Bright pylons are placed at the outer acceleration lines during testing so that the patient can easily visualize the end of the walk distance.

5 m test: I—2 m——5 m——2 m—I

* * * pylon

Test Protocol

1. **General:** Using a digital stopwatch, the time it takes for the subject to traverse the central 5 m or 10 m portion of the walkway at comfortable and maximum walking speeds is measured.

2. **The Subject:** The subject wears supportive footwear, and comfortable clothing. They walk with their usual orthosis and/or ambulatory aid. The evaluator ensures that the subject wears his/her glasses when required.

3. **Pylon Placement:** Depending on the distance being tested, the orange pylons are placed at the outer acceleration marks, and the subject is asked if they can visualize the pylon.

4. **Start Position and Instructions:** The subject starts in a standing position, at the outer acceleration mark. Depending on the speed of walking being tested, the following instructions are given:

Instructions for COMFORTABLE walking speed:

> "I am going to measure your comfortable walking speed. When I say 'go', walk in a straight line at a pace which is **safe and comfortable for you**, until you reach the second pylon."
>
> "Nous allons mesurer votre vitesse normale de marche. Lorsque je vous direz "partez", vous marcherez en ligne droite à une vitesse **normale et sécuritaire pour vous,** et ce, jusqu'au deuxième pylône."

Instructions for MAXIMUM walking speed:

"I am going to measure your maximum walking speed. When I say "go", walk **safely** in a straight line **as fast as you can**, until you reach the second pylon."

"Nous allons mesurer votre vitesse maximale de marche. Lorsque je vous direz "partez", vous marcherez en ligne droite **aussi vite que possible**, tout en étant **sécuritaire**, jusqu'au deuxième pylône."

5. **Timing Procedure:** To minimize the level of fatigue, the subject is not given a practice run. During testing, **no verbal encouragement** is given to the subject, as this has been shown to influence walking speed, and would make the test environment even more artificial. On the word 'go', the subject begins to advance through the 2 m acceleration distance. The evaluator starts timing when the subject's first foot crosses the start line, and stops timing when the first foot crosses the stop line although the patient continues to walk a final 2 m. The evaluator walks beside the patient for safety, and to maximize the accuracy of timing especially as the subject is crossing the start and stop lines.

6. **Rest Procedure:** After each walk, the subject is allowed to sit and rest. Provide water as needed. Do not begin the next test until the subject feels that she/he has recovered.

7. **Comments:** The evaluator should comment on aspects of the test that he/she feels is important. In addition, comments should be made on specific problems experienced with the subject regarding:

- abnormal sway
- inability to walk in a straight line
- comprehension of instructions
- gait pattern abnormalities
- significant fatigue

THE STEP UP AND DOWN STAIR TEST (SUDS)

There are two components to the Step Up and Down Stair Test (SUDS):

1. The SUDS-4 measures the amount of time the subject takes to ascend and then descend a flight of 4 stairs
2. The SUDS-Full measures the numbers of stairs per minute to ascend and then descend a full flight of stairs.

Ascent and descent are measured separately when performing this test. The steps for the SUDS-4 are of standard height (8″) and depth (8″) while the dimensions of the steps for the SUDS-Full will vary slightly depending on the staircase.

SUDS-4

There are five levels at which an individual can be tested:

1. two hand rails
2. one hand rail and walking aid (a cane)
3. one hand rail and no walking aid
4. no hand rail and walking aid
5. no hand rail and no walking aid

SUDS-Full

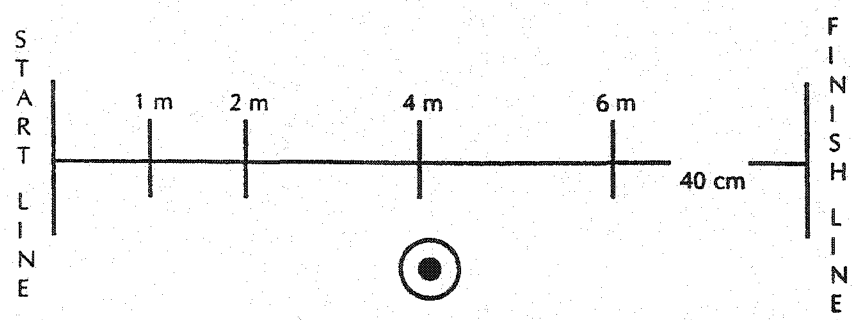
Only levels 2, 3, 4 and 5 are applicable since most standard staircases do not have two handrails that can be used at the same time due to their width.

Test conditions

1. All subjects will perform both tests: the SUDS-4 and the SUDS-Full. The evaluator will chose the appropriate level for the subject to perform the test where the least amount of support is needed to negotiate the stairs safely (safely implies that no supervision is required and the subject is not at any risk to fall). Once the specific level is chosen, the subject can be given a practice trial.

2. Subjects begin by standing at the bottom of the steps and are asked to first walk up the steps, then walk down the steps at a comfortable pace.

3. Their score is the time taken to complete each component from when the subject initiates a lifting movement of either foot to when the second foot reaches the top step on ascent and the floor on descent.



1. Unilateral Stance (timed test)

INSTRUCTIONS: *Stand on your right/left leg and hold for as long as you can up to 45 seconds. Look straight ahead.*

- 0 unable to sustain unilateral stance independently, eg. able to unweight leg for brief moments only
- 1 able to sustain unilateral stance for 2 - 4 sec.
- 2 able to sustain unilateral stance for 5 - 9 sec.
- 3 able to sustain unilateral stance for 10 - 19 sec.
- 4 able to sustain unilateral stance for ≥ 20 sec.
- 5 able to sustain unilateral stance for 45 sec. in a steady and coordinated manner
  NOT ACCEPTABLE: excessive use of equilibrium reactions

2. Tandem Walking

INSTRUCTIONS: *Walk forward on the line heel touching toes. Keep your feet pointing straight ahead. Look ahead down on the track, not at your feet. I will tell you when to stop.*

- 0 unable to complete 1 step on the line independently, eg. requires assistance, upper extremity support, or takes a protective step
- 1 able to complete 1 step independently, acceptable to toe out
- 2 able to complete 2 or 3 steps consecutively on the line, acceptable to toe out
- 3 able to complete more than 3 steps consecutively, acceptable to toe out
- 4 able to complete more than 3 steps consecutively, in good alignment (heel-toe contact, feet straight on the line, no toeing out), but demonstrates excessive use of equilibrium reactions
- 5 able to complete 7 steps consecutively, in good alignment (heel-toe contact, feet straight on the line, no toeing out), and in a steady and coordinated manner
  NOT ACCEPTABLE: excessive use of equilibrium reactions or looking at feet

3. **180° Tandem Pivot**

INSTRUCTIONS: *Lifting your heels just a little, pivot all the way around to face the opposite direction without stopping. Put your heels down and maintain your balance in this position.*

0 unable to sustain tandem stance independently, eg. requires assistance or upper extremity support
1 able to sustain tandem stance independently, but unable to unweight heels and/or initiate pivot
2 able to initiate pivot, but unable to complete 180° turn
3 able to complete 180° turn but discontinuous, eg. pauses on toes during pivot
4 able to complete 180° turn in a continuous motion but unable to sustain reversed position
NOT ACCEPTABLE: heel-toe distance > 8 cm (3 inches)
5 able to turn 180° in a continuous and coordinated motion and sustain reversed position
Acceptable to have feet slightly angled out in reversed position
NOT ACCEPTABLE: heel toe distance > 8 cm (3 inches) or excessive use of equilibrium reactions

4. **Lateral Foot Scooting**

INSTRUCTIONS: *Stand on your right/left leg and move sideways by alternately pivoting on your heel and toe. Keep pivoting until you reach the line and maintain your balance in this position.*

0 unable to sustain unilateral stance independently, eg. requires assistance or upper extremity support
1 able to perform 1 lateral pivot in any fashion
2 able to perform 2 lateral pivots in any fashion
3 able to perform ≥ 3 lateral foot pivots, but unable to complete 40 cm
4 able to complete 40 cm in any fashion, and/or unable to control final position
5 able to complete 40 cm in a continuous and rhythmical motion, demonstrating a controlled stop briefly maintaining unilateral stance
NOT ACCEPTABLE: pausing while pivoting to regain balance, veering from a straight line course, excessive use of equilibrium reactions, or excessive trunk rotation while pivoting

5. **Hopping Forward**

INSTRUCTIONS: *Stand on your right/left foot. Hop twice straight along this line to pass the 1 metre mark with your heel. Maintain your balance on your right/left leg at the finish.*

0 unable to sustain unilateral stance independently or hop, eg. requires assistance or upper extremity support
1 able to perform 1 or 2 hops with poor control, eg. unable to sustain 1 foot landing for even brief moments, unable to complete 1 metre
2 able to perform 2 hops sequentially in a controlled manner, unable to complete 1 metre
3 able to complete 1 metre in 2 hops, but unable to sustain 1 foot landing, eg. touches down or steps with opposite limb upon landing
Acceptable to deviate from line
4 able to complete 1 metre in 2 hops, but difficulty controlling landing, eg. hops or pivots on stance foot to maintain landing
Acceptable to deviate from line
NOT ACCEPTABLE: touching down or stepping with opposite limb to achieve stability on landing
5 able to complete 1 metre in 2 hops in a coordinated manner and sustain a stable landing
NOT ACCEPTABLE: deviate from line or excessive use of equilibrium reactions

6. **Crouch and Walk** (timed test)

INSTRUCTIONS: *Walk forward, and without stopping, bend to pick up the bean bag and then continue walking down the line.*

0 unable to crouch (descend) to pick up the bean bag independently, eg. requires assistance or upper extremity support
1 able to crouch (descend), but unable to maintain crouch to pick up bean bag or rise to stand independently, eg. requires assistance or touches hands down to floor
2 able to crouch to pick up bean bag and rise to stand independently but must hesitate at anytime during activity, eg. unable to maintain forward momentum
3 able to crouch and walk in a continuous motion (maintaining forward momentum) with time < 8 seconds and demonstrates protective step at any time during the task
4 able to crouch and walk in a continuous motion with time < 8 seconds and/or uses excessive equilibrium reactions to maintain balance at any time during the task
NOT ACCEPTABLE: veering off course
5 able to crouch and walk in a continuous and rhythmical motion with time ≤ 4 seconds
NOT ACCEPTABLE: veering off course or excessive use of equilibrium reactions

7. **Lateral Dodging** (timed test)

INSTRUCTIONS: *Move sideways along the line by repeatedly crossing one foot in front of the other. Place part of your foot on the line with every step. Reverse direction whenever I call "Change". Do this as fast as you can, yet at a speed that you feel safe.*

0 unable to perform one cross-over in both directions without loss of balance or use of support
1 able to perform one cross-over in both directions without use of support, but unable to contact the line with part of the foot
2 able to cross-over for 1 or more cycles to and from the 2 metre mark, but unable to contact the line with every step
3 able to perform 2 cycles in any fashion (to the 2 metre line and back twice) and one part of each foot must contact the line during each step
4 performs 2 cycles as described in level 3 in from 12 to 15 seconds
5 performs 2 cycles in less than 12 seconds in a continuous, rhythmical fashion with coordinated direction changes immediately after verbal cue

8. **Walking & Looking** (timed test)

INSTRUCTIONS: *Walk at your usual pace to the end of the line. I will tell you when to look at the circle. Keep looking at it while you walk past it. I will then tell you when to look straight ahead again. Try not to veer off course while you walk.*

0 unable to walk & look, eg. has to stop to look, or requires assistance or upper extremity support at any point during the test
1 able to continuously walk and initiate looking, but loses visual fixation on circle at or before 4 m mark
2 able to continuously walk and look, but loses visual fixation on circle after 4 m mark, eg. while looking back over the shoulder
3 able to continuously walk and fixate upon the circle between the 2 and 6 m mark, but demonstrates a protective step

4 able to continuously walk and fixate upon the circle between the 2 and 6 m mark, but veers off course at any time during task
5 able to continuously walk and fixate upon circle between the 2 and 6 m mark, maintains a straight path, in a steady and coordinated manner, time ≤ 7 seconds
NOT ACCEPTABLE: inconsistent/reduced speed or looking down at feet

9. Running with Controlled Stop (timed test)

INSTRUCTIONS: *Run as fast as you can to the end of the track.*

0 unable to jog (with both feet off the round for brief instant), rather demonstrates fast walking or leaping from foot to foot
1 able to jog in any fashion, time > 5 seconds
2 able to jog in any fashion, time > 3 seconds but ≤ 5 seconds, and perform a controlled stop with both feet on the line
NOT ACCEPTABLE: excessive equilibrium reactions
4 able to jog in any fashion, time ≤ 3 seconds, but is unable to perform a controlled stop with both feet on the line, eg. uses protective step(s) or excessive equilibrium reactions
5 able to jog in a coordinated and rhythmical manner and perform a controlled stop with both feet on the line, time ≤ 3 seconds
NOT ACCEPTABLE: excessive equilibrium reactions

10. Forward to Backward Walking (timed test)

INSTRUCTIONS: *Walk forwards to the half way mark, turn around and continue to walk backwards until I say "Stop". Try not to veer off course. Walk as quickly as you can, yet at a speed that you feel safe.*

0 unable to complete task, eg. requires assistance or upper extremity support
1 able to complete task independently, but must stop to maintain/regain balance at any time during this task
2 able to complete task without stopping but must significantly reduce speed, eg. total time is > 11 seconds and/or requires 4 or more steps to complete the turn
3 able to complete task with time ≤ 11 seconds and/or veers from straight path during backward walking
4 able to complete task in a continuous motion, time ≤ 9 seconds and/or uses protective step(s) during or just after turn
5 able to complete task in a continuous motion with brisk speed, time ≤ 7 seconds and maintaining a straight path throughout

11. Walk, Look & Carry (timed test)

INSTRUCTIONS: *Walk at your usual pace to the end of the line carrying the grocery bags. I will tell you when to look at the circle. Keep looking at it while you walk past it. I will tell you when to look straight ahead again. Try not to veer off course while you walk.*

0 unable to walk & look, eg. has to stop to look, or requires assistance or upper extremity support at any point during the test
1 able to continuously walk and initiate looking, but loses visual fixation on circle at or before 4 m mark

2 able to continuously walk and look, but loses visual fixation on circle after 4 m mark, eg. while looking back over the shoulder

3 able to continuously walk and fixate upon the circle between the 2 and 6 m mark, but demonstrates a protective step
Acceptable to demonstrate inconsistent or reduced speed

4 able to continuously walk and fixate upon the circle between the 2 and 6 m mark, but veers off course at any time during task
Acceptable to demonstrate inconsistent or reduced speed

5 able to continuously walk and fixate upon circle between the 2 and 6 m mark, maintains a straight path, in a steady and coordinated manner, time ≤ 7 seconds
NOT ACCEPTABLE: inconsistent/reduced speed or looking down at feet

12. Descending Stairs

INSTRUCTIONS: *Walk down the stairs. Try not to use the railing.*

0 unable to step down 1 step or requires the railing or assistance

1 able to step down 1 step with/without use of cane
NOT ACCEPTABLE: use of railing (from this level onwards)

2 able to step down 3 steps in any pattern with/without the use of cane, eg. step-to pattern with/without cane or reciprocal pattern with cane

3 able to step down 3 steps in a reciprocal pattern, without cane or able to step down a full flight in a step-to pattern, without cane

4 able to step down a flight in a reciprocal pattern but awkward, uncoordinated

5 able to step down a flight in a reciprocal pattern in a rhythmical pattern and coordinated manner

13. Step Ups x 1 Step (timed test)

INSTRUCTIONS: *i) Step up and down on this step as quickly as you can until I say "Stop". The pattern is Right-Left Up and Right-Left Down. Try not to look at your feet. ii) Step up and down on this step as quickly as you can until I say "Stop". The pattern is Left-Right Up and Left-Right Down. Try not to look at your feet.*

0 unable to step up independently, requires assistance and/or railing to ascend

1 able to step up independently, but unable to step down independently, eg. requires railing and/or assistance to descend

2 able to step up and down (1 cycle) independently without railing or assistance
Acceptable to look at feet

3 able to complete 5 cycles
Acceptable to demonstrate uncoordination or inconsistent speed/rhythm
NOT ACCEPTABLE: to look at feet

4 able to complete 5 cycles in 7 to 10 seconds
Acceptable to demonstrate uncoordination or inconsistent speed/rhythm
NOT ACCEPTABLE: looking at feet

5 able to complete 5 cycles in ≤ 6 seconds, in a rhythmical and coordinated manner
NOT ACCEPTABLE: to look at feet or inconsistent speed/rhythm

THE SIX MINUTE WALK TEST

In an unpublished study by Dr. Gibbons, Nadine Fruchter and Sherry Sloan at the Montreal Chest Hospital, a multiple linear regression equation was derived to calculate the normal distance for the 6-minute walk test. Variables in the equation include sex, height and age since these were factors which were found to influence distance walked. In order to use this equation, it is important to conduct the 6 minute walk test in the same manner as was done in the above study, particularly with respect to the distance marked* to do the test, the instructions used, and the encouragement given. The protocol for the above study was obtained in consultation with Nadine Fruchter. The regression equation is included below.

Definition: Submaximal functional test of walking endurance

Outcome: Distance walked over 6 minutes

Purpose:

1. To document sustained walking capacity in terms of distance walked over time
2. To document response to self-paced exercise stress in terms of pulse, respiratory rate, number of rest periods, dyspnea level, desaturation and rapidity of return to baseline level
3. To provide, over time, a record of the patient's functional status to monitor improvement, deterioration or stability

Population: Patients whose level of endurance has become dysfunctional due to cardiac or pulmonary disease or deconditioning

Space Requirements: Corridor, preferably uncongested and free of obstacles

Distance: A distance of 20 metres should be marked off, with markers every 5 metres to improve accuracy of measure

Equipment: Stopwatch, a pulse oximeter, and supplemental O_2 tank carrier are used for patients with cardiopulmonary disease when indicated

N.B. The test should be performed WITHOUT supplemental O_2 for patients with cardiopulmonary disease whenever possible in order to clearly observe the patient's response to this functional stress. Attempt to perform the test on room air

1. Record patient's baseline pulse, oxygen saturation, respiratory rate and level of dyspnea using the Visual Analogue Scale for Dyspnea, or a scale of your choice. For patients with poor endurance due to deconditioning, use the Borg Scale of Perceived Exertion instead of a scale of dyspnea.

2. Say to the patient:

   "Walk as quickly as you can for 6 minutes to cover as much ground as possible. You may rest if you need to, but continue walking as soon as possible".

   The pace will be determined by the patient. The physiotherapist should walk slightly behind the patient so as not to pace them. If there is equipment (oximeter, O_2 tank carrier) the therapist can handle the equipment for the patient. However, the patient can be allowed to push an O_2 tank carrier if he or she prefers.

3. Oxygen needs are determined by the patient's habitual use; desaturation is allowed as long as the patient tolerates his/her symptoms. The physiotherapist may judge it necessary to increase supplemental O_2 flow rates once the walk has started and will record it at that point.

4. Encouragement must be standardized as it has been shown to increase walking speed.[1] Standardized encouragement was given to all subjects in the above study conducted at The Montreal Chest Hospital every 30 seconds. The subjects were told:[*]

   "You're doing well, keep up the good work".

5. Pulse and saturation can be recorded at 1, 3 and 6 minutes, or every minute as deemed necessary. Maximal respiratory rate may be recorded. Dyspnea is measured using the visual analogue scale pre-and post-testing. Alternatively, perceived level of exertion is measured on the Borg scale for patients not having pulmonary disease. Total distance walked and the number and duration of rest periods required are noted.

6. O_2 saturation and pulse are monitored after the walk until baseline values are achieved. The time this takes can be noted.

7. Research has shown that there is a significant improvement in the distance walked over the first three trials of the test due to a training or learning effect.[2] It is suggested that patients who have never performed the test before, should do 2 trial runs. The distance walked for the third test should be taken as the most accurate result.

8. The 2-minute walk test has been found to be as reproducible as the 6- and 12-minute walk tests. Although the 6-minute walk test is more sensitive to change, the 2-minute test can be done instead of a 6-minute test when there is insufficient time available. Two practice trials are still necessary.[3]

1. **Feeding**

   10 = Independent. The patient can feed himself a meal from a tray or table when someone places the food within his reach. He is able to put on an assistive device if required, cut up his food, use salt and pepper, spread butter, etc. He must be able to accomplish this in a reasonable time.

   5 = Needs some assistance (with the tasks listed above).

   0 = The patient can not meet the criteria as defined above.

2. **Personal Hygiene**

   5 = Independent. The patient can wash his hands and face, comb hair and brush teeth. Male patients must be able to shave with any kind of razor but must be able to put in the blade, plug in the razor and get it from the drawer or cabinet by themselves. Female patients must be able to apply their own make up, if used, but do not need to be able to braid or style their hair.

   0 = Needs some assistance.

   0 = The patient can not meet the criteria as defined above.

3. **Bathing**

   5 = Independent. The patient must be able to use a bathtub, a shower or take a complete sponge bath. He must be able to perform all the steps involved in any one of these tasks without another person being present.

   0 = Needs some assistance.

   0 = The patient can not meet the criteria as defined above.

4. **Dressing and Undressing**

   10 = Independent. Patient is able to put on, remove and fasten all clothing and tie shoe laces (unless it is necessary to use adaptive aids for this). This includes putting on, removing and fastening corsets or braces when they are prescribed.

   5 = Some help is necessary. The patient needs help in putting on, removing or fastening any clothing. He must do at least half the work himself and accomplish this within reasonable time. Women need not be scored on the use of a brassiere or girdle unless these are prescribed garments.

   0 = The patient can not meet the criteria as defined above.

5. **Getting On and Off the Toilet**

   10 = Independent. The patient is able to get on and off the toilet, fasten and unfasten clothes, prevent soiling of clothes and use toilet paper without help. A wall bar or any other stable object may be used for support if needed. If a bedpan is used, he must be able to place it on the chair, empty it and clean it.

   5 = Needs some assistance. The patient requires help because of imbalance, in handling clothes or in using toilet paper.

   0 = The patient can not meet the criteria as defined above.

6. **Continence of Bowels**

10 = Independent. The patient is able to control his bowel and have no accidents. He can use a suppository or take an enema when necessary.

5 = Needs some assistance. The patient needs help in using a suppository, taking an enema or has occasional accidents.

0 = The patient can not meet the criteria as defined above.

7. **Bladder Control**

10 = Independent. The patient is able to control his bladder day and night. Spinal cord injury patients who wear an external device and a leg bag must be able to put them on independently, clean and empty the bag and stay dry day and night.

5 = Needs some assistance. The patient has occasional accidents, can not wait for the bed pan, get to the toilet in time or needs help with an external device.

0 = The patient can not meet the criteria as defined above.

8. **Chair / Bed Transfers**

15 = Independent. The patient can transfer from a chair to a bed and back again safely. For those in a wheelchair, the patient can safely approach the bed in his wheelchair, lock breaks, lift footrests, move safely onto the bed, lie down, come to a sitting position on the side of the bed, change the position of the wheelchair, if necessary, to transfer back into it safely.

10 = Needs some assistance. The patient needs to be reminded or supervised for safety of one or more steps of this activity.

0 = The patient can not meet the criteria as defined above.

9. **Walking on a Level Surface**

15 = Independent. The patient can walk at least 50 yards without help or supervision. He may wear braces or prostheses and use crutches, canes or a walkerette but not a rolling walker. He must be able to lock and unlock braces if used, assume the standing position and sit down, get the necessary mechanical aids into position for use and dispose of them when he sits (putting on and taking off braces is scored under #4. Dressing and Undressing).

10 = Needs some assistance. The patient needs supervision in any of the above tasks but can walk at least 50 yards with minimal help.

0 = The patient can not meet the criteria as defined above.

10. **Ascending and Descending Stairs**

10 = Independent. The patient is able to go up and down a flight of stairs safely without help or supervision. He may, and should, use handrails, canes or crutches when needed. He must be able to carry the cane or crutches as he ascends and descends the stairs.

5 = Needs some assistance. The patient needs help with or supervision of any one of the above tasks.

0 = The patient can not meet the criteria as defined above.

OARS - INSTRUMENTAL ACTIVITIES OF DAILY LIVING

1. Can you use the telephone...
   - (2) without help, including looking up numbers and dialing
   - (1) with some help (can answer the phone or dial the operator in an emergency, but needs a special phone or help in getting the number or dialing)
   - (0) or are you completely unable to use the telephone
   - — not answered

2. Can you get to places out of walking distance...
   - (2) without help (can travel on buses, taxis or drive your own car)
   - (1) with some help (need someone to help you or go with you when traveling
   - (0) or are you unable to travel unless emergency arrangements are made for a specialized vehicle like an ambulance
   - — not answered

3. Can you go shopping for groceries or clothes (assuming has transportation)...
   - (2) without help (taking care of all shopping needs yourself assuming that you had transportation)
   - (1) with some help (need someone to go with you on all shopping trips)
   - (0) or are you completely unable to do any shopping
   - — not answered

4. Can you prepare your own meals...
   - (2) without help (plan and cook meals yourself)
   - (1) with some help (can prepare some things but unable to cook full meals yourself)
   - (0) or are you completely unable to prepare any meals
   - — not answered

5. Can you do your own housework...
   - (2) without help (can scrub floors etc.)
   - (1) with some help (can do light housework but need help with heavy work)
   - (0) or are you completely unable to do any housework
   - — not answered

6. Can you take your own medicine...
   - (2) without help (in the right doses at the right time)
   - (1) with some help (able to take medicine if someone prepares it for you and/or reminds you to take it)
   - (0) or are you completely unable to take your own medicine
   - — not answered

7. Can you handle your own money...
   - (2) without help (write checks, pay bills, etc.)
   - (1) with some help (manage day to day buying but need some help with managing cheque book and paying bills)
   - (0) or are you completely unable to handle your own money
   - — not answered

THE REINTEGRATION TO NORMAL LIVING INDEX

The next set of questions will be a set of statements and you will have three choices. The choices are: yes, partially or no.

	Y	P	N
1. Do you move around your living quarters as you feel is necessary?	0	1	2
2. Do you move around your community as you feel is necessary? (shopping, banking, etc.)	0	1	2
3. Are you able to take trips out of town as you feel necessary?	0	1	2
4. Are you comfortable with how you feel your self–care needs are met?	0	1	2
5. Do you spend most of your days occupied in activity that is necessary or important to you?	0	1	2
6. Are you able to participate in recreational activities as you want to? (hobbies, sports, cards, etc.)	0	1	2
7. Are you participating in social activities with family, friends, and/or business acquaintances as is necessary or desirable to you?	0	1	2
8. Are you assuming a role in your family which meets your needs and those of other family members? (family means people with whom you live and/or relatives who you see on a regular basis)	0	1	2
9. In general, are you comfortable with your personal relationships?	0	1	2
10. In general, are you comfortable with yourself when you are in the company of others?	0	1	2
11. Do you feel that you can deal with life events when they happen?	0	1	2

Total ____/22

Appendix 4.4.

Descriptions of Study Measures

Appendix 4.5. Diagrammatic Representation of Statistical Analyses

Cross-Sectional Analyses

Raw Data

↓ Pre ↓ Post

⇩

Descriptive Statistics

↓ Pre ↓ Post

Using VAS, PCS, MCS, 16 phys. perf. variables

calculated mean, SD, range, median, correlations

⇩

MCS was removed from analyses due to low and negative correlations with phys. perf.

Univariate Asso. Between HRQL and Phys. Perf.
Simple Linear Regression

↓ Pre ↓ Post

Using VAS, PCS, 16 phys. perf. variables

Calculated std. β (β x SD), 95% CIs, R^2

Groups that differ one SD on phys. perf. variable will differ by "x" on the outcome

⇩

From this point on, used only VAS as outcome measure.

Multivariate Asso. Between HRQL and Phys. Perf.
Multiple Linear Regression

↓ Pre ↓ Post

<u>Step I</u>
Using Type I regression where variables were forced in model in a specific order

Using VAS, 16 phys. perf. variables, potential confounders

Calculated raw R^2, adj. R^2 of model, semi-partial R^2 for each variable

<u>Step 2</u>
added other variables to explain Social and Psych. Func.
Using above variables + SF, MH, BP, VT
New variables were added in last

OARS and confounders were removed from analyses due to insignificant asso. with VAS.

⇩

Verification of Regression Assumption
Generated residual plots

Regression Diagnostics
Examined collinearity and outliers

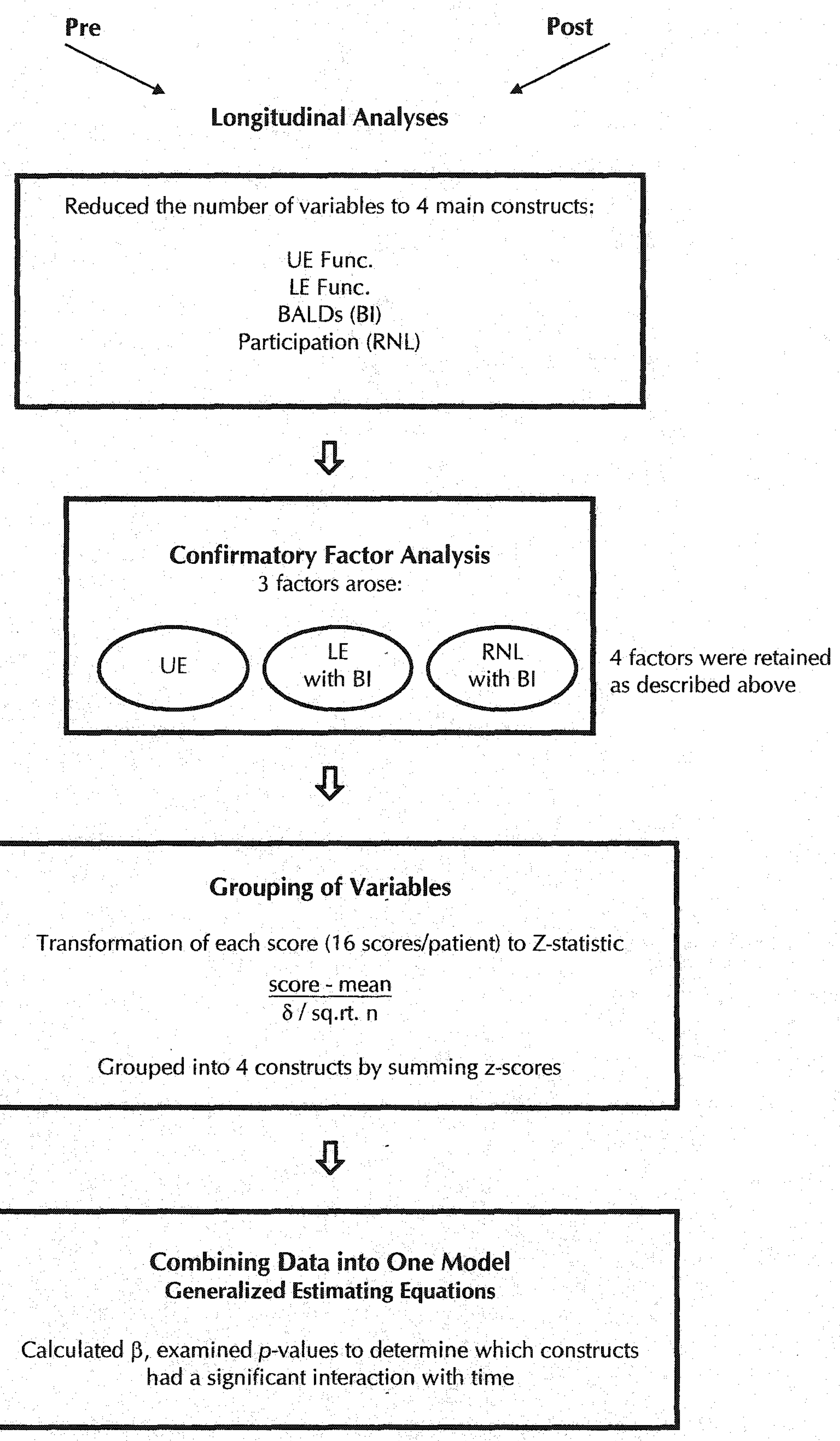
⇩

The contribution of each construct (R^2) changed from baseline to post-intervention (raw and adj.)

Is time a significant factor?

⇩

Appendix 4.5. Cont'd



Appendix 5.2a. Correlations Between EQ-5D Health Dimensions and SF-36 Subscales Baseline (n = 43)

Health Dimensions	PF	RP	BP	GH	VT	SF	RE	MH
Mobility	0.4*	0.0	0.4*	0.3*	0.2	0.2	0.3	0.1
Self-Care	0.6*	0.1	0.3*	0.2	0.2	0.3*	0.2	0.0
Usual Activities	0.6*	0.2	0.3*	0.4*	0.1	0.2	0.1	0.2
Pain	0.1	0.0	0.6*	0.2	0.1	0.0	-0.2	0.0
Anxiety / Depression	0.1	0.3*	0.1	0.2	0.2*	0.2*	0.1	0.5*

* statistically significant association ($p < 0.05$)

Appendix 5.2b. Correlations Between EQ-5D Health Dimensions and SF-36 Subscales Post-Intervention (n = 43)

Health Dimensions	PF	RP	BP	GH	VT	SF	RE	MH
Mobility	0.6*	0.2	0.2	0.5*	0.5*	0.2	0.0	0.2
Self-Care	0.7*	0.4*	-0.2	0.3*	0.2	0.1	0.1	0.2
Usual Activities	0.5*	0.5*	-0.1	0.0	0.1	0.0	-0.1	0.0
Pain	0.3	0.3	0.4*	0.3	0.2	0.2	0.2	0.2
Anxiety / Depression	0.4*	0.1	0.1	0.4*	0.4*	0.2	0.3	0.5*

* statistically significant association ($p < 0.05$)

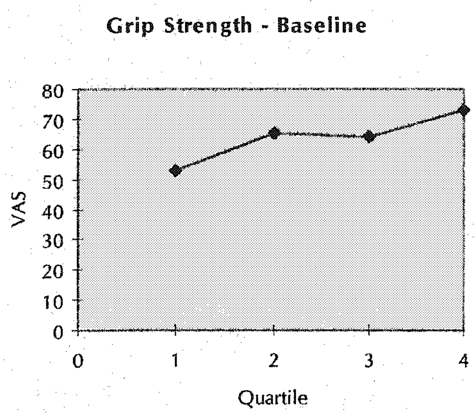
Appendix 5.4a. Correlations Between Outcome Variables and Physical performance Measures Baseline and Post-Intervention (n=43)

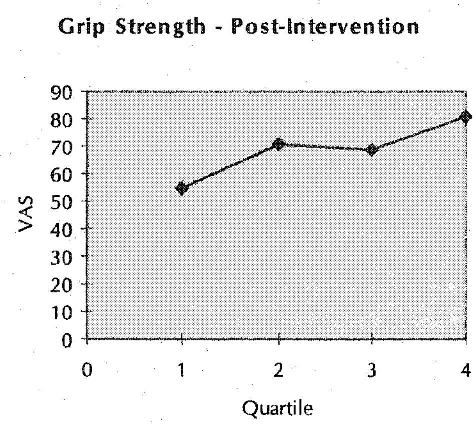
Measures	VAS - Pre (r)	VAS - Post (r)	PCS - Pre (r)	PCS - Post (r)	MCS - Pre (r)	MCS - Post (r)
STREAM - UE (scored 0 to 20)	0.2	0.4*	0.2	0.3	0.0	-0.3
Grip Strength (kg of force)	0.3	0.5*	0.4*	0.5*	0.1	-0.2
Box & Block (no. of blocks)	0.1	0.4*	0.3	0.2	-0.1	-0.3
Nine-Hole Peg† (time in sec)	0.1	0.4*	0.2	0.3	0.0	-0.3
TEMPA (scored -207 to 0)	0.1	0.4*	0.2	0.2	-0.1	-0.3
STREAM - LE (scored 0 to 50)	0.4*	0.4*	0.3	0.5*	0.0	-0.3
Berg Balance (scored 0 to 56)	0.4*	0.5*	0.4*	0.5*	0.0	-0.2
Com. Gait Speed† (time in sec)	0.4*	0.5*	0.4*	0.4*	0.0	-0.2
Max. Gait Speed† (time in sec)	0.4*	0.5*	0.4*	0.4*	0.0	-0.1
Stair Climbing† (time in sec)	0.4*	0.4*	0.4*	0.5*	0.1	-0.1
Timed "Up & Go"† (time in sec)	0.5*	0.5*	0.4*	0.4*	0.1	-0.1
CB&M (scored 0 to 96)	0.3	0.4*	0.4*	0.5*	0.0	-0.3
Six-Min. Walk (distance in m)	0.5*	0.5*	0.3	0.5*	0.1	-0.1
Barthel Index (scored 0 to 100)	0.4*	0.4*	0.4*	0.5*	0.1	-0.2
OARS-IADL (scored 0 to 14)	0.2	0.4*	0.3	0.4*	-0.1	-0.1
RNL Index† (scored 22 to 0)	0.3*	0.5*	0.5*	0.5*	0.1	0.1

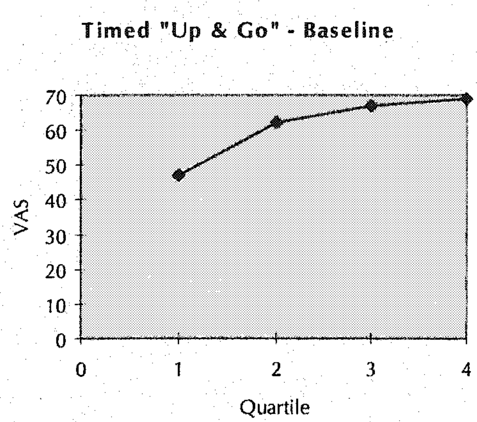
* statistically significant association ($p < 0.05$)

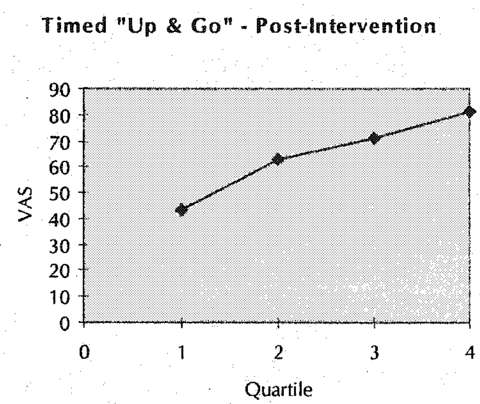
† scores were multiplied by (-1) for standardization of interpretation (since lower scores indicated better performance)

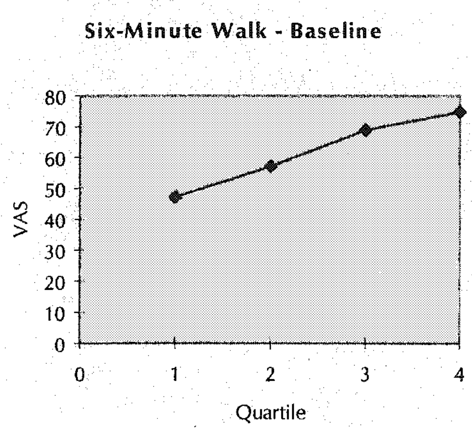
Appendix 5.4b. Scatter Plots of VAS versus Quartiles for Specific Measures

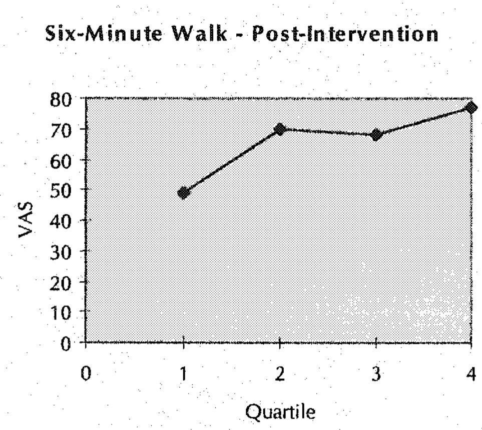






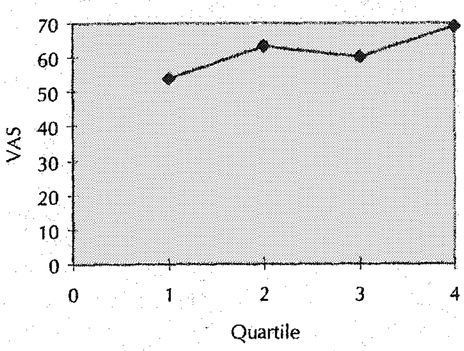




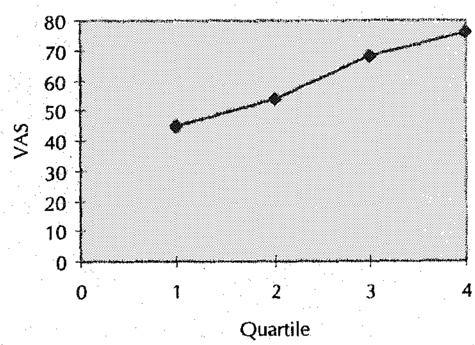


Appendix 5.4a Cont'd

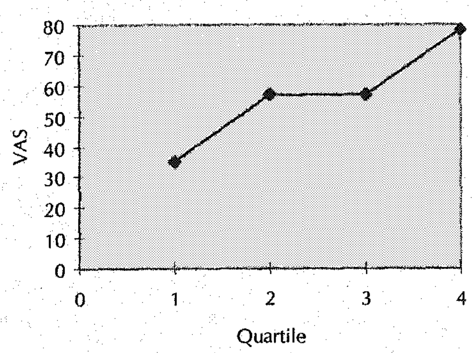
Barthel Index - Baseline



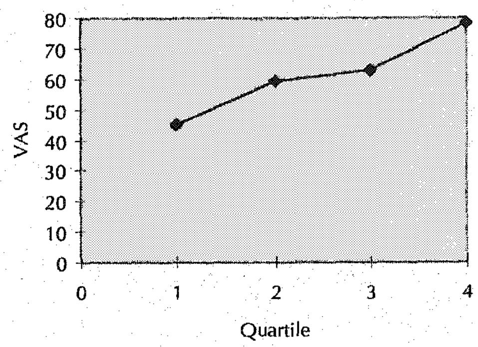
Barthel Index - Post-Intervention



RNL Index - Baseline



RNL Index - Post-Intervention



Appendix 5.6a. Univariate Models of HRQL
VAS - Baseline (n=43)

Measures	Parametre Est. (β)	Standard Error (SE)	Standardized β	95% CIs	R-Squared
STREAM - UE (scored to 20)	0.7	0.5	5.1	(-2.4, 12.6)	0.05
Grip Strength (kg of force)	0.5	0.3	6.2	(-1.2, 13.7)	0.07
Box & Block (no. of blocks)	0.2	0.2	3.3	(-4.1, 10.7)	0.02
Nine-Hole Peg† (time in sec)	0.4	0.7	1.8	(-5.8, 9.4)	0.01
TEMPA (scored -207 to 0)	0.1	0.1	2.4	(-5.2, 10.0)	0.01
STREAM - LE (scored 0 to 50)	0.8	0.3	8.3*	(1.2, 15.4)	0.13
Berg Balance (scored 0 to 56)	0.9	0.3	9.8*	(2.8, 16.8)	0.18
Com. Gait Speed† (time in sec)	0.7	0.2	10.0*	(3.1, 16.9)	0.19
Max. Gait Speed† (time in sec)	0.7	0.3	9.3*	(2.2, 16.3)	0.16
Stair Climbing† (time in sec)	0.9	0.2	13.7*	(7.6, 19.8)	0.38
Timed "Up & Go"† (time in sec)	0.5	0.1	10.9*	(4.1, 17.6)	0.22
CB&M (scored 0 to 96)	0.4	0.2	8.2*	(0.4, 16.0)	0.08
Six-Min. Walk (distance in m)	<0.1	<0.1	10.9*	(5.4, 16.4)	0.23
Barthel Index (scored 0 to 100)	0.8	0.3	9.6*	(2.6, 16.6)	0.17
OARS (scored 0 to 14)	1.4	1.2	2.7	(-2.2, 7.8)	0.03
RNL Index† (scored 22 to 0)	1.7	0.8	7.4*	(0.2, 14.6)	0.10

* statistically significant association ($p < 0.05$)
† scores were multiplied by (-1) for standardization of interpretation (since lower scores indicated better performance)

Appendix 5.6b. Univariate Models of HRQL
VAS - Post-Intervention (n=43)

Measures	Parametre Est. (β)	Standard Error (SE)	Standardized β	95% CIs	R-Squared
STREAM - UE (scored to 20)	1.2	0.5	8.1*	(1.9, 14.2)	0.16
Grip Strength (kg of force)	0.8	0.2	9.7*	(3.8, 15.6)	0.23
Box & Block (no. of blocks)	0.4	0.2	8.6*	(2.4, 14.8)	0.18
Nine-Hole Peg† (time in sec)	1.8	0.6	8.8*	(2.7, 14.9)	0.19
TEMPA (scored -207 to 0)	0.2	0.1	8.2*	(2.0, 14.4)	0.16
STREAM - LE (scored 0 to 50)	0.9	0.3	6.7*	(0.6, 12.7)	0.20
Berg Balance (scored 0 to 56)	0.8	0.2	9.9*	(4.0, 15.8)	0.24
Com. Gait Speed† (time in sec)	0.5	0.2	9.6*	(3.6, 15.6)	0.22
Max. Gait Speed† (time in sec)	0.5	0.1	9.6*	(3.8, 15.4)	0.22
Stair Climbing† (time in sec)	0.3	0.1	7.6*	(1.0, 14.3)	0.14
Timed "Up & Go"† (time in sec)	0.4	0.1	11.8*	(5.6, 16.4)	0.30
CB&M (scored 0 to 96)	0.5	0.2	8.7*	(2.7, 14.7)	0.20
Six-Min. Walk (distance in m)	<0.1	<0.1	9.8*	(4.1, 15.5)	0.26
Barthel Index (scored 0 to 100)	0.7	0.2	8.7*	(2.7, 14.7)	0.18
OARS (scored 0 to 14)	2.6	0.9	8.0*	(1.8, 14.2)	0.16
RNL Index† (scored 22 to 0)	1.9	0.5	10.7*	(4.9, 16.4)	0.27

* statistically significant association ($p < 0.05$)
† scores were multiplied by (-1) for standardization of interpretation (since lower scores indicated better performance)

Appendix 5.6c. Univariate Models of HRQL
PCS - Baseline (n=43)

Measures	Parametre Est. (β)	Standard Error (SE)	Standardized β	95% CIs	R-Squared
STREAM - UE (scored to 20)	0.3	0.2	2.1	(-0.8, 4.9)	0.06
Grip Strength (kg of force)	0.3	0.1	3.2*	(0.5, 5.9)	0.13
Box & Block (no. of blocks)	0.1	0.1	2.4	(-0.2, 5.0)	0.07
Nine-Hole Peg† (time in sec)	0.4	0.3	1.9	(-0.9, 4.8)	0.05
TEMPA (scored -207 to 0)	0.1	0.0	2.1	(-0.7, 4.8)	0.05
STREAM - LE (scored 0 to 50)	0.2	0.1	5.5*	(2.7, 8.3)	0.07
Berg Balance (scored 0 to 56)	0.3	0.1	3.8*	(1.3, 6.3)	0.19
Com. Gait Speed† (time in sec)	0.2	0.1	3.4*	(0.8, 6.0)	0.16
Max. Gait Speed† (time in sec)	0.3	0.1	3.5*	(0.8, 6.2)	0.16
Stair Climbing† (time in sec)	0.3	0.1	4.3*	(1.7, 6.9)	0.26
Timed "Up & Go"† (time in sec)	0.2	0.1	3.5*	(0.9, 6.2)	0.16
CB&M (scored 0 to 96)	0.2	0.1	3.3*	(0.5, 6.2)	0.13
Six-Min. Walk (distance in m)	<0.1	<0.1	2.7	(-0.03, 5.5)	0.09
Barthel Index (scored 0 to 100)	0.3	0.1	3.5*	(0.8, 6.1)	0.17
OARS (scored 0 to 14)	0.9	0.5	1.9	(0.1, 3.7)	0.10
RNL Index† (scored 22 to 0)	0.9	0.3	4.0*	(1.4, 6.6)	0.21

* statistically significant association ($p < 0.05$)
† scores were multiplied by (-1) for standardization of interpretation (since lower scores indicated better performance)

Appendix 5.6d. Univariate Models of HRQL
PCS - Post-Intervention (n=43)

Measures	Parametre Est. (β)	Standard Error (SE)	Standardized β	95% CIs	R-Squared
STREAM - UE (scored to 20)	0.4	0.2	2.9	(-0.2, 6.0)	0.09
Grip Strength (kg of force)	0.4	0.1	4.8*	(2.0, 7.7)	0.24
Box & Block (no. of blocks)	0.1	0.1	2.7	(-0.4, 5.8)	0.08
Nine-Hole Peg† (time in sec)	0.4	0.3	2.2	(-1.0, 5.4)	0.05
TEMPA (scored -207 to 0)	0.1	0.1	2.1	(-1.4, 5.5)	0.05
STREAM - LE (scored 0 to 50)	0.4	0.1	4.5*	(1.6, 7.4)	0.22
Berg Balance (scored 0 to 56)	0.5	0.1	5.4*	(2.5, 8.2)	0.29
Com. Gait Speed† (time in sec)	0.2	0.1	4.0*	(1.2, 6.8)	0.16
Max. Gait Speed† (time in sec)	0.2	0.1	3.6*	(0.5, 6.7)	0.14
Stair Climbing† (time in sec)	0.2	0.1	5.2*	(2.4, 7.9)	0.27
Timed "Up & Go"† (time in sec)	0.2	0.1	4.3*	(1.6, 7.0)	0.18
CB&M (scored 0 to 96)	0.3	0.1	5.2*	(2.6, 7.8)	0.27
Six-Min. Walk (distance in m)	<0.1	<0.1	5.6*	(2.8, 8.4)	0.30
Barthel Index (scored 0 to 100)	0.4	0.1	5.0*	(2.1, 7.9)	0.25
OARS (scored 0 to 14)	1.4	0.5	4.3*	(1.4, 7.3)	0.19
RNL Index† (scored 22 to 0)	0.8	0.2	4.5*	(1.7, 7.4)	0.21

* statistically significant association ($p < 0.05$)
† scores were multiplied by (-1) for standardization of interpretation (since lower scores indicated better performance)

Appendix 5.7.1a. Correlations Between VAS and SF-36 Subscales Baseline and Post-Intervention (n=43)

Subscales	VAS - Pre (r)	VAS - Post (r)
Physical Functioning	0.5*	0.5*
Role Physical	0.4*	0.5*
Bodily Pain	0.4*	0.3
General Health	0.5*	0.6*
Vitality	0.4*	0.3*
Social Functioning	0.4*	0.5*
Role Emotional	0.2	0.1
Mental Health	0.4*	0.4*

* statistically significant association ($p<0.05$)

Appendix 5.7.1b. Regression Co-efficient Between VAS and SF-36 Subscales Baseline and Post-Intervention (n=43)

Subscales	Parameter Est. (β)		Standard Error (S_E)		R-Squared	
	Pre	Post	Pre	Post	Pre	Post
Physical Functioning	0.4*	0.4*	0.1	0.1	0.2	0.3
Role Physical	0.2	0.3*	0.1	0.1	0.1	0.2
Bodily Pain	0.3*	0.3*	0.1	0.1	0.1	0.1
General Health	0.5*	0.5*	0.2	0.1	0.2	0.3
Vitality	0.5*	0.3*	0.2	0.1	0.1	0.1
Social Functioning	0.3*	0.3*	0.1	0.1	0.1	0.2
Role Emotional	0.1	0.1	0.1	0.1	<0.1	<0.1
Mental Health	0.5*	0.5*	0.2	0.2	0.1	0.2

* statistically significant association ($p<0.05$)

Appendix 5.8.1. Factor Analysis

Two factors: upper extremity and lower extremity

Subscales	Factor 1	Factor 2
STREAM - UE	0.8	0.4
Grip Strength	0.6	0.5
Box & Block	0.8	0.3
Nine-Hole Peg	0.8	0.3
TEMPA	0.9	0.3
STREAM – LE	0.7	0.5
Berg Balance	0.5	0.7
Gait Speed	0.3	0.7
Stair Climbing	0.2	0.8
Timed "Up & Go"	0.3	0.7
CB&M	0.4	0.6
Six-Min. Walk	0.4	0.8

Four factors: upper extremity, lower extremity, participation, psychosocial functioning

Subscales	Factor 1	Factor 1	Factor 3	Factor 4
STREAM - UE	0.7	0.4	0.1	<0.1
Grip Strength	0.6	0.2	<0.1	<0.1
Box & Block	0.9	0.2	0.1	<0.1
Nine-Hole Peg	0.8	0.2	0.1	<0.1
TEMPA	0.8	0.2	0.1	<0.1
STREAM – LE	0.5	0.5	0.1	<0.1
Berg Balance	0.4	0.8	<0.1	<0.1
Gait Speed	0.3	0.8	0.1	<0.1
Stair Climbing	0.2	0.8	0.1	<0.1
Timed "Up & Go"	0.4	0.6	0.2	<0.1
CB&M	0.4	0.6	<0.1	<0.1
Six-Min. Walk	0.3	0.8	<0.1	<0.1
Barthel Index	0.1	0.6	0.5	<0.1
RNL Index	<0.1	0.2	0.8	0.1
Social Func.	0.1	0.2	0.1	0.8
Mental Health	0.1	<0.1	0.1	0.7
Bodily Pain	0.1	0.1	0.2	0.6
Vitality	<0.1	0.1	0.2	0.8

Appendix 5.8.2a. Transformation of Raw Scores to Z-Scores Baseline and Post-Intervention (n=43)

Measures	Pre Raw Scores Range	Pre Raw Scores SD	Pre Z-Scores* Range	Pre Z-Scores* SD	Post Raw Scores Range	Post Raw Scores SD	Post Z-Scores* Range	Post Z-Scores* SD
STREAM - UE (scored 0 to 20)	0 - 20	6.7	-2.0 - 0.7	0.9	0 - 20	6.5	-2.3 - 0.7	0.9
Grip Strength (kg of force)	0 - 59	12.2	-0.7 - 1.1	0.5	0 - 43	12.8	-0.6 - 1.0	0.5
Box & Block (no. of blocks)	0 - 52	18.4	-0.5 - 0.5	0.3	0 - 56	19.1	-0.5 - 0.5	0.3
Nine-Hole Peg (time in sec)	243.4 - 22.7	93.4	-0.1 - 0.1	0.1	172.7 - 22.7	60.7	-0.1 - 0.1	0.1
TEMPA (scored -207 to 0)	-120 - 0	34.3	-0.4 - 0.2	0.2	-101 - 0	34.3	-0.4 - 0.2	0.2
STREAM - LE (scored 0 to 50)	13 - 49	10.0	-1.5 - 0.8	0.6	11 - 50	10.3	-1.7 - 0.6	0.6
Berg Balance (scored 0 to 56)	16 -56	11.1	-1.3 - 0.7	0.6	10 - 56	11.7	-1.5 - 0.6	0.5
Com. Gait Speed† (time in sec)	62.5 - 3.9	14.3	-1.5 - 0.3	0.4	96.3 - 3.2	17.4	-1.7 - 0.2	0.4
Max. Gait Speed† (time in sec)	62.6 - 2.1	13.4	-1.8 - 0.3	0.5	106.3 -2.1	19.1	-1.6 - 0.2	0.3
Stair Climbing† (time in sec)	67.7 - 4.3	15.9	-0.4 - 1.1	0.4	125.0 - 4.3	27.3	-0.2 - 0.9	0.2
Timed "Up & Go"† (time in sec)	100.0 - 7.0	22.2	-0.9 - 0.2	0.3	154.4 - 7.1	26.8	-1.1 - 0.2	0.2
CB&M (scored 0 to 96)	0 - 66	17.5	-0.3 - 1.0	0.4	0 - 64	18.6	-0.3 - 0.8	0.3
Six-Min. Walk (distance in m)	31 - 594	135.8	-0.1 - 0.1	0.1	20 - 550	140.1	-0.1 - 0.1	0.1
Barthel Index (scored 0 to 100)	60 - 100	12.0	-1.3 - 0.5	0.5	45 - 100	11.9	-2.1 - 0.3	0.5
RNL Index† (scored 22 to 0)	19 - 0	4.3	-3.8 - 2.6	1.5	17 - 0	4.8	-3.0 - 5.8	1.5

Cont'd

Measures	Pre Raw Scores Range	Pre Raw Scores SD	Pre Z-Scores* Range	Pre Z-Scores* SD	Post Raw Scores Range	Post Raw Scores SD	Post Z-Scores* Range	Post Z-Scores* SD
Social Functioning (scored 0 to 100)	0 - 100	28.1	-0.5 - 0.3	0.2	0 - 100	27.5	-0.6 - 0.3	0.2
Mental Health (scored 0 to 100)	44 - 100	16.1	-0.6 - 0.7	0.4	40 - 100	17.8	-0.6 - 0.5	0.3
Bodily Pain (scored 0 to 100)	20 - 100	25.7	-1.2 - 0.7	0.6	0 - 100	27.2	-1.3 - 0.7	0.5
Vitality (scored 0 to 100)	15 - 95	17.7	-0.7 - 0.8	0.4	0 - 85	21.2	-0.7 - 0.8	0.4

* calculated using z-statistic transformation
† lower scores indicate better functioning

Appendix 5.8.2b. Total Z-Scores for Grouped Constructs

Variables	Pre Z-Score Range	Pre Z-Score SD	Post Z-Score Range	Post Z-Score SD
Upper Extremity Functioning	-3.3 - 2.6	1.6	-3.6 - 2.2	1.7
Lower Extremity Functioning	-6.2 - 2.9	2.1	-7.1 - 2.4	1.9
BADLs (Barthel Index)	-1.3 - 0.5	0.5	-2.1 - 0.3	0.5
Participation (RNL Index)	-3.8 - 2.6	1.5	-3.0 - 5.8	1.5
Psychosocial Functioning (SF, MH, BP, VT)	-2.0 - 2.1	0.8	-1.6 - 1.3	0.8

Appendix 6.2a. Interquartile Ranges for Specific Physical Performance Measures (n = 43)

Measures	Minimum		25%		Median (50%)		75%		Maximum	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Grip Strength (kg)	0	0	6	7	13	15	24	26	59	43
Timed Up & Go (sec)	100	154	26	27	17	16	12	11	7	7
Six Min. Walk (m)	31	20	104	101	208	240	293	326	594	550
Barthel Index (0-100)	60	95	83	90	95	100	100	100	100	100
RNL Index (22-0)	19	17	10	8	7	6	5	1	0	0

Appendix 6.2b. Correlations Between Changes in Physical Performance with Changes in VAS (n = 43)

Measures	Correlation Co-efficient (r)*
STREAM - UE	0.1
Grip Strength	<0.1
Box & Block	<0.1
Nine-Hole Peg	0.3
TEMPA	<0.1
STREAM - LE	0.1
Berg Balance	0.1
Com. Gait Speed	<0.1
Max. Gait Speed	0.1
Stair Climbing	0.1
Timed "Up & Go"	0.1
CB&M	0.3
Six-Min. Walk	0.1
Barthel Index	0.2
OARS-IADL	<0.1
RNL Index	0.2

* all non-significant associations ($p > 0.05$)