Measuring and Predicting Early Functioning Post-Stroke

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In dedication to my husband James Andrew Finch, whose support, love, and friendship is and always has been immeasurable

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Abstract

Functioning, the most important outcome of stroke interventions, is complex to characterize. Stroke survivors measure functioning compared to what they did in their pre-stroke lives; hence equating functioning with recovery. To optimize the recovery of functioning, research suggests that rehabilitation interventions should start early post-stroke. To quantify changes in function owing to different interventions, the average value on an index comprised of multiple items related to function is compared or the proportions of people categorized into different functional levels are compared. Currently, there is no agreed upon method of quantifying improvements in functioning and using multiple indices is problematic. This thesis examined combining a method of quantifying behaviours, Rasch analysis that produces measures with interval properties from ordinal observations, with the components of the International Classification of Functioning (ICF), to conceptualize, define, and quantify functioning in a single measure. The ensuing prototype measure was limited in scope. Therefore, using data from a longitudinal prognostic study involving people with acute stroke assessed at three days and followed up at three months, a Functioning measure at three months, the F3m, was developed. The F3m is a valid and reliable measure that amalgamates tests where performance is observed and self-report questionnaires where people rate their difficulties in performing physical activities. The F3m covers all ICF components and can be used to quantify recovery at three months. Interventions to improve early functioning post-stroke must impact favourably on the factors that affect early recovery. The most influential factor related to recovery, to date, has been early functioning. As a measure of such early functioning did not exist, a measure of functioning at three days, the F3d, was constructed in a manner similar to the F3m. Univariate and multivariate analyses were then used to identify strong early factors collected 24-72 hours post-stroke, and link the factors to function at 3 months. A seven-variable predictive model of functioning was derived. The most important influential predictor of functioning in the model, the comprehensive F3d measure, can now be used to evaluate and develop early interventions to enhance functioning, and to act as a covariate explaining the recovery of functioning.

Abrégé

Le résultat le plus important des interventions auprès des personnes ayant subi un accident vasculaire cérébral (AVC), le niveau de fonction de la personne, est très complexe à décrire. Les personnes ayant survécu à un AVC mesure leur degré de fonction en le comparant à ce qu'ils étaient en mesure d'accomplir avant leur AVC et considèrent leur degré de fonction comme étant équivalent au niveau de récupération. Afin d'optimaliser la récupération de la fonction, diverses études suggèrent que les interventions de réadaptation doivent débuter tôt après l'AVC. Pour quantifier les changements de la fonction qui sont dus aux diverses interventions, la moyenne d'un score obtenu sur index ou un test composé de plusieurs items relies à la fonction sont comparés ou, encore, la proportion des personnes classifiées dans divers niveau de fonctionnement est comparée. A ce jour, il n'y a pas de mesure convenue qui quantifie les améliorations de la fonction et l'utilisation de tous ces tests et index est problématique. Dans cette thèse, un examen de la combinaison d'une méthode de quantification des variables latentes, l'analyse de Rasch, qui produit des mesures à échelle d'intervalle à partir d'observations sur des échelles ordinales, et des composantes de la Classification internationale du fonctionnement, du handicap et de la santé (CIF), a été fait afin de conceptualiser, définir et quantifier la fonction en n'utilisant qu'une seule mesure. La mesure prototype résultante avait une portée limitée. En utilisant des données provenant d'une étude pronostique longitudinale, dans laquelle des personnes ont été évaluées à l'intérieur des 3 jours suivant leur AVC et réévaluées trois mois plus tard, une mesure de la fonction, le F3m a été développée. Le F3m est une mesure valide et fiable qui amalgame différents tests où la performance des personnes est observée ainsi que des questionnaires d'auto-évaluation où les personnes évaluent leur niveau de difficulté à accomplir diverses activités physiques. Le F3m englobe toutes les composantes de la CIF et peut être utilisé pour quantifier la récupération au troisième mois suivant l'AVC. Les interventions visant à améliorer la fonction de la personne tôt après un AVC doivent avoir un impact favorable sur les facteurs qui affectent les premières étapes de la récupération. Le facteur ayant le plus d'influence, à ce jour, est le niveau de fonction dans les premiers jours suivant l'AVC. Comme une mesure de la fonction aussi tôt suivant un AVC n'existait pas, une mesure de la fonction au troisième jour suivant l'AVC, le F3d, a été construite d'une manière

similaire à celle du F3m. Des analyses à une variable et à variables multiples ont été utilisées par la suite afin d'identifier les variables recueillis entre 24 et 72 heures suivant l'AVC ayant le plus d'influence, et celles-ci ont été reliées au niveau de fonction au troisième mois suivant l'AVC. Un modèle prédictif comprenant sept variables a été dérivé de cette analyse. La plus importante des variables explicatives dans le modèle, la mesure F3d complète, peut maintenant être utilisée pour évaluer et développer des interventions hâtives afin de maximiser la fonction et être utilisée comme covariable expliquant la récupération de la fonction.

Preface

Background to the Thesis

This thesis started out as a randomized control trial of early intense therapy post-stroke. The protocol for a multi-site, stratified, block-randomized controlled trial was written, but we were unable to decide on how to stratify the subjects. Stroke severity, one option, was felt to be inadequate. We also felt that the outcome, the Barthel index, would not capture the full set of activities a person considered important for functioning. A more comprehensive measure of functioning was needed. I have included a short précis of the methods section as an indication of what the trial would have entailed.

Title of the Protocol

Does early and intense rehabilitation in acute stroke impact on the motor and functional recovery in acute stroke?

Précis of the Methods

This is a prospective, multi-site, stratified, block randomized, single blinded, controlled study with 3 sites and 307 acute stroke patients randomized into 4 groups, 77 per group, receiving either: early intense, early standard, late intense or late standard therapy for 10 days post-stroke. Randomization will be stratified according to site and severity of stroke after baseline assessment, 24-48 hours post-stroke. All strokes not in a moribund state, without serious cardiac conditions, which remain for 7 days, will be selected and closely monitored for any adverse effects. Assessors, blinded to group assignment will measure motor recovery (STREAM) and functional recovery (Barthel) at baseline and 10 days post-stroke. A number of secondary recovery measures, compliance to and with therapy protocols and all co-intervention will also be assessed. Task oriented interventions will be strictly regulated for similarity across all 4 groups. Subjects will start either ***early*** *at 48 hours or* ***late*** *at 96-120 hours post-stroke. The intensity will be:* ***Early Intense,*** *120 minutes X 10 days =1200;,* ***Early Standard,*** *30 minutes X 8 days =240,* ***Late Intense,*** *120 minutes X6 days = 720;* ***Late Standard,*** *30 minutes X5 days =150 minutes. The primary outcome, the mean difference in motor and functional recovery across the 4 interventions* *will be analyzed with an orthogonal analysis of variance to partition out the contribution of each intervention to recovery.*

To provide effective specialized care for a stroke population the timing and intensity of rehabilitation as a component of care must be delineated. Little consensus exists on which model of therapy is most effective for which deficit. The models could be tested and a more focused and cost effective approach to therapy initiated, but for whom?

The intent of the thesis changed and we designed a two part cohort study with the following two objectives*:* (1) To identify the anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that will predict the extent of an individual's recovery at three months and (2) To estimate the distribution and magnitude of activation patterns suggestive of brain recovery and how much these patterns reflect physical recovery.

The Second Objective

The second objective, sadly, is not included in this thesis, but will be carried out after the obligations for this thesis have been fulfilled. The second objective was to perform functional Magnetic Resonance Imaging (fMRI) studies using the blood oxygen level dependent technique (BOLD) on a subset of the cohort at three months post-stroke. The brain activation patterns seen in individuals at different functioning levels were to be compared to their individual ratings of recovery on the new measure of functioning and the brain activation patterns of an aged matched control group.

The Difficulties in Fulfilling the Second Objective

Brain activation patterns are difficult to accurately evaluate in people after stroke and it took longer than expected to refine and produce a scientifically rigorous imaging protocol. The final protocol included: (1) developing a method for measuring the movement in the scanning machine of each subject via electronic sensors, and (2) developing a vibrator to provide sensory-motor simulation to the brain.

To test the feasibility of using a vibrator as a stimulus to examine motor cortex excitability in persons unable to move post-stroke, we used transcranial magnetic stimulation. This was abandoned, as using vibration would have increased the scanning time, per subject, from 90 to 120 minutes. The scanning protocol was then reworked.

To validate the fMRI BOLD signal in stroke survivors required a perfusion scanning paradigm. This was added to control for potential blood flow inadequacies in subject's brains post-stroke. Once a perfusion protocol was perfected and pre-tested, scanning started. Nine control subjects and one stroke survivor have been scanned. The data have yet to be fully analysed, but the learning experience has been phenomenal.

Organization of Thesis

This is a manuscript-based thesis, a format allowed by the Faculty of Graduate Studies at McGill University. The advantage of this method is that the expected contributions to the clinical and research community are quickly transferable; a disadvantage is that thesis becomes repetitive

The McGill University manuscript thesis requirements, a review of the literature beyond that in the manuscripts, and a final summary and conclusion- results inevitably in repetition. Additional duplication occurs in the method sections, as the analysis techniques are similar and the data for manuscripts 2 to 5 are from the same cohort of people with acute stroke.

A brief outline of the thesis follows. After a short introduction, *Chapter 1* reviews the impact of stroke and the process of stroke rehabilitation. In addition, the effectiveness of the interventions in reversing this impact is outlined. The lack of understanding on what comprises the best intervention to improve function for an individual led to an appraisal of the literature on interventions. What constituted functioning and how it was evaluated was a persistent question.

Chapter 2 provides the background information for the conceptualization and quantification of functioning. Methodologically, the International Classification of Functioning model (ICF) was used to conceptualize functioning and the Rasch measurement model was used to quantify functioning; this led to the rationale and objectives of the thesis.

Using the data from the Montreal Stroke Cohort, the first manuscript, in Chapter 3, entitled *The Development of a Prototype Measure of Functioning for Stroke Recovery: The Prototype Functional Recovery Measure,* provides the basis for the conceptualization of functioning from which to quantify recovery. This first manuscript determined that different items from a component of the ICF could be combined through a Rasch analysis to form a single measure of functioning with interval-like properties to quantify recovery. The results of the analysis, a prototype measure of functioning, although adequate to measure functioning at six months proved limited in covering the full scope of the ICF. This led to the next two manuscripts.

Chapter 4 and 5 comprise the second and third manuscripts, respectively. The second manuscript, entitled *A Measure of Functioning to Define Stroke Recovery at Three Months,* extends the measure of functioning, based on the prototype measure in the first manuscript, to include all components of the ICF. Additionally, it was felt that information from observed performance and from questionnaires in which individuals rate their own performance would improve the definition of functioning and what stroke survivors report as meaningful functioning. The second manuscript combines these two types of information to develop, through Rasch analysis, a measure of functioning at three months, the F3m.

To characterize the impact of interventions on a person and his or her brain requires adequate quantification of early functioning. This is the focus of manuscript 3, presented in Chapter 5, entitled *The Impact of Stroke on Early Functioning: The Functioning Measure at three days, the F3d,* which develops a comprehensive measure of the impact of stroke on early functioning. As in the second manuscript, the third combines information to develop, through Rasch analysis, a measure of functioning at three days, the F3d. This is one of the earliest and most comprehensive measures of early functioning.

To limit redundancy, a chapter reviewing the literature on the factors predictive of functioning has been replaced by Manuscript 4, in Chapter 6. Manuscript 4, entitled *A Profile of Functioning at Three Days and Three Months Post-Stroke and Associated Factors,* investigates the details of functioning at two time points, at three days and at three months post-stroke. It outlines the univariate relationships of numerous individual factors related to functioning, an essential element to appropriately optimize interventions to improve functioning.

Chapter 7 includes Manuscript 5, entitled *Early Predictors of Individual Functioning Three Months Post-Stroke,* which continues from Manuscript 4 to outline the multivariate relationships between significant factors and functioning at three months.

The first three manuscripts provided a frame work, and measures of functioning post-stroke. The patient characteristics influential in interpreting the effects of an intervention are then developed and linked to functioning in the last two manuscripts.

Chapter 8, the final chapter entitled "Summary and Conclusions", as per the requirements of the Faculty of Graduate Studies, McGill University, presents a review of the findings, future research and final conclusions.

Relevant tables and figures are presented at the end of each Chapter or Manuscript and the references are included at the end of Chapter 8. Additional information presented in the Appendices at the end of the thesis includes: consent forms, certificates of ethical approval, study collection forms and indices used, a detailed description of the factors, and information to clarify the analyses.

Contribution of Co-Authors

The candidate designed the study, recruited and assessed the subjects at three days and preformed or supervised the follow up assessments at three months. She developed the study questions, performed the statistical analyses, and wrote the manuscripts. The co-authors functioned as consultants providing feedback on study design, the analyses, and the final manuscripts.

The data for the prototype measure of functioning presented in the first manuscript came from a previous study that evaluated the long-term outcome of stroke. The candidate used these data to analyse and develop a prototype measure of functioning at six months. The candidate developed the concept of a prototype measure to investigate the methodology necessary to define and quantify functioning.

Dr Nancy Mayo provided expert guidance throughout for the design, and analyses of the study and for the writing of the manuscripts.

Johanne Higgins and the candidate learnt Rasch analysis together. Johanne proved to be an excellent sounding board for analytical ideas and concepts.

Dr Sharon Wood-Dauphine, PhD, provided valuable assistance in helping me understand the principles behind measurement and provided editorial comments on the manuscripts.

Dr. Robert Côté, MD, was instrumental in determining whether some of the subjects were competent enough to participate in the study. He aided the candidate in critiquing the literature to define the normal criteria for the variables in Manuscript 4. He also provided useful clinical discussions on the factors related to stroke.

Dr Jeffery Chankowsky verified the imaging data report forms for accuracy used in Manuscript 4 and assisted in defining and refining the scanning report form used to collect the imaging information.

The candidate integrated the information from the first four manuscripts to develop a predictive model of functioning with feed-back from the co-authors (Manuscript 5).

In summary, this candidate is responsible for the originality of the ideas, the scientific quality of the research, and for the writing of the manuscripts.

Statement of Originality

Throughout my career as a physical therapist, I treated patients early post-stroke to enhance their functioning. As my practice was in acute care, the challenge of measuring early functioning was an every day occurrence. To fully identify my patients' needs and abilities required many tests and indices. With increasing experience gained through lengthy assessments, I developed a strong understanding of the challenges faced in measuring outcomes, including an appreciation of what abilities constituted functioning, what functioning meant to patients, and what they actually considered as functioning. The burden of long assessments meant the patient was often too tired to participate in the activities required to regain functioning. Therapists do not always have the time to assess patients. A quicker, comprehensive way of measuring functioning was obviously needed.

My interests did not rest with measurement alone as the strongest motivation for measurement is to evaluate whether the interventions I applied as a therapist were effective, to establish whether the early initiation of therapy resulted in better functioning.

The challenge was to determine which patients would benefit most from which therapy or how to match a patient to a therapy, as all patients are different. Currently, we do not have the appropriate tools, nor do we have a single measure of functioning. My original contribution was to recognize that these challenges had to be dealt with before embarking on a trial of early stroke therapy. I subsequently designed a study to quantify functioning and to identify the factors associated with functioning.

An original component of this thesis was to combine Rasch analysis, a statistical approach producing measures with interval properties from ordinal observations, with the International Classification of Functioning (ICF), to conceptualize, define, and quantify functioning in a single measure. It was my original idea to elicit the information necessary to partially validate the content of the measure from a consensus exercise that solicited the opinions of health care professionals and in conjunction with statistical tools begin the process of quantifying functioning. The outcome was an original measure of functioning that combined, for the first time, the activity and participation components of the ICF.

Subsequently, a longitudinal prognostic study involving people with acute stroke was initiated. The original outcomes from this work are two measures of functioning that cover all the components of the ICF, one to evaluate early functioning at three days, the Functioning measure at three days, or F3d, and one to evaluate later functioning, the Functioning measure at three months, or F3m. These two measures are the first to amalgamate items from tests where performance is observed and self-report questionnaires where people rate their difficulties in performing physical activities. The F3d is one of the few measures of early functioning and the only comprehensive one.

Another original contribution was to link the F3m with the F3d and other variables related to functioning to define a predictive model of functioning at thee months: Functioning on the F3m = 32.9 + 0.59*(F3d score) - 8.05*(severity of stroke at onset) - 5.77*(admission for a first/subsequent stroke) + 0.09*(level of pre-stroke physical function) + 3.03*(presence/absence of comorbid diabetes) -3.3 * (gender) - 0.20*(age in years). The strong relationship between the F3d and the F3m suggests that the F3d can be used to stratify subjects to evaluate early interventions, to aid in the development of interventions to enhance function, and to explain the recovery of functioning.

Acknowledgements

My supervisor, Dr Nancy Mayo, has a few key sayings that every one of her students knows well by the time they are finished. The most relevant one is "it takes a village to grow a thesis". It also takes a village leader to guide the process, Nancy is that leader. For the past 8 years, Nancy Mayo has been my PhD supervisor. She encouraged me to enter graduate studies and took a chance on training a mature student. Her excellent grasp of research methods and protocol writing set the stage for my PhD. Her organized, logical approach helped me through the process. As a result, my research area has blossomed into something unique, innovative and worthwhile to which I owe many thanks to Nancy. Her enthusiasm, patience and faith in my abilities kept me going throughout. I wish to thank her for the training she has provided, in research design, statistical analysis, critical thinking and grantsmanship. Her abilities helped to obtain the funding for my research (CSN project funding) and for my personal financing (CHIR, PFC and FRSQ). These funding agencies should be acknowledged: Fonds de Recherché en Santé du Québec (FRSQ), the Canadian Stroke Network (CSN), the Physiotherapy Foundation of Canada (PFC) and the Canadian Institutes for Health Research (CHIR).

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I wish to thank Susan Scott for her statistical expertise and advice on the analytical approaches, and for her SAS programming ability. As well, I wish to thank Lynne Nadeau for her patience, understanding and invaluable assistance with the concepts behind Rasch analysis and for her SAS programming assistance in the analysis.

The support of my clinical colleagues through has make the results of this thesis meaningful

I could not have accomplished this thesis without the support of my family. I wish to thank James Finch, PhD, FRSC, my husband, for the numerous discussions on Rasch analysis and measurement, for reading every word of this thesis and for his faith in my abilities, to Jessica, my daughter, who supported me with hugs and for doing the tables, and Jacob my son, for understanding what it takes to do research.

Introduction

The impact of stroke is highly variable with deficits spanning the range of physical, sensory, cognitive, and emotional functions (1). Interventions to lessen the impact on the vulnerable brain can do the most, for good or harm, in these first few days after stroke (2) (3) (4) (5) (6). Rehabilitation is such an intervention (7) (8) (9) (10) but is time consuming and costly. Improving the process may lessen the human and financial burden. Furthering the effectiveness of rehabilitation interventions to impact on early functioning depends on what is given, to whom, and how it is measured (11) (12).

To optimize the recovery of functioning the most effective interventions have been those that require extensive practice and repetitive training of a task (13) (14) (15). Studies suggest that this repeated practice therapy, if initiated early, can lead to changes in synaptic properties and the neural circuits of the brain (16) (9) (8) (6) (17). Early rehabilitation interventions could potentially be more effective if aimed at those patients with the capacity for the recovery of function, or effective brain reorganization.

Before developing a method to guide in evaluating therapy for specific individuals, an operational definition of functioning relevant to recovery is necessary. Stroke survivors measure functioning compared to what they did in their pre-stroke life (18), hence equating functioning and recovery. Quantifying recovery requires a mathematical comparison of a stroke survivor's current and pre-stroke functional state: without a measure of functioning, recovery cannot be quantified (19) (20). A critical step in evaluating therapeutic interventions for persons with stroke is, therefore, an accurate quantification of functioning.

Measuring a person's ability to function independently is part of a standard evaluation for stroke and existing tests and indices assess various aspects of functioning post-stroke, but few capture the spectrum from basic activities to participation. Measuring function using multiple indices is methodologically difficult, but a single index quantifying functioning in stroke does not exist. For such a measure, adequate conceptualization of the concept and an indication of quantity are crucial (21) (22) (23).

The World Health Organization's International Classification of Functioning, Disability and Health (ICF) (24) characterizes functioning as having two components, 1) body functions and body structure, and 2) activities and participation. The ICF identifies the necessary components of functioning, but does not provide a measure to quantify functioning.

Rasch analysis is a statistical approach which transforms ordinal observations from items onto an interval scale and produces a unidimensional measure on which items and people are organized hierarchically, by difficulty and ability, respectively, on the same measurement scale in natural logarithm linear units or logits (25) (26). Rasch analysis has assisted in developing, summarizing, refining, and combining items from different indices into a single measure (27).

This thesis examines whether uniting a method such as Rasch analysis, with the components of functioning as characterized by the ICF, could conceptualize, define, and quantify functioning in a single measure. Information was gathered from items in tests where performance is observed and self-report questionnaires where people rate the amount of difficulty they experience in performing physical activities. These were then combined into a single measure of functioning. Once a measure of functioning is available, recovery can be quantified. Improvement of early functioning post-stroke requires the interventions to impact favourably on the factors that affect stroke recovery. Many such factors are known (28) (29) (30) (31) (32), not all are understood. This thesis examines whether strong early factors could be identified and linked to functioning at three months. These factors could then be used to characterize people according to their probability of recovery from stroke and more accurately target interventions to enhance the recovery of functioning.

Thesis Objective

The overall purpose of this thesis was to define a set of anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that will predict the extent of an individual's recovery of functioning at three months.

The specific objectives of thesis are:

1. To develop a prototype measure of functioning for an individual after a stroke. Specifically, to create a parsimonious list of items that would measure the construct functioning as conceptualized by the ICF that could be used to quantify recovery.
2. To develop a comprehensive, parsimonious measure of functioning quantified through interval scaling properties that incorporated all the concepts of functioning within the ICF framework; a measure that can be used to define recovery three months after stroke
3. To develop a comprehensive measure of the early impact of stroke on functioning three days after stroke incorporating the framework of functioning within the ICF model.
4. To identify the anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that will predict the extent of an individual's recovery of functioning at three months.

Chapter 1 The Impact of Stoke

Stroke is one of the most disabling of chronic diseases (33) (34) (35). In Canada, in 1994, there were 50,000 new strokes, with 300,000 Canadians living with the after effects of stroke (36). Persons experiencing a stroke are usually admitted to an acute care center to minimize the insult to the brain and to promote recovery through therapeutic interventions and good medical management. This acute phase is the most expensive component of care with an average cost of approximately $10,000 per person (37) (38).

1.1 The Impact of Stroke

A stroke impacts on the range of physical, sensory, cognitive, and emotional components of life (1) and combine to form a portrait of a stroke survivor. The initial five most prevalent deficits in persons post-stroke include: hemiplegia of the extremities (57-92%), dysphasia or aphasia (46-57%), memory loss or disorientation (47%), loss of sensation (26-46%), and dysphagia or tongue deviation (30-40%) (39). A difficulty arises in comparing the impact of these deficits, as the definitions of the impairments, the activities and life roles a person performs vary widely across studies. Nevertheless, among stroke survivors, 87% report restrictions in activities of daily living, 42% mobility problems, 21% cognitive problems and 69% of post-stroke seniors report their health status as poor (36).

The natural history of stroke has its major impact over a period of 3 to 6 months. Progress is rapid over the first 5 weeks, slows down by 13 weeks (39) (40) (41) but may continue for up to a year post-stroke (42) (43). By six months, 66% of survivors are living at home, the remainder, approximately 15%, has residual problems caring for themselves (44).

To describe the impact of stroke on functioning necessitates an organizational structure on which to classify the various components. The World Health Organization (WHO) (24) provides a universal framework and common language for conceptualizing functioning, the International Classification of Functioning, Disability and Health (ICF). This framework describes functioning and its antithesis, disability. Functioning includes two components: 1) body functions and structures, and 2) activities and participation. Disability refers to impairments of body structures and functions, limitations of activities and restrictions to participation. Body functions are the physiological expressions of body systems, body structures are anatomical parts of the body, organs and limbs, while impairments are deviations in either. Activities are tasks or actions an individual performs; involvement in life situations is considered participation. Functioning is further qualified by distinguishing between capacity, what a person does in a standard environment or test situation, and performance, what a person does in their usual environment in the community or at home.

The ICF classification system assesses functioning at different levels of importance to an individual within the context of the environment.[1] Environmental factors are external to the individual and impact positively, as facilitators, or negatively, as barriers to functioning. As yet to be defined by the ICF, personal factors make up the background of a person's life that is not part of a health condition. Figure 1 depicts the ICF model as a consequence of stroke.

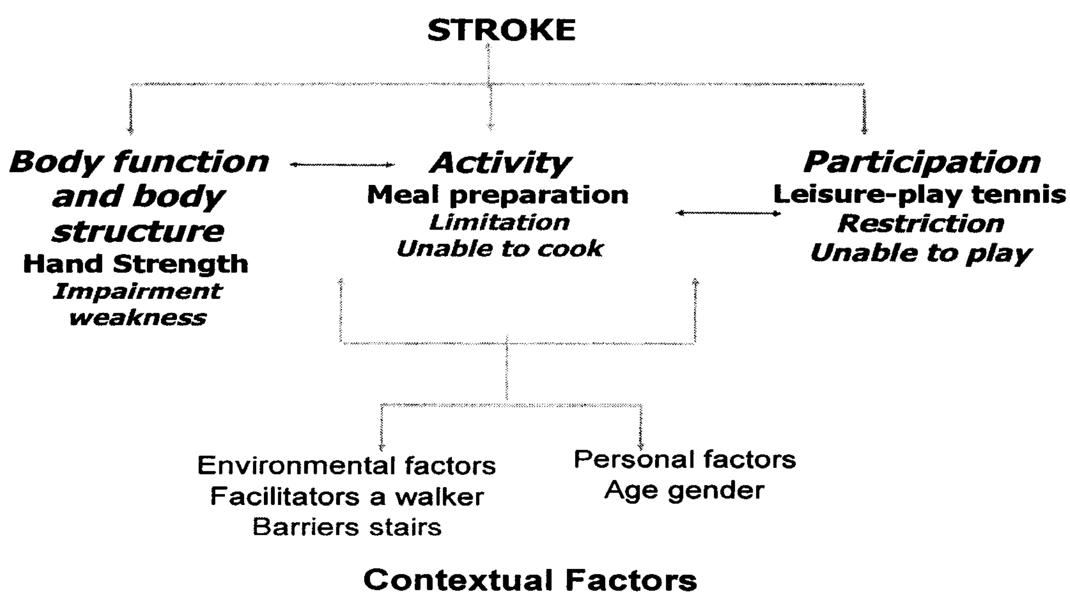

Figure 1 The International Classification of Functioning, Disability and Health Concept as applied to stroke.

The items in black indicate the positive aspects of functioning, while the items in gray represent disability. The arrows are bidirectional, as the ICF components impact on each

[1] This framework was formerly the ICIDH consequences of disease, impairments disabilities and handicaps. As the terms were considered too negative the terminology was reworked to consider the components of health, body structure, function, activity and participation (24).

other. For example, a person with impaired hand strength may use the hand less, increasing the weakness, which could lead to difficulties in using a walking aid that could limit activity and result in restricted community reintegration and lead to more hand weakness.

1.2 The Impact of Stroke at the Impairment Level

One of the greatest impairments is hemiplegia, a loss of motor functioning on one side of the body. The concept of motor functioning varies and can include: weakness of the limbs or trunk, poor limb control, postural instability, abnormal tone and pain. One of the earlier descriptions of motor functioning post-stroke is attributed to Twitchell (45) based on personal observation of 19 patients with hemiplegia. The process of return of movement he described followed a sequential pattern of initial flaccidity, followed by a return of reflexive movement and finally by gradual resumption of the control of normal movements. The degree and timing of return varied, but not the pattern (45) (46) (47). These descriptive patterns led to the development of numerous ordinal indices used today to evaluate motor functioning and include, for example: the Fugl-Meyer (46), the Rivermead Motor Assessment (48), the Motor Assessment Scale (49), the Chedoke-McMaster Stroke Assessment Impairment Inventory (CMSA) (50) (51) (52), and the Stroke Rehabilitation Assessment of Movement (STREAM) (53) (54).

Bonita and Beagle (55) were among the first to estimate the level of motor deficit or weakness of the limbs post-stroke in a large cohort of 680 subjects. From the onset of stroke to 6-months post, the proportion of subjects demonstrating a weakness decreased from 88% to 71% to 62% depending on the severity of the initial weakness. Strength returned within the first month, but improved throughout the next 6 months, at which time 75% of the survivors had no deficit. The extent of the final deficit was related to the initial severity, and subjects without a significant initial paralysis were 10 times more likely to improve than those with a significant weakness. No differences in the deficits between the arm and leg were noted.

A comprehensive community study of stroke, the Copenhagen study (56) (57), provided information on the extent and time course of motor impairments. A cohort of 1,197 subjects with stroke were measured weekly from admission to hospital, to discharge, or death, and at 6 months with the Barthel Index (BI) of activities of daily living and the Scandinavian Stroke Scale, an index of neurological functioning (SSS). The motor section of the SSS assessed limb weakness on admission: 19% of the sample had very severe weakness, 26% moderate, and 41% mild weakness; at discharge, only 4% had very severe weakness, 11% a moderate and 78% a mild or no weakness. No significant changes in the SSS scores occurred in the 72% of the sample that survived to six months.

Duncan et al. (40) examined the return of arm movement in 95 subjects stratified by stroke severity on the Fugl Meyer (FM, scored from 0-100). The results of serial evaluations of limb movement using the FM, from onset of stroke to 6-months post, are summarized in Table 1.1. The rate and extent of recovery were related to severity. Generalizability of the results is limited by the inclusion criteria that restricted the sample to those with an anterior circulatory infarct, older than 40, and without major comorbidity and also by the ceiling effect of the FM.

Beyond weakness and gross movement of the arm measured by the Fugl Meyer, the return of finer, more coordinated movements of the upper extremity categorized by the block and box test of hand dexterity is illustrated in a cohort study by Mayo et al. (1) (58). At 8-days post-stroke, the return of hand dexterity was 34% of age matched norms, but continued to improve to 51% by 5 weeks post-stroke: the results are only relevant for patients in the middle band of severity. The recovery of dexterity for subjects considered severely affected with flaccid arms (11) differed from the less severe. Some dexterity had returned by 6 months in 38% of subjects and only 11% had completely recovered on the Action Research Arm Test.

Arm functioning was studied in 421 subjects admitted to hospital within 13 hours of stroke onset using two items in the BI 'grooming' and 'feeding'(59). Those with the severest stroke had the poorest arm function and level of improvement over the study period, but full or stable functioning of the arm was seen in 89% of sample at 1-month. Of the 115 survivors at time of discharge, 64% had a useless arm, 25% had improved function and 18% had full functional recovery of the upper extremity (60) (61). The 31% (26/84) of subjects with the severest stroke, who had a good functional outcome (BI ≥50), tended to be younger, recover neurological functioning earlier and have family support, compared to the 69% with a poor outcome (BI <50).

Return of arm function occurred over three months (60) (62) and was related to the severity of the initial paralysis. The best possible functioning (highest BI score that remained stable) was reached by 80% of the sample within the first three weeks, but only 1/5 of the severest cases regained full function. The SSS and BI item used to determine arm function lacked sensitivity (63) and demonstrated a ceiling effect, especially in the subjects with a mild or moderate stroke.

Hendricks et al. (14) in their review of studies on motor recovery after stroke concluded that 65% of hospitalized patients had some degree of lower extremity motor return, but the data were insufficient to estimate a global figure for return in the upper extremity. The most important predictor of motor return was the initial severity of stroke. Depending on the index used to assess motor functioning, the probability of improving ranged from an odds ratio (OR) of 4.58 to 24 by level of severity and time of assessment. Earlier assessments, within five days, produced the least accurate predictions.

1.3 The Impact of Stroke at the Level of Activity Limitation

The first days post-stroke are dominated by the concerns of regaining walking and the basic self-care activities of toileting, bathing, getting dressed and climbing stairs (1).

Return of walking ability over the first 3 months post-stroke is best summarized by the Copenhagen study (64) results in Table 1.2. Using the BI item, 'walking 50 feet independently', to define walking 63% of the population had difficulty walking, 51% were unable to walk and 37% walked independently. The ability to walk was related to the initial walking ability and leg weakness. A larger proportion of those with mild paresis (66%) regained independent walking, compared to the 15% unable to walk and the 6% with significant leg paralysis. The best walking level, on the BI walking item, was reached in 95% of the population by 11 weeks. The prognosis for the return of walking ability could be determined by 3 weeks, but it took 6 weeks in the severest of cases. Some form of walking function returned for most individuals, either through the actual return of walking ability or by adapting for the lack of ability through compensation with a leg brace and/or cane. The main predictors of walking were: stroke severity, poorer initial walking ability, poor sitting balance and incontinence (28). The most influential factor affecting both the extent and rate of return was stroke severity (64) (65) (34).

The crude BI walking item may not be as indicative of functioning as walking speed. In a cohort (N=50) of mild to moderate stroke survivors, walking speed (over 5 meters), measured sequentially from 8 days of stroke onset, at 4-weeks and three months, improved from 0.55 meters per second (m/s) to 0.85 m/s. Although the speed increased by 67%, it was only 66% of the age expected norm. Walking speed is associated with other functions, for example a walking speed greater than 0.85 m/s is required to cross a street and walking at a slower speed may limit a person's ability to reintegrate into the community (66) (67).

Activities of daily living (ADL), the most assessed area of activity limitation due to stroke, is frequently measured by the BI or the Functional Independence Measure (FIM) (68) (69). These two measures are similar, despite differences in the number of items (FIM has 29; BI has 10) and response options (FIM has 7; BI has 3-4), (70) (71) (72). Both assess independence by assigning ordinal values for the amount of assistance required.

The return of ADL functioning followed a pattern similar to that seen with the impairments of motor ability; the majority of return occurred in the first month, and depended on the initial severity of both the impairments and the ADL limitations. The percentage of subjects with ADL limitations within a week of stroke onset varied between 40% and 70% across studies (64) (1) (73) (41) (74) (75).

The most difficult tasks were climbing stairs, transfers, toileting, bathing and walking, and those least affected were continence and grooming (75) (41) (76). At three months, 5% of subjects in a study by Duncan et al. (75) were dependent, while 26% had no ADL limitations. In the McGill cohort stroke study (1) (34), at a year post-stroke, only 60% of individuals were fully independent on the BI, 18% had difficulties climbing stairs, and 24% had difficulties bathing. Similar results on ADL limitations from the Copenhagen study are summarized in Table 1.3 (1).

Although rates of motor and ADL return parallel each other, the return of ADL functioning was usually greater than motor recovery (77) (41) (78), and lagged two weeks behind neurological functioning (76).

The models developed for predicting the re-establishment of ADL functioning (79) (80) (28) (77) suffer from methodological problems: small sample sizes, inadequate statistical analysis, and lack of model validation. Recent reviews (74) (81) of predictive studies suggest that despite the methodological differences the variables that independently and significantly predict ADL include: admission disability, degree of paresis, older age, loss of consciousness within 48 hours, disorientation, poor sitting balance, with weaker evidence for social support as a variable. These were the same variables that predict walking and arm functioning.

Independence in basic ADL is possible, despite persistent neurological deficits, through behavioural adaptation by compensating for the lack of ability with the unaffected side. Nevertheless, subjects may remain dependent for higher level activities, such as instrumental activity of daily living (IADL), including home management and leisure activities (82).

The lack of IADL ability was illustrated in the McGill Cohort Stroke study (1) where only 50% of subjects attained IADL independence, while 42% found housework difficult, 33% found shopping difficult, 27% found meal preparation difficult, and 25% of the subjects had difficulty using transportation. The limitations in IADL performance were further confirmed in a cohort of 287 stroke subjects, 90 days post-stroke (83) who had a score of 66/100 on the ADL/IADL component of the Stroke Impact Scale (SIS). The SIS has a stroke specific ADL/IADL domain that includes items related to basic self-care, mobility, housework and shopping.

1.4 The Impact of Stroke at the Level of Participation Restrictions

Participation includes a person's ability to work and fulfill his/her roles in society. Gauging the impact of stroke on participation depends on the indices used, the definition of participation and the timing of the assessment. Participation should be assessed later in the recovery process, at least 3 months post-stroke, when a subject has had the opportunity to engage in life's roles.

One participation index, the Reintegration to Normal Living index (RNL), covers social reintegration with items on: social, leisure and mobility activities, and interpersonal relationships (84). When participation was measured by the RNL, in the McGill Stroke Cohort, the most problematic areas encountered were travelling: engaging in social activities and recreational activities, and establishing an important activity to fill the day. The proportion of subjects demonstrating difficulty ranged from 21-36% (34). Employment and educational opportunities, concepts not covered in the RNL, were found to be the most difficult areas in a study of 102 subjects with stroke (85).

When the relationships between impairments, activity limitations, and participation restrictions were examined in the above mentioned 102 subjects, impairments and activity limitations were equally related to participation restrictions (r: 0.43). However, the leg impairments were more strongly related to the restrictions than the arm impairments. The reason hypothesized for the difference was the limitation of the London Handicap Scale (LHS) used to evaluate participation which is heavily biased towards mobility items (85). In contrast to these results, participation, assessed by the LHS, was only partly related to activity limitations and impairments in a study of post-stroke handicap in a large cohort study (86). The disparity seen in the two studies is more than likely due to methodology: participation and impairment were measured at different times and the sample inclusion criteria differed.

The RNL and the LHS are generic measures of participation. The stroke specific measure, the SIS, has a participation domain with 10 items (87) related to: social, leisure, religious, and interpersonal relationships. The participation restrictions measured by the SIS were evident in 81 stroke survivors whose scores were 13 points lower out of 100, adjusted for age, diabetes and gender, compared to a stroke free group (88) at three months. These independent (BI >95) post-stroke subjects were restricted in their work and leisure activities. These results were supported by others (86) (89).

A critical review of the factors predictive of participation highlighted the diversity present in this component of the ICF (90). Participation restrictions have been associated with decreased physical abilities (86) (90), depression, and poor cognition (89). Determining the strength of the relationship between social support and participation is limited by the definition of support (91). Physical and cognitive disabilities explained 50% of participation on the RNL, one year post-stroke, in a cohort of 135 stroke survivors, but the relationship was thought to be due to environmental barriers more than physical disability (86) (89).

1.5 Measuring the Impact

The impact of stroke on the various components of the ICF has been reported here as average values that do not necessarily indicate the impact of stroke on an individual. Summary scores across ordinal categories increase the ambiguity in understanding the exact nature of an individual's lack of functioning or disability (92) (93). For example, the average total BI or FIM score, indicative of activity limitations, can be obtained from various combinations of responses to the items in each index, but, without an item by item analysis, it is challenging to determine which tasks are problematic. We are able to estimate that a group of subjects is limited, but we are unable to discern which individual is limited on which task. The majority of instruments used in rehabilitation are ordinal and can merely rank the subjects. The information gained from this ranking has little relevance to how people function and can provide little input into how they should be rehabilitated (94) (93). Additionally, the floor and ceiling effects and lack of sensitivity to change in the ordinal indices hamper the understanding of the full impact of stroke on functioning (95) (96) (70), especially at higher levels of ability. An interval measure that comprehensively quantifies functioning might provide a better understanding of the rate and extent of the patterns of functioning post-stroke and lead to a better estimation of recovery (92).

1.6 Reducing the Early Impact of Stroke

The brain is influenced the most, for good or for harm, in the first days after stroke (3) (4) (5) (6). To date, the intervention with the greatest early benefit for a person with an infarct is thrombolysis with tissue plasminogen activator (97). Thrombolysis focuses on decreasing the immediate effects of the stroke infarct by promoting vascular reperfusion of brain tissue (98). This intervention must be affected within the first 3-6 hours post ischemia and is not widely applicable (99).

The other early intervention of import is the organization of the care provided for patients within an acute stroke unit (SU) (100) (99). The organization of post acute stroke rehabilitation has been shown to matter (101). Randomized controlled trials evaluating inpatient SU services with multidisciplinary rehabilitation care have been compared to conventional care or multidisciplinary care that was less structured. The patients were recruited within seven days to two weeks post-stroke. The results demonstrated that organized, inpatient, multidisciplinary rehabilitation was consistently associated with reduced probability of death (odds ratio 0.66), death or institutionalization (OR 0.70) and death or dependency (OR 0.85) (101). The beneficial effects of a SU were not confined to a select group of stroke patients, but the most severely affected benefited the most (100) (102). Follow up evidence on SU care indicates these positive results were maintained for five to 10 years after stroke (103) (104).

Although the studies mixed the timing, intensity, type and expertise of care, there is good evidence for the effectiveness of stroke units. The SU features leading to the improvement were stated to be: early initiation of rehabilitation, the organization of the provision of care and better control of physiological parameters (hydration, control of glucose, temperature and blood pressure) (102) (105) (106) (107).

1.7 The Stroke Rehabilitation Process

The rehabilitation process has been founded on several theoretical principles, based on a number of assumptions that have been used to select and justify the use of a therapeutic approach. Therapeutic reviews (108) (109) have described the approaches used to treat persons with stroke. The *traditional approach* emphasizes the normalization of function through compensation with the unaffected limbs rather than the improvement of the affected side. The neurofacilitation based approach, which encompasses well known methods such as N*euroDevelopmental Therapy* (NDT), the *Brunnstrum approach*, and *Proprioceptive Neuromuscular Facilitation approach* (PNF) (110) (111) (112) (113) (114) emphasizes the normalization of motor performance through techniques that inhibit abnormal motor patterns and facilitate isolated movement sequences without compensation. The *Motor Control* and the *Motor Learning* approaches (115) (116) are based on central nervous system models of control of movement, as modified by the musculoskeletal system, and the principles of learning. Motor performance is enhanced through the practice of specific components of functional tasks. Therapy would comprise practice sessions of tasks that are specific to the acquisition of those skills (117) (118) (119) (116).

The best approach to facilitate recovery for an individual has not been found. Despite a number of comparative studies, no one approach has been shown to be superior to another. Rehabilitation may be effective, but when therapy should start, the type of therapy to give for how long, and for whom is still unresolved (120) (121) (122) (123) (124) (77) (125) (126) (15) (127) (128) (129).

1.8 Efficacy of Rehabilitation Interventions

The global aim of rehabilitation is to enhance the return of functioning through an approach to recovery that is directed at the person as a whole. The underlying premise is that the return of motor ability in the hemiplegic limbs, over and above that occurring through natural healing, will only happen if the therapy actually has an effect on the individual and his or her brain. If patients recover from stroke, despite a persistent lesion, it will be because other intact areas of the brain have potential and are utilized to regain those lost functions. Compensation for a permanent loss by behavioural adaptation with the unaffected parts is not considered true recovery (130).

Over the past five decades, rehabilitation approaches to therapy that normalization motor ability and functioning have been applied to all stroke patients with a minimal regard to the capacity of the individual to benefit from such therapy (131) (132). Although evidence on effectiveness of therapeutic interventions is building, there are no universally tested clinical practice guidelines for stroke rehabilitation (133) (134) (135) (136) (137). The type of therapy offered aimed at functioning depends on the therapist and the work setting (138) (139). As a result, many individuals with the capacity for recovery have received therapy that focused on the return of functioning through developing compensatory strategies, while others with limited capacity for recovery have received therapy targeted at control of limb movement. The mismatch of therapy to the individual's capacity for functioning has resulted in frustration on the part of the individual, and the therapists, and may contribute to the inconclusive research findings on the efficacy of rehabilitation post-stroke (131) (132).

The effects of rehabilitation interventions, summarized in meta-analyses (129) are positive, as the research methodology and interventions have advanced so has the strength of the evidence. Effect sizes now range from 0.13 to 0.92 standard deviation units (140) (135) (15) (141) (125) (126) (129) (142) with the methodical quality explaining some of the variability: the more rigorous the methodology, the smaller the effect.[2] That therapy improves functioning is clear, but it is unclear whether everyone benefits equally from each intervention.

Table 1.4 summarizes the effects of the reviews of interventional studies to 2004. The quality of the reviews varies. Each literature review provided an overview of the available evidence by analyzing and synthesizing information from available studies, occasionally with a specific view point in mind. Statistical techniques, including meta-analysis, were only used by a few reviewers to combine the results from multiple studies into a single estimate to test for significant intervention effects. The reviews included 676 studies, 200 of which were included in other reviews. Only the 12% of studies that had therapeutic interventions starting within 7 days of stroke onset are described in Table 1.4. When the results from early interventions are summarized the effects are small; they remain positive. The evidence of the impact of early interventions can be diluted by subjects selection criteria, the types of care delivered, and the varied types and intensities of therapy compared (126) (144) (145) (129) (146) (147) (142) (15) (80) (125) (141). In some studies, covariates have not been adequately controlled (148) (149), and functioning has been inadequately quantified (13) (12) (129).

1.9 Successfully Selecting Individuals for Therapeutic Interventions

Although few criteria exist on which to base the selection of patients for a specific rehabilitation intervention (150), when the study sample is chosen *a priori* to benefit from a specific therapy (151) (152) (153), the results are better. As an illustration, Lincoln et al. (150) studied 282 patients post-acute stroke and found no benefit of adding an extra 20 minutes a day of therapy over a five-week period. A post-hoc analysis revealed a benefit, but only in the least severely affected group (154), the only group that could actually complete the therapeutic program. The group analysis concealed the benefits and possible

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* Effect sizes are calculated as the ratio of change to variability. By convention, effect sizes > 0.8 are considered large, those around 0.5 are considered moderate and those less than 0.2 small (143).

harms of the intervention for specific subgroups. The authors concluded that the research question would have been better addressed if the therapy could be matched to individuals in advance. They emphasized the advantage of being able to create homogeneous strata *a priori*. More recent studies have suffered from a similar lack of selection criteria and their interventions have not proven to be as beneficial as expected (155) (156).

An illustration of a study with an *a priori* selection of patients is that of Kwakkel et al. (151). A sample of 101 acute stroke survivors, chosen *a priori* to be the most likely to tolerate and benefit from additional intensity of therapy, demonstrated an effect size of 0.6 from an extra 50 minutes a day of therapy over a 20 week-period. They based the selection of subjects according to stroke type, lesion characteristics, severity of impairments and disability. The selection of a more homogeneous group resulted in the larger effect size compared to that of Lincoln et al. (150). Only 3% of all stroke patients screened for the study fitted the inclusion criteria. The study took three years to accrue the sample of 101 subjects and brought into question the generalizability of the results. Taking the view that therapy should fit the individual's capacity to recover, the issue of generalizability is moot. There is no "one size fits all" and tailoring therapy to the person would likely yield greater benefits for the population as a whole.

The differences in the target populations between the two trials (150) (151) undoubtedly contributed to the variation in effect. Other important elements also varied in these two studies. Lincoln et al. (150) evaluated the impact of intensity and quality of the neurodevelopmental approach, whereas Kwakkel et al. (151) evaluated the impact of adding repetitive task oriented therapy to standard care. The amount of therapy given may be a factor in the extent of improvement (20 extra minutes a day over 5 weeks versus 50 extra minutes a day over 20 weeks). The effective ingredients used by Kwakkel et al. (151) appear to be specificity of training, repetitive intensive practice and patient selection.

1.10 Effective Components of Rehabilitation Interventions

Reviews of the effectiveness of rehabilitation treatments summarized in Table 1.4 suggest that more substantial benefits of rehabilitation have been seen in the mild and moderately affected patients with the most effective interventions being those that emphasize extensive practice and repetitive training of a task offered early (107) (157) (158) (13) (126) (15) (141) (129) (159). The effects of the early timing of therapy are inseparable from those of the setting of care, intensity of therapy and the interventions themselves. The reviews in Table 1.4 demonstrate a small to moderate, but positive effect for therapy that starts early post-stroke, especially if combined with intensive practice. Yet, as in the study by Lincoln et al. (150) and other subsequent studies of early intense therapy, a proportion of the patients were unable to complete the required amount of therapy (155) (156).The specific components of the interventions that make up rehabilitation programs and how they are administered to patients are only recently being studied (160) (149). The components of therapy if selected to match an individual's specific needs could improve an individual's outcome. A method of selecting those patients capable of early intense therapy and a different method of administering this therapy to increase compliance is needed for success (131) (132).

1.11 Impact of Rehabilitation Interventions at the Level of the Brain

Therapy with extensive practice has been shown to produce observable changes in parameters of brain structure and function in individuals with chronic stroke. Liepert et al. (161) studied 13 individuals with chronic stroke using Transcranial Magnetic Stimulation. They examined the size of the cortical motor area maps representing the affected hand muscles following a 12-day period of intensive (6 hours per day) task-practice training and found the training not only improved the quality of movement but also increased the cortical motor map area of the affected hand muscles. The results suggested that the mechanism for the clinical improvement might be a result of recruitment of brain areas adjacent to the original injured area. Evidence from animal studies and imaging studies support this (162) (163) (164).

Data from functional magnetic resonance imaging (fMRI) in subjects post-stroke support the necessity of an early start to rehabilitation (17). Longitudinal fMRI studies of eight subjects performing motor tasks at 10-14 days and 20 subjects three months post-stroke demonstrated a negative relationship between functional performance and brain activation in motor networks. Functional performance was based on a composite score derived by combining 9 indices of ability using principal component analysis (PCA). The sample size and the ordinal nature of the indices used precluded the development of a summary score via a PCA (165). Nevertheless, this composite score was felt to be a better indicator of functioning as it was easier to relate to brain activation than nine separate index scores. Figure 2 illustrates the relationship for the 20 subjects scanned at three months. The X-axis represents the subjects ordered from high ability on the left to low ability on the right and the Y-axis represents the number of brains areas activated. The relationship at 10 days post-stroke was similar. Although the amount of brain activated at the two time points was similar, the areas differed anatomically by time and disability. The subjects with a poorer motor outcome recruited more secondary motor brain areas in the earlier stages compared to those with better outcome (17). The results led the researchers to suggest that therapeutic approaches should differ over time and be individualized to target the specific brain areas related to the person's capacity (166).

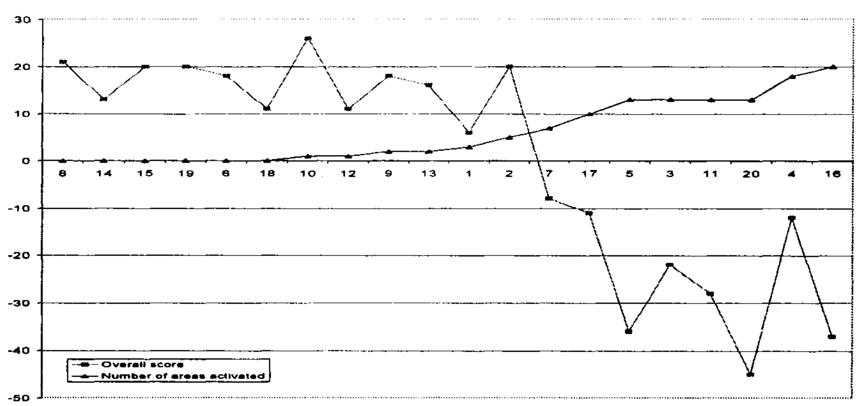

Figure 2 The number of activated brain areas related to a composite functioning score (0-100) in 20 subjects three months post-stroke (5).

These promising results, combined with evidence from animal experiments illustrated below, suggest that repeated practice therapy, especially if initiated early after lesion onset, can lead to changes in synaptic properties and the neural circuits of the motor cortex (8) (9) (16) (4) (6) (167) (17).

1.12 Animal Models of Early Rehabilitation Interventions

A debate exists as to what type of rehabilitation therapy to offer and the optimum time at which to offer it to an individual post acute stroke (15) (141) (129). Studies suggest that the majority of the benefits of rehabilitation are from repeated practice therapy that, if initiated immediately post-brain insult, leads to changes in the motor cortex of the brain.

Recovery through repetitive practice is time consuming and costly, especially when there might be a permanent loss of ability, in which case learning compensatory activities would likely lead to better functional outcomes. Although a therapeutic strategy of compensation may be more effective and preferred in some instances, this approach can interfere with recovery of the affected limb (168) (169) and, therefore, should only be offered selectively. Additionally, if repetitive practice is initiated too early or too intensely after a stroke it could prove harmful (3) (170), while, limiting the amount of therapy can negatively affect surviving brain tissue decreasing the available tissue for recovery (169); hence a dilemma.

Neuronal plastic changes could be fostered by earlier and more intense use of paralyzed limbs. But surviving brain tissue may be vulnerable to these excessive behavioural demands. An optimal interplay between neural and behavioural demands may exist that would enhance recovery (2) (170) (4).

A set of animal experiments illustrates this concept. Rats given cortical lesions had their unaffected forepaw placed in a cast for 15 days to force them to use their affected limbs. The goal of casting was to enhance the increase of dendritic growth of neurons in these animal's brains. Although the animals were forced to use their limbs, no specific training was provided. When the rat group with a cast was compared to a control group of rats with a lesion but no cast, the volume of the initial lesion had expanded by $51mm^3$ in the casted group only. No other group showed an increase in lesion size. Additionally, the motor recovery in the rats wearing a cast took longer and was considerably poorer. This was the exact opposite of the expected results. In combination with other experiments, this research group was able to demonstrate that it is the first week when the brain is most vulnerable to excessive use (2) (3) (170).

A more recent set of randomized controlled rat experiments (6) set out to determine the most sensitive time to enhance dendritic growth of neurons in the rat brain through rehabilitation. Rats were pre-trained on a reaching task, and then enhanced therapy was started, 6 hours a day, for five weeks at three time points, post-focal-cortical infarct: 5 days, 14 days, and 30 days, Therapy was task oriented and spread out over the day, with rest periods that encouraged, but did not force the use of the affected limb. The changes in brain neuromorphology and functional abilities after training were compared to a control group of rats kept in an enriched environment. The lesion size did not increase as in other intensive animal rehabilitation studies (3) and all the rats improved to some degree. The rats that started therapy at five days post-infarct had the best performance on all tests, and retained the improvement compared to the other groups. It appears that a delay in the start of rehabilitation may limit the efficacy and maintenance of a therapeutic intervention. The type of therapy in both studies was similar; how it was delivered differed. There appears to be in animals, and possibly in humans, a sensitive period early after injury when neural growth in the remaining intact brain is optimal and can be impacted on.

Early rehabilitation interventions effecting neural plastic reorganization of the brain could be more effective and safer if targeted to those patients with the capacity for effective brain reorganization. This requires establishing very specific criteria for selecting individuals for the different therapeutic approaches. If patients can be classified into homogeneous subgroups reflective of their capacity for brain recovery, we could provide each individual with the optimal therapy at the appropriate time.

1.13 Existing Selection Criteria

Previous attempts at classifying stroke patients *early* in the recovery period to benefit from specific interventions have used neurological and imaging characteristics (171) (172) (97). These studies were geared to medical interventions, usually a thrombolytic agent like tPA, not rehabilitation (97) (10), and focused on one or two potential factors at a time and a single outcome. Imaging and neurological criteria are appropriate for the selection of patients for biological interventions as the action of these therapies is at the physiological level. The criteria for the matching of patients to rehabilitation interventions would need to differ as the focus in rehabilitation is on improving functioning across a wide range of activities. These more complex outcomes have not been shown to be predictable by neurological status and imaging parameters alone (173) (174) (175) (176) (31). Therefore, basing an early rehabilitation therapeutic choice on this limited set of factors might lead to sub-optimal outcomes.

The Chedoke-McMaster Stroke Assessment, a method of classifying patients and a guide in the selection of rehabilitation treatments based on a classification is available for patients admitted to rehabilitation centers, This reliable and valid tool (50;177) consists of two parts, an Impairment Inventory and a Disability Inventory. The Disability Inventory measures change in gross motor function and mobility. The Impairment Inventory classifies patients into homogenous groups based on the stage of motor recovery of different limb segments (leg, foot, arm, hand) and postural control. It is based on the patterns of motor recovery in 19 patients observed by Twitchell (45) that were refined and quantified into stages by Brunnstrum (47). The Chedoke-McMaster Stroke Assessment Impairment Inventory (CMSA) has seven stages of motor recovery [3]. The predictive models based on the CMSA Impairment Inventory (51) (50) predict motor recovery based on initial motor ability at admission to rehabilitation with varying accuracy (arm stage recovery model: R^2: 0.81; leg stage recovery model: R^2: 0.69). The models have not been tested in the early stages post-stroke. In clinical terms, the Chedoke-McMaster Stroke Assessment Impairment Inventory criteria seems limited, as the link between the stage of motor recovery and the capacity for functioning at that stage is lacking. Additionally, the accuracy of the models may be adequate for the prediction of the stage of recovery on average, but not on an individual basis and not early. Furthermore, therapists have expressed the need to aim their choice of treatment on a meaningful functional prognosis rather than solely on a grading of motor recovery (179). Criteria for early accurate decision-making linked to functioning across rehabilitation outcomes are needed.

A classification system to delineate the potential for recovery using clinically based information gathered early, within three days, from the observation of performance on tasks and self-report indices of functioning may be possible in stroke survivors. If the potential level of functioning capacity post-stroke of an individual could be linked to potential brain capacity, the ability to select individuals for specific early, safe therapeutic interventions would improve.

Before a link between functioning and reorganization can be determined to guide in selecting patients for a specific therapy, functioning as a concept must be outlined with an

[3] The 7 Stages of motor recovery are: 1) flaccid paralysis, no active movement possible, 2) no voluntary movement present only reflexive stimulation of limb synergies in stereotypic flexion or extension movements possible, 3) only synergistic movements are possible and spasticity is marked, 4) movement from one synergy to another is possible, 5) synergistic movements less influential, 6) movement is near normal but lacks speed, 7) normal movements returns (178).

operational definition and a method of quantifying functioning for recovery must be delineated.

1 **Table 1.1 The Time to Full Recovery and Distribution of Upper Extremity Movement in Subjects Stratified by Severity on the Fugl Meyer(40).**

	Upper extremity severity based on initial Fugl Meyer scores (0-100)			
(N=95)	Very severe (0-35)	Severe (36-55)	Moderate (56-79)	Mild (>80)
Number of subjects at day 180 (estimated from scatter plots)	33	12	18	17
Return at onset (%)	10	42	70	95
Return at 6 months (%)	42	83	90	95
Time to maximal return (days)	180	90	90	30

2 **Table 1.2 The Time to Full Recovery and Distribution of Walking in Subjects Stratified by Severity on the Scandinavian Stroke Severity Scale ***

	Initial Stroke Severity on the Scandinavian Stroke Scale				
	Mild (41%)	Moderate (26%)	Severe (14%)	Very severe (1%)	All (N=1197)
Restoration of walking (%)	89	61	55	24	Not stated
Time taken by 80% of the sample to reach maximal score (weeks)	3	3	5	1	5
Time taken by 95% of the sample to reach maximal score (weeks)	9	9	11	11	11

* Adapted from Mayo (34)

3 Table1.3 The Time to Full Recovery and Distribution of Overall Restoration of ADL Functioning in Subjects Across Stroke Severity

	Initial Stroke Severity on the SSS*				
	Mild	Moderate	Severe	Very severe	All
Full Restoration of function (BI 100/100) (%)	68	36	26	4	46
Time taken for 80% of the population to reach maximal score (weeks)	3	7	11.5	11.5	6
Time taken for 95% of the population to reach maximal score (weeks)	8.5	13	17	20	12.5

*SSS, (Scandinavian Stroke Scale); ADL, (Activity of daily living);

(adapted from Mayo) (34)

4 Table 1.4 Summaries of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Dombovy et al. (147)					
Summary of methods: descriptive review of more than 40 papers. **Inclusion criteria:** not stated presumed to be all rehabilitation papers to 1986. **Purpose:** answer two questions 1 does intensive therapy reduce disability 2 is rehabilitation cost effective **Comments:** difficult to differentiate spontaneous recovery from early rehabilitation effects, no tool adequate to select patients for rehab	**Functioning**: functional independence **Indices**: standardized ADL indices: BI, KATZ, KENNY, PECS, PULSES, MRS and study specific ones	Not stated	Not stated but early papers select patients 7-10 days confounded by stroke unit care	Spontaneous recovery accounts for early rehab effects but there is some evidence to state earlier is better	**Strengths:** authors critical appraisal of papers, excellent comments on methodology, papers categorized and reviewed by benefits **Weakness**: descriptive only

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Jongbloed (77)					
Summary of methods: selective review of 33 papers from 1950 to 1986. **Inclusion criteria:** those with a systematic measure of function within 3 months of stroke **Purpose:** critical review of prediction of function at 3 months to describe recovery, define factors and determine the value of single factors **Comments:** poor measurement and timing of assessment make interpretation of results and conclusions for papers difficult	**Functioning:** ability to perform ADL **Indices:** ADL measured by various indices from individual tasks to standardized indices most of unknown reliability and validity	Only goals of studies stated: to determine predictors of improved functioning post-stroke	10 of the 33 studies assessed subjects within 48 hours to 7 days. 6/10 were at 7 days of onset of stroke	The effect of the relationship between the start of rehabilitation (delay to rehabilitation admission) from acute care is ambiguous	**Strengths:** all studies listed with characteristics and strength of association if present. Through critiques of papers **Weakness:** studies varied greatly in purpose, outcome, timing of assessments, sample size, and statistics used, could have grouped them by characteristics or strength of evidence.

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review **Author, Methods**	**Functioning Definition**	**Intervent-ions**	**Definition of Early**	**Results**	**Strengths/Weakness**
Ernst (180)					
Summary of methods: descriptive review of rehabilitation in stroke units and studies comparing rehabilitation approaches **Inclusion criteria:** 4 SU papers and 10 therapy comparison papers no details on methods or criteria for choice **Purpose:** answer two questions: (1) is stroke rehabilitation effective, (2) which is the optimal approach **Comments:** the only early ones reviewed are SU papers and these are in other reviews below	**Functioning:** Independence, ADL survival motor performance Indices not stated	Stroke unit care vs medical or intensive or traditional care other wise not stated. Comparison therapy papers: EMG, Bobath, PNF, traditional	In SU 3 to 7 days	SU rehab care was better than any comparison group, but effects were not always maintained at FU	**Strengths**: lists strengths and weaknesses of studies **Weakness:** descriptive only no summary effect size of intervention on outcome. Number of poor quality studies thus unable to define effects

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Wagenaar and Meijer (107;157)					
Summary of methods: Electronic search and manual search methods listed. Selected 165 studies dated 1959 -1990 against internal, external and statistical criteria. Papers grouped by categories, 2 early therapies and 9 SU papers in the stroke rehab wards group. **Inclusion criteria:** Published rehabilitation studies designed to improve function with experimental evidence of efficacy of intervention in general and physio & occupational therapy divided by type of therapy. **Purpose:** review interventional studies of physio & occupational therapy in stroke to answer two questions (1) do people benefit from rehab (2) are there differences in therapies **Comments:** Unable to define the state of the art in stroke rehabilitation 2nd to poor quality of studies	**Functioning:** ADL **Indices:** varied from standardized ADL	Defined as expert care	Therapy in SU Expert care: 26 hours to 7 days. Early start of therapy: 72 hours to 25 days	Expert care: 9 studies the earlier it starts the better, but the outcome varied. Only 3 studies had an early start of therapy. No definite conclusions were possible as the methods were not rigorous enough to define effects.	**Strengths**: broad review of interventions well described. Studies separated as to intervention, time and setting. large number of papers reviewed. Conclusions per type of intervention summarized the quality criteria listed per study **Weakness:** no summary effect size for intervention on outcome. Number of poor quality studies and unable to define effects

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Interventi-ons	Definition of Early	Results	Strengths/Weakness
Ottenbach and Jannell (142)					
Summary of methods: Electronic search and manual search methods listed. Selected 36 out of 124 dated 1960 -1990 against criteria. **Inclusion criteria:** Published rehabilitation studies designed to improve function, operationalized functioning construct, a comparison group, and enough information on which to judge analysis **Purpose:** review quality of studies to identify effectiveness of rehabilitation to improve function and discharge destination. **Comments:** Methodology varied across studies: weaknesses were related to blinding, randomization, adequate description of methods, and controlling for confounders. Unable to define what type of therapy is right for what type of person.	**Functioning:** defined by a number of indices **Indices:** any motor or reflex performance, language, visual or perceptual function, and ADL	Not stated but defined as rehabilitation services that included any service that lead to the improvement of performance and behaviour	Admission to rehab from onset of stroke approximately 7 weeks	Effects sizes were inversely related to start of rehabilitation with larger effects sizes related to earlier start. The better the methodology of the studies the smaller the effects size. The summary effect size was 0.4	**Strengths:** Summary effect sizes and effect sized determined corrected for sample size. **Weakness:** included quasi experimental studies of poorer quality as inclusion criteria were more inclusive than most reviews. Broad definition of rehabilitation. No early rehab papers.

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review **Author, Methods**	**Functioning Definition**	**Intervent-ions**	**Definition of Early**	**Results**	**Strengths/Weakness**
de Pedro-Cuesta et al. (127)					
Summary of methods: limited electronic search and manual search methods listed. Selected 22 out of 44 dated 1984 -1991 against criteria. **Inclusion criteria:** Only RCTs 80% of sample must be stroke, no single case studies **Purpose:** to evaluation studies to define the gaps for future research **Comments:** Methodology varied across studies: weakness were related to blinding , randomization, adequate description of methods, drop outs and controlling for confounders	**Functioning:** ADL motor function , disability and death **Indices:** not stated	Stroke unit or intensive rehab vs conventional type not specified	Not stated	Inconclusive and positive effects were related to stroke unit care and not early therapy	**Strengths:** detailed description of strengths and weakness of the papers **Weakness:** standardized quality criteria not used to judge the papers and methodology to determine quality inadequately described. Early and intense effects studied in combination in stroke units, no effect sizes

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review **Author, Methods**	**Functioning Definition**	**Intervent-ions**	**Definition of Early**	**Results**	**Strengths/Weakness**
Ashburn et al. (159)					
Summary of methods: descriptive only: no methodology stated except collection of available evidence on efficacy of physiotherapy: Four papers reviewed with early start of therapy **Inclusion criteria:** papers on type of therapy with details of therapy **Purpose:** to review efficacy of physiotherapy **Comments:** evidence not clear secondary to methodological complexities as in other reviews; no optimal type of therapy defined	**Functioning:** ADL, mobility strength, global function **Indices:** not defined	Compared schools of therapy Bobath, Kabat, Bruunstrum Rood, PNF. In SU no therapy type stated in the papers	Not stated only SU papers defined as early probably from admission to SU	4 papers with results listed: conclusion: earlier is better evidence beyond a descriptive conclusion not stated	**Strengths:** descriptive review of papers by theory of therapy and aspects of therapy: intensity, service delivery and timing **Weakness:** standardized quality criteria not used to judge the papers methodology to determine quality inadequately described. no effect sizes

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review **Author, Methods**	**Functioning Definition**	**Intervent-ions**	**Definition of Early**	**Results**	**Strengths/Weakness**
Langhorne et al. (158)					
Summary of methods: Electronic search and manual search methods listed. Selected 7 RCT studies only 2 that could be considered early, the rest started with in 2 months of stroke and are covered in subsequent reviews (140) (126) (129) **Inclusion criteria:** RCTs identified in the literature not comparing specific techniques and not comparing different stroke services **Purpose:** answer the question does more therapy produce better results. **Comments:** most studies and reviews till now are confounded by service delivery variables or type of therapy comparisons	**Functioning:** dichotomized death or death and poor outcome	Type of therapy not explicit defined as enhanced.	Not explicitly studied, but early studies started therapy within 7 days	increased therapy had a non significant relationship to case fatality (OR 0.60; 95% CI, 0.33-1.09) and significantly reduced probability of death and poor outcome (OR 0.54 95% CI 0.34-0.85)	**Strengths:** detailed description of studies strength of relationships presented as odds ratios **Weakness**: unable to separate time from intensity but the objective was to study intensity .Only two early studies. Criteria for judging quality of papers not provided. Descriptive.

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Duncan (13)					
Summary of methods: not stated **Inclusion criteria;** 38 clinical trials of interventions to improve motor control. **Purpose:** Evaluate the evidence on interventions to improve motor control **Comments:** Methodology varied across studies: weakness were related to blinding , randomization, adequate description of methods, and controlling for confounders	**Functioning**: motor control **Indices:** self-care, gait analysis, gait speed	Traditional Bobath treadmill BWS, FES	3 studies with therapy starting before 7 days	Evidence ambiguous due to lack of methodological vigour including: poor follow up, lack of details to judge study, drop outs, limited power.	**Strengths:** descriptive review of papers by theory of therapy and aspects of therapy: intensity, service delivery and timing **Weakness:** no statistical comparison; no effect size; no quality indictors used to judge studies

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Kwakkel et al.(140) (181)					
Summary of methods: Electronic search and manual search methods listed. Selected 9 out of 11 dated 1966 -1995 against internal, external and statistical validity criteria. **Inclusion criteria:** Published studies with ADL as an outcome and intensity of physio & /or occupational therapy with experimental or quasi experimental methodology **Purpose**: review quality of studies 2. Identify effects of intensity of therapy on ADL and related factors **Comments:** Methodology varied across studies: weakness were related to blinding , randomization, adequate description of methods, and controlling for confounders	**Functioning**: ADL **Indices:** predominately BI	See below	See below	All studies are included in subsequent reviews below; the effect of rehabilitation is summarized as small but statistically significant. effect size of intensity on ADL between 0.28 and 0.34	**Strengths:** 16 reliable and valid validity criteria scored per paper, Ranked studies by scores on criteria Summary effect sizes and effect sizes determined and corrected for sample size Analysis with fixed and random effect models dependent on the heterogeneity of the studies. Post hoc analysis for setting blinding and intensity of therapy **Weakness**: unable to separate time from intensity but the objective was to study intensity

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Cifu and Stewart (126)					
Summary of methods: Electronic search and manual search methods listed. Selected 79 out of 200 dated 1950 -1998. Criteria for review based on Sackett's rules of evidence (182) **Inclusion criteria:** papers with an association between rehab interventions and functional outcome **Purpose:** define the relationship between rehabilitation interventions and function **Comments::** critical review is limited due to heterogeneity of studies by methodology, analysis measures inclusion/exclusion criteria interpretation of results	**Functioning**: Differed across studies, defined as :Functional abilities at rehabilitation discharge and follow up **Indices used:** not stated	4 of 15 studies defined evidence for effect of early timing of rehabilitation on functioning,	From 3 to 30 days post-stroke	Positive correlation between early rehabilitation and improved functioning. 1.Evidence delay to start of rehab detrimental 2.rehab within 72 hours improved function 3&4 early start of rehab improved function independent of severity or initial functioning	**Strengths:** strength of association based on evidence with strong evidence: level I & II studies and 75% agreement on effect; weak evidence level I & II studies and 74-50% agreement on effect **Weakness**: reliability or validity for evidence in papers not stated; unable to define effect sizes.

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review **Author, Methods**	**Functioning Definition**	**Intervent-ions**	**Definition of Early**	**Results**	**Strengths/Weakness**
Anderson (80)					
Summary of methods: limited descriptive review of 8 rehabilitation papers to 1990 **Inclusion criteria:** not stated **Purpose**: 1.review quality of studies 2. identify rehab outcome and factors related to outcome **Comments:** comparison between studies is hampered by methodology: different measures and length of time since stroke	**Functioning** varied definition **Indices:** Barthel, Katz, mobility measures	Not stated	Not stated	Positive association between early initiation of rehabilitation and functional outcome	**Strengths:** description of paper results. **Weakness**: descriptive only no effect sizes for comparison or indication of the strength of the intervention
Van der lee et al. (125)					
Summary of methods: extensive electronic search and manual search methods listed. Selected 15 from initial 72 dated 1996-2000 against internal, external and statistical validity **Inclusion criteria:** only RCT papers with interventions to improve upper extremity **Purpose**: 1. identify intervention and relationships to characteristics of sample and methodology **Comments:** compared the same studies other authors unable to relate sample characteristics to results	**Functioning** varied definition **Indices:** BI, ARAT, FM	Varied intervent-ions that improved upper extremity function	2 studies with start of therapy before 7 days review by others	All studies are included in subsequent reviews below; results summarized as: no firm effect but a trend towards positive results for increased intensity of rehabilitation on functional outcome for the upper extremity	**Strengths:** description of paper results attempt to characterize factors related to outcome beyond intensity and methodology **Weakness**: descriptive only no effect sizes

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Steultjens et al. (141)					
Summary of methods: extensive electronic search and manual search methods. Selected 36 from 62 dated 1966 -2002 against internal, external and statistical criteria **Inclusion criteria:** efficacy studies with outcomes related to impairments, ADL or extended ADL, and participation, 18 RCT, 6 CCT, 8 OD **Purpose**: determine whether OT improves stroke outcome **Comments:** conclusions difficult due to heterogeneity of study methodology: selection criteria unavailable to determine which subject benefits most from occupational therapy;	**Functioning**: ADL **Indices:** BI Nottingham extended ADL SIP ARAT cognitive skills NEADL, intellectual function and housework assessment	defined as OT by specific criteria from cognitive training to retraining ADL skills	4 early studies time reported in inclusion criteria of each study as < 7 days	Difficult to separate early effect sizes from the rest of the studies. Appears that effect sizes depended on quality of studies and the outcome range from 0.00-0.33. Overall early occupational therapy has a small benefit	**Strengths:** defined global OT interventions Summary effect sizes and effect sized determined corrected for sample size. Analysis with fixed and random effect models dependent on the heterogeneity of the studies **Weakness:** no specific components in definition of therapy, very heterogeneous sample of studies making conclusions difficult

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Teasall et al. (146)					
Summary of methods: extensive electronic search and manual search methods in separate paper. Selected 252 RCTs dated to 2003 reviewed by committee against levels of evidence of effect with specific criteria **Inclusion criteria:** RCTs with physio &/ or, OT interventions **Purpose**: review current evidence for or against specific treatments to direct stroke care across the continuum of care **Comments**: provides a basis of evidence to define best practise	**Functioning:** outcomes not stated **Indices:** not defined	varied included: Remedial vs compensatory Constraint induced positioning exercise FES Drugs education	Not defined	Limited evidence that early admission to rehab improves functional outcomes	**Strengths:** all aspects of rehabilitation care reviewed from care paths to treatment for spasticity. Short statement of evidence criteria **Weakness:** More descriptive than quantitative evidence base for therapy listed in tables No indication of strength of effects of treatments. Effects of treatments on outcome and effects of risk factors on treatment outcomes combined in the reviews making it difficult to associated therapeutic interventions with effects.

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ions	Definition of Early	Results	Strengths/Weakness
Kwakkel et al. (129)					
Summary of methods: extensive electronic search and manual search methods listed. Selected 32 from 507 dated 1966 -2003 against internal, external and statistical criteria. 20 studies were eligible for review **Inclusion criteria:** RCT with intensity of physio &/ or OT and an outcome of ADL (walking ability, hand dexterity or IADL). **Purpose**: 1.review quality of studies 2. Identify effects of intensity of therapy on ADL, walking and dexterity **Comments:** papers excluded for lack of randomization, pre-post test design & missing information.	**Functioning**: ADL including walking, hand dexterity and IADL or leisure activities **Indices:** Lehman's ADL, BI, BI ambulation item, MBI, ARAT, gait speed	varied per study and included: 1) intensive therapy unspecified vs normal in 4 studies 2.)intensive vs immobilization in 1 study 3).early intense vs routine without early in 1 study	5/20 studies with rehab starting within 7 days but varied between 3.5 and 13 days	ADL: 5 studies ES from -0.38 to 0.75; Walking: 2 studies -0.38 to 0.48; Dexterity: 1 study no effect; IADL: 1 study 0.13 to 0.48; Some effect of start of early therapy	**Strengths:** 14 reliable and validity criteria scored per paper, Ranked studies by criteria scores Summary effect sizes and effect sized determined corrected for sample size Analysis with fixed and random effect models dependent on the heterogeneity of the studies **Weakness**: unable to separate time from intensity

Table 1.4 Continued. Summary of Reviews of Early Rehabilitation Interventions

Review Author, Methods	Functioning Definition	Intervent-ion	Definition of Early	Results	Strengths/Weakness
Van Peppen et al (15)					
Summary of methods Electronic and manual search outlined. Selected 151out of 735 papers to 2004 against PEDro criteria scored 0-10. **Inclusion criteria:** Physical therapy interventions and agreement between 2 authors on123 RCTs and 28 CCTs **Purpose:** establish the evidence that physiotherapy interventions improve function **Comments:** average PEDro score:5/10; for high quality papers: ≥4/10; for low quality:3/10; When combining of studies not possible due to methodological variation quality based on RCT and PEDro criteria **Summary Effect Sizes:** 0.13 to 0.92; effects attributed to early studies: 0.13 for intensity of exercise to 1.41 for FES	**Functioning** various definitions: **Indices:** strength, walk tests , FM, BI , FIM FAC, ARAT, AMAT, MAL, PROM NEADL	Traditional neurological Aerobic training, Treadmill without BWS, Upper extremity, Constraint induced, Intensity training, and FES for the shoulder	18 studies started 7-8 days post-stroke # per intervention: 1) Traditional neurological N=2, 2) Aerobic training N=1, 3) Treadmill without BWS N=2, 4) Upper extremity N=4, 5) Constraint induced N=1, 6) Intensity training N=7, and 7) shoulder FES N=2	**Traditional neurological** no effect , **Aerobic training** increase leg strength and aerobic capacity, **Treadmill without BWS** improved walking ability, **Upper extremity,** insufficient evidence to state **Constraint induced** improved dexterity, **Intensity training,** improved gait ADL IADL, **Shoulder FES** improved ROM decreased subluxation concludes that early has an important effect	**Strengths:** validity criteria scored 0-10. Summary effect sizes and effect sized determined corrected for sample size Analysis with fixed and random effect models dependent on the heterogeneity of the studies. Definition of best evidence **Weaknesses:** heterogeneity of studies based on timing, some study samples too small for adequate quantification of SES. Quantification of results for RCTs only. Cut points for quality could be higher than 5/10 for high quality papers. Unable to separate early effects for other effects.

Abbreviations: #, (number); ADL, (activity of daily living); AMAT, (Arm Motor Activity test); ARAT, (action research arm test); BI, (Barthel Index); BWS, (body weight support); CCTs, (clinically controlled trials); FAC, (functional ambulation classification); FAI, (Frenchay arm test); FES, (functional electrical stimulation); FIM, (Functional Independence Measure); FM, (Fugl Meyer sensorimotor test); GCS, (Glasgow Coma Scale); MAL, (motor assessment log); MMSE, (Mini Mental State Examination); MRS, (modified Rankin Scale); NHP, (Nottingham Health Profile); OD, (other experiment design of a study); NEADL, (Nottingham Extended Activities of Daily Living scale); OR (odds ratio); OT, (occupational therapy); PECS, (Patient Evaluation Conference System); PEDro, (Physiotherapy Evidence Database); PROM, (passive range of movement); PNF, (Proprioceptive Neuro-Facilitation); Pulses, (Pulses profile); RCT, (Randomized Controlled Trials); SIP, (Sickness Impact Profile)

Chapter 2 Quantifying Functioning

2.1 Towards an Operational Definition of Functioning

After a stroke the ultimate goal for most people is to return to their previous level of functioning (183) (184) (185) (186). Inherent in the term recovery is an improvement in functioning. Without a measure of functioning, recovery cannot be quantified. Attempts to define functioning post brain injury have varied depending on the level at which it was measured: tissue, organ, behaviour or as a global outcome. Many researchers believe that the recovery of functioning, as a construct, should include the concepts of injury, deficits and a full restitution of previous abilities (187) (169) (188) (189). This definition; however, would merely describe the person's abilities and would be a poor guide in exploring the relationships between functioning and any other construct. Functioning needs to be defined in both measurable and meaningful terms.

No single measure adequately defines or quantifies functioning for an individual (68) (175) and there is no consensus on the specific activities that should be included in a definition of functioning or the amount of improvement in performance or capacity necessary to define the recovery of functioning (189) (175). As a result of the lack of consistency in the definition of functioning, recovery has often been dichotomized as "independent" or "dependent" (68) (175) (57). This dichotomization is inadequate for a number of reasons: it decreases the information obtained, limits the detection of change in outcome, and is often clinically irrelevant (68) (175) (12). Statistically, it causes misclassification whereby persons with different functioning levels are classified within the same range either above or below a cut-off point defining recovery. Misclassification occurring at random would increase the noise making it difficult to find the effects, whilst a systematic misclassification would bias the results (190).

Sulter et al. (68) reviewed 15 acute clinical stroke trials evaluating drugs in the treatment of stroke that used an ADL measure, the BI, scored 0-100, worst to best, and a global measure of outcome, the MRS as measures of outcome. The different trials used arbitrary cut points to classify patients as achieving a "favourable" outcome. Sulter et al. (68) argued that a single definition of outcome is difficult to defend. Which definition should it be? On what should it be based? To illustrate, a BI score with a cut off point ≥ 95, that defines people as having a minimal or no disability, is as valid as a score of 85, that indicates a person has an acceptable level of autonomy (191), while a score of 100 would reflect that the person can independently perform 10 basic activities of daily living. Which cut point is best? Are they all equally adequate from a patient's point of view? Sulter et al. (68) felt that a "poor outcome" may be easier to define, but suggested that a distribution of scores of disability rather than a single score would allow a better evaluation of shifts in regaining functions.

A definition of functioning post-stroke across a series of measures is needed, especially as the recovery of functioning occurs unevenly across a gamut of functional activities. One attempt at a definition of recovery of functioning across activities is demonstrated in a cohort of 459 patients, followed for 6 months. Only "successful" recovery was assessed across the outcomes indicated in Table 2.1 (12). The rate and range of recovery differed between the outcomes and the percentage of patients considered recovered depended on the index, and the cut point used. The rate of recovery was also depended on the severity of stroke (12).

These criteria adequately defined successful recovery, but not all patients recovered successfully. The 116 patients who improved from a MRS score of 4 to 3 out of 5 did not "successfully" recover (MRS<2), but they did improve. A system to match patients to therapeutic interventions needs to quantify the improvement in performance over a distribution of possible functioning scores. In addition to quantifying functioning, activities that should be included in a definition of functioning to define recovery need to be determined.

2.2 Defining the Content of Functioning

Functioning or the ability to perform tasks necessary for daily living, leisure, vocational and societal interactions, (93) is the predominant area of concern in rehabilitation (192) (193) (194) (22) (134) (195). The assessment of an individual's level of functioning provides a portrait of the whole person and acts as the starting point in the evaluation of that individual's needs (93). The conceptual framework for what constitutes functioning, required for measurement, is provided by the ICF model of Functioning, Health and Disease (24).

The ICF has a coherent and definite content to which items for a measure of functioning can be addressed (196). Additionally, a panel of experts have defined a brief list of components to rate functioning as a result of a stroke (197) that incorporates patients' and health care professionals' perspectives. The brief core set for stroke is available to base the contents of a measure of functioning for stroke. However, the ICF was not developed as a measure and as such does not quantify functioning. Quantification necessitates that the items in a measure of functioning be located at different levels of difficulty, from easy to hard, across the continuum of functioning from body structures to participation (198) (20) (93)and demands a mathematical comparison of a stroke survivor's current and pre-stroke functional state.

To date, the approach to quantifying functioning has been to develop separate tests and indices for one or more of its components (199) (200). The profile of the impacts of stroke on functioning, described above, illustrates the difficulty when multiple indices are used. As observed previously, the summary scores provided to describe the amount of functioning across ordinal categories increases the ambiguity in understanding the exact nature or patterns of disability in an individual (195) (201). A categorical index of functioning used for recovery would limit the identification of the recovery levels of functioning that may be important to an individual.

2.3 A Method to Quantify Functioning: Rasch Analysis

A complex construct such as functioning can not be measured directly only indirectly by the activities thought to represent that construct. Most published measures that have been developed to conceptualize functioning in rehabilitation are ordinal (93) (199) (202) (203). They quantify functioning by summing ordinal response options over the collection of items in the index to a total score. The addition of the different numerals assigned to the response options of each item assumes that each numeral contributes equally to the total score of the index. Only items measured on an interval scale where the units are equally spaced should be added to produce a total score (202) (204). The important distinction between ordinal and interval scales means an index with summed ordinal values may not adequately measure change. Ordinal scales discriminate poorly between people and may not adequately reflect the magnitude of change within an individual (205). A change in functioning provides the natural basis for a definition of recovery

Additionally, the proliferation of ordinal indices has made the choice of index to quantify functioning more arduous. The indices tend to be narrowly focused, or assess more than a single construct (e.g., ADL and continence); or it requires a multitude of indices to quantify the full range of functioning resulting in an increased burden for the patient and health care professional.

2.4 The Rasch Measurement Model

A method of analysis developed by Georg Rasch has helped to resolve these difficulties (25). Rasch analysis provides a quantitative framework to create a measure of functioning that permits mathematical manipulations. Rasch analysis provides a method of quantifying constructs or latent traits such as functioning. Based on a person's total score, a Rasch analysis models the interaction between the difficulties of an item a person is attempting and that person's ability. The probability a person can answer a question or perform a task correctly is defined based on the person's total score (206) (207). The estimate of every individual's ability and each item's difficulty are calculated by the model, with a standard error for each (26).

Unlike more traditional analyses where a model is fitted to the data, Rasch analysis requires the data fit the chosen model. The outcome of a Rasch analysis, when the data fit the model, is a unidimensional measure on which items and people are organized hierarchically on the same measurement scale, based on the log of the odds ratio (ratio of probability of success to failure of completing the task) or a logit. When the amount of ability required for success on an item (the item's difficulty), and the respondent's level of functioning (ability) match; the individual's probability of succeeding on that item is 50%. That item represents his or her average functional ability (207). A person with a positive logit score has more of the construct "functioning" and a person with a negative logit score has less.

Each item's response option in the measure is placed on an interval scale using a logistic transformation and is then centered on the average ability of a person on an average item.

By convention, the average difficulty of the items is set at "zero" (208) and helps determine whether the match between item difficulty and person ability is adequate. A match exists when the average person ability is within 0.5 logits of the average item difficulty (209) (207). The full continuum of functioning is difficult to quantify unless the characteristics of an individual are matched by the items in the measure (19). To date, most ordinal measures tend to be limited in the range of functioning they measure.

2.5 Sufficiency of the Total Score

A measure that fits the Rasch measurement model provides a total score that contains all the necessary information about that person's functional ability (206) (26). The sufficiency of the total score in describing a person's ability is an advantage in quantifying functioning. The total score would quantify the person's functioning defined by the items or tasks within the measure that represent that total score as impacted on by a stroke.

The existing methods of quantifying functioning are limited by the inappropriate summing of items with ordinal response options to a total score (210) (211) (202) (204) (206). The difficulty with a total score based on an ordinal index is that the tasks a person is capable of performing are not associated with a defined level of difficulty; this makes the interpretation of the total score almost impossible. Total scores from ordinal based indices can misrepresent a person's true ability. Measurement with responses scaled hierarchical represents ability along a continuum (212) (213) and enables health care professionals to make decisions about a person's ability based on a single test score. Additionally, the extent to which a person's performance is consistent with what is expected of him or her, given the total score, can also be assessed.

2.6 Rasch Model Requirements

The Rasch model has, as key requirements, unidimensionality and invariance. All the items must measure the same single construct and the construct must not change; it is invariant, across persons with different characteristics. The item difficulty and person ability estimates remain invariant across the scale of measurement as the level of item difficulty does not depend on the particular characteristics of the people responding to the items, and the ability of the people does not depend on the characteristics of the items

(214). These properties are assessed primarily through fit statistics and are considered met when the data fit the model.

The fit of the data to the model is determined in a number of ways (standardized residuals, χ^2 and F-statistic) with the power of the test of fit based on the spread of the persons across the continuum being measured (215). Most fit statistics are based on an analysis of the residuals of the observed responses minus the expected modelled responses of persons to an item, with the persons grouped by their scores into class intervals. The residuals are calculated, standardized, squared and summed across all class intervals per item to form an χ^2 statistic, that is transformed to a z statistic and log transformed to approximate a standard normal distribution (216). The data fit the model when the standardized fit residuals are close to '0' and their standard deviations are close to '1'. The χ^2 statistic indicates the data fit if its p value is >0.05; a p value< 0.05 indicates that the difference between the observed and expected responses are larger than expected by chance alone. The reason for the poor fit is then evaluated (217) (218) (219) (220) (26) (215). As the χ^2 statistic only approximates a χ^2 distribution, an F-statistic, the result of a one way analysis of variance on the standardized residuals can provide a more precise estimate of the data fit than the χ^2. The F-statistic is calculated on an individual, not a group basis (215) (219). Although there are no absolute criteria on which to base judgments of quality it depends on the Rasch model, the estimation method and the statistical program used. All indicators should be considered in any discussion of data fit and the quality of the resultant measure. The literature provides information to judge the appropriate statistics (208) (207) (26) (221) (222) (223) (215) (224) (225) (219) (214).

Another requirement of the model is that the difficulty level of each item's response option must be ordered (208) (226) (26) (227). For proper structuring of the measure, the item response options should be ordered such that the probability of responding to any item's response option is possible. A disordered category results when people with more ability do not have a greater probability of successfully responding to a more difficult level of a question than those with lower ability. This is judged by an item's threshold or the pivotal points in an item's response options, the point at which the likelihood of failure becomes the likelihood of success at a specific option; for example, between 0 and 1 or between 1 and 2 (228) (208). The threshold or the difference in difficulty between response categories should indicate a distinct functioning level per response category. For adequate item discrimination, the difference in threshold values within an item should be evenly spaced. If they are too far apart (represented by large numbers), the impact of stroke that falls between the two response options is unknown; and option difficulty levels that are too close together are indistinguishable (226) (208) (228). Items with disordered response options are rescored usually by collapsing categories.

Category fit statistics assess the quality of the rating scales as is done for the item itself. The adequacy of the response category fit is also examined graphically via category characteristic curves that illustrate the performance of each scoring category (208) (215). Ideally, as illustrated in Figure 3, a series of 'hills' should be evident such that each scoring category is the most probable at a particular level of recovery (226) (208) (229) (215) (228).

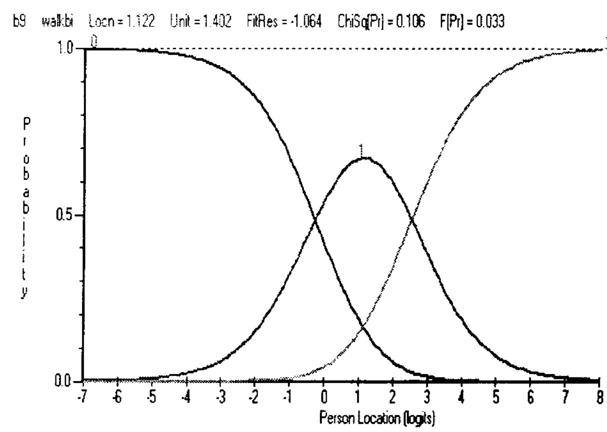

Figure 3 An example of properly ordered categories in the walking item from the BI (211).

The number on the category characteristic curves represents the response options 0, 1, and 2. The X-axis represents person ability from less able on the left to more able on the right and the Y-axis the probability of a response.

2.7 Rasch Models

A number of Rasch models can be employed to develop a measure, the one chosen depends on the data and the objectives of the measure (207) (230). There are upwards of

50 or more models, six of which are well described by Wright and Mok, who have included a decision algorithm to assist in choosing the appropriate model (230). One method, the conditional pair-wise estimation method for ordered response categories within an extended logistic Rasch model (26) (216) (231) (228), is appropriate for fitting the data where the number of item responses and meanings differ across the items (228) (232). This is the method used throughout this thesis and is described in the Manuscripts 1 to 3.

2.8 Psychometric Qualities of a Rasch Measure

Adequate psychometric properties insure that a measure is measuring what it is intended to measure accurately and reliably. Rasch analysis provides indicators on which to estimate these qualities throughout the process of developing a measure. A summary of the quality indicators can be found in Table 5.2, Manuscript 3, Chapter 5, and throughout the remaining chapters of the thesis. By the end, the reader should have a clear understanding of Rasch analysis and its implications.

Recent applications of the Rasch model in rehabilitation have led to the development of new measures (209) (233) (234) and the combining of former indices (27) (235) into a single measure. Although these new measures provide a more comprehensive assessment of the impact of stroke on functioning, concerns remain (236): the response burden to the subject is sizeable, the population targeted is limited, and the focus is on activities of daily living (ADL) and instrumental activities of daily living (IADL). A measure developed through a Rasch analysis with items that fit the model would form and define the construct functioning with a total score that would be sufficient to quantify that person's ability on the underlying construct (26) (237) (22). The measure of functioning could then be the basis for a definition of recovery.

5 **Table 2.1 Criteria for Successful Recovery**

Recovery Construct	Criteria for successful recovery	% Reaching criteria (N=459)
Neurological	NIHSS*<1	44.9
Motor	Fugl-Meyer >90	36.8
ADL	BI >90	57.3
Activity level	PF-SF-36 >66 for women; PF-SF-36 >75 for men	25.0
Global	MRS <1	25.0
Global	MRS<2	53.8

Abbreviations: ADL, (Activity of Daily Living); BI, (Barthel Index); MRS, (modified Rankin score); NIHSS; (National Institute for Health Stroke Scale); PF, (physical functioning scale of the Medical Outcomes Trust Short Form Sf-36).

Chapter 3: Manuscript 1. *The Development of a Prototype Measure of Functioning for Stroke Recovery: The Prototype Functional Recovery Measure.*

Preface to Manuscript 1:

Manuscript 1 provides the basis for the conceptualization of functioning from which to quantify recovery. Although functioning is part of a standard evaluation for patients after a stroke, the understanding of what constitutes comprehensive functioning has been hindered by the more than 100 indices used to assess and define it (236) (193). As a basis for the content of the construct of functioning we chose the World Health Organization framework provided in the International Classification of Functioning, Health and Disease (ICF), augmented by a consensus exercise that solicited the opinions of health care professionals (24). The ICF furnishes a biopsychosocial model for rehabilitation that goes beyond the causes and pathology of the medical model to include activities and participation. We considered it to be the best model to identify the content for a comprehensive, complex construct such as functioning.

The impact of rehabilitation on stroke recovery can only be assessed through the quantification of change in functioning. The "changes, achievements and benefits from rehabilitation programs are found in the outcomes" (193) (Granger CV) p235; thus, the most prevalent outcome in rehabilitation is functioning (94) (236). The next step in this first manuscript was to develop a prototype measure of functioning for an individual after a stroke with a content defined by the ICF. The objective is to develop a measure that would quantify recovery following stroke, specifically to develop a prototype measure of the functioning ability of an individual after a stroke.

The Rasch measurement model was chosen as the best method to quantify functioning as it produces a unidimensional measure with interval properties and a total score reflective of functioning. Other methods, such as principal component analysis (PCA) or factor analysis (FA), could generate linear combinations of items to explain functioning (165) (238) (239). A measure developed thorough a PCA or FA does not provide a measure with the items and the people ordered by difficulty and ability on the same scale. As a factor analysis only reveals the factor structure underling the pattern within the item correlation matrix, a Rasch analysis is essential to provide an accurate estimation of the level of difficulty for each item. This property is required to actually measure functioning and subsequently to quantify recovery (238). The important feature in a definition of functioning was felt to be the ability to quantify the interaction between the item difficulty and a person's ability, at the individual level on the same scale. Rasch analysis is the best method for this (240) (241). Data that fit a Rasch model provide an estimate of an individual's functioning that can be compared across time to define the change in functioning or recovery.

A relatively large data set originally collected to estimate the long-term outcome of stroke was used to develop a measure of functioning six months post-stroke (242). Through Rasch analysis, 39 items, from 5 indices, were combined into a parsimonious 12-item measure of functioning. Although both the consensus and factor analysis demonstrated an item structure and hinted at the difficulty level, Rasch analysis was required to produce an interval-like measure and quantify recovery. Although measures that combine basic ADL and IADL items (27) (212) exist, our measure is the first to extend the concept of functioning to include participation. The measure outlines what is deemed necessary and important for community recovery; an area often underestimated by therapists, but the goal of many stroke survivors (209) (243) (90).

The specific objective addressed in the following manuscript was to create a parsimonious list of items that would measure the construct functioning as conceptualized by the ICF that could be used to quantify recovery. The details of this study are presented in the following manuscript which is to be submitted to the journal *Disability and Rehabilitation.*

Title Page

Development of a Prototype Measure of Functioning for Stroke Recovery: The Prototype Functional Recovery Measure.

For submission to: *Disability and Rehabilitation*

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Keywords: Measurement, Functioning, Stroke recovery, Participation

Abstract

Measurement of a person's ability to function safely and independently in the environment is part of a standard evaluation for stroke. More than 100 indices of functioning exist, but none capture the full spectrum of functioning, from basic activities of daily living (ADL) to participating in life roles. The items in these indices can be irrelevant, redundant, or exhibit floor and ceiling effects. Rasch analysis has been used to develop, summarize, refine, and combine items from different indices condensing functioning into a single measure. These Rasch measures provide a more comprehensive assessment of functioning, but still target persons with mild to moderate stroke, focus on ADL and have a moderate response burden.

Purpose: To illustrate the development of a parsimonious measure of functioning for persons with stroke using Rasch analysis.

Method: The data were from a subset of 202 subjects with a first stroke, interviewed within nine months. Thirty nine items from five indices were used to assess functioning. Information was collected on influencing variables: age, stroke type and severity, and previous health. Two statistical methods, exploratory factor analysis and Rasch analysis, confirmed the item factor structure, hierarchy and dimensionality of the measure. Statistics confirmed fit to the model; internal consistency was also assessed. The worst fitting items were removed iteratively until the best fit of the data was achieved.

Results: A 12-item unidimensional measure of functioning was developed. All items and persons fit the model with reliability indices of 0.91 and 0.98, respectively, indicating a stable person item hierarchy. Item precision (standard error) ranged from 0.14 to 0.37 logits. Gaps in measurement occured at the extremes of the measure and there was an 11 % ceiling.

Conclusion: The 12 items captured the concept of functioning despite gaps in the continuum and an 11% ceiling effect. These items now form the basis for an item bank on functioning. The interpretation and content coverage of the measure would be increased with the addition of specific items whose calibration fills the gaps in the measure.

Introduction

After a stroke, what an individual desires most is to return to his or her previous level of functioning (183) (184) (18) (185) (186). This forms the individual's definition of recovery and matches that proposed by researchers: "the post-lesion reinstatement of the behaviours disrupted by the brain injury" p2 (187) (169) (244). While the researcher and patient may concur the definition fails to delineate the specific functions or level of improvement required to fully characterize recovery. If the goal of rehabilitation is to enhance recovery by restoring function, the targeting of rehabilitation interventions can only be achieved when the unique and complex abilities needed to conceptualize functioning are delineated. The International Classification of Functioning, Disability and Health (ICF) (24) of the World Health Organization (WHO) provides a universal framework and common language for conceptualizing functioning. This framework describes functioning and its antithesis, disability. Functioning includes two components, 1) body functions and structures, and 2) activities and participation, while disability refers to impairments of body structures and functions, limitations of activities and restrictions to participation. Body functions are the physiological expressions of body systems; body structures are anatomical parts of the body, organs and limbs, while impairments are deviations in either. Activities are tasks or actions an individual performs. Involvement in life situations is considered participation. Functioning is further qualified by distinguishing between capacity, what a person does in a standard environment (test situation), and performance, what a person does in his or her usual environment (community, home).

Recovery following stroke is frequently described as an improvement in the capacity or the performance of two subsets of the components of functioning (as defined by ICF), namely mobility and self-care tasks (186) (245) (82) (121). Both the ICF model and empirical evidence, however, show that these are not the only activities needed to function, as instrumental activities of daily living and social participation are required to capture its full spectrum (246) (247) (242).

To date, the approach to measuring function has been to develop separate tests and indices for one or more of its components. Although some researchers contend that no single test or index could be considered sufficient to capture the full range or complexity of functioning (175), others suggest that all concepts need not necessarily be fully specified to produce a single comprehensive measure (248).

Although the ICF provides an excellent classification system, it is not a measure (24) nor are the indices commonly used to evaluate functioning. Most health indices have been created by summing ordinal response options over a collection of items. The addition of the different numerals assigned to the response options of each item assumes that each numeral contributes equally to the total score of the index. In truth, only items measured on an interval scale where the units are equally spaced should be added to produce a total score (202). An interval measure may provide more consistency of item meaning over time as any variation in the item's contribution to the scale over time adds noise to the interpretation and can obscure change [95]. The important distinction between ordinal and interval scales means an index with summed ordinal values may not adequately measure change. Ordinal scales discriminate poorly between people, particularly if each took a different route to the same total score, and may not adequately reflect change within an individual.

The Rasch model provides a method for constructing a measure of functioning by transforming ordinal observations onto an interval scale (25). The outcome of a Rasch analysis, when the data fit the model, is a unidimensional measure on which items and people are organized hierarchically, by difficulty and ability respectively, on the same measurement scale in natural logarithm linear units or logits. Items that fit a Rasch model would form a measure of functioning with a total score that is sufficient to determine that person's ability on the underlying construct (206). Inherent in the term recovery is an improvement in functioning. Without a measure of functioning recovery cannot be quantified.

Recent applications of the Rasch model in rehabilitation have led to the development of new measures (209) (234) and the combining of former indices (27) into a single measure. These new measures provide a more comprehensive assessment of the impact of stroke on functioning. One such measure, the Stroke Impact Scale (87) (209), contains 60 items capturing functioning from impairment to participation restrictions across 8 domains, with 9 total scores and two physical composite scores of either 34 or 16. Despite this advancement in measuring stroke outcomes, concerns remain (236). The response burden to the subject is sizeable; the population targeted is persons with mild to moderate stroke; and the focus remains strongly on activities of daily living (ADL) and instrumental activities of daily living (IADL). Currently, there is no single measure that could be used to quantify stroke recovery that would satisfy the properties of a true interval measure and that would cover, parsimoniously, the range inherent in the term functioning as framed by the ICF.

Purpose

This study set out to develop a measure that would quantify recovery following stroke. Specifically it was to develop a prototype measure of the functioning ability of an individual after a stroke.

Methods

Subjects

The data for this analysis came from a prospective inception cohort of persons with a first stroke, recruited from 10 acute-care hospitals in the Montreal area, the Montreal Stroke Cohort. Details of the methodology and outcomes for the community dwelling stroke survivors have been reported elsewhere (242). Included in this analysis is a subset of 202 persons who, in addition to being interviewed within nine months, had complete data and a validated Computed Tomography scan. The original study had ethical approval from the McGill University Institutional Review Board and from the Research Ethics committees of all participating hospitals (242).

Defining the Items

The ICF model was used to identify the items in the global construct of functioning post-stroke. The items were chosen from indices commonly used to assess activity and participation. Table 3.1 provides a list of the indices, the number of items, their response options and psychometric properties. The three point scale of the RNL was used preferentially here to improve the subject's understanding of the Reintegration into Normal Living (RNL) items (84) (249). The RNL is one of the few scales that includes a participation component inherent in functioning. All items were transformed such that a higher score represented higher function. For the RNL this is the reverse of the original scoring. Although the indices appear to represent different constructs, they are all related to the consequences of stroke. The hypothesis underlying this study is that, even though stroke manifests itself in a heterogeneous manner, a unidimensional measure targeted to persons living in the community with stroke will emerge by combining items from diverse but related indices.

Influencing Factors

Information on stroke as well as previous and current health conditions associated with functional ability after stroke was obtained by medical chart review and questionnaire. Prior health conditions and stroke risk factors were assessed by questionnaire. Information on the type of stroke was obtained from the neurological and radiological reports. The health of individuals in the past was determined based on the number of previous health conditions, such as: cancer, heart disease, previous stroke, respiratory disease, arthritis, and grouped into four levels: none, one, two, and three or more health conditions. Age was categorized into 4 groups: below 55, between 55 and 64, between 65 and 79, and above 80 years.

The type of stroke was classified as ischemic or hemorrhagic. Stroke severity was estimated based on the Canadian Neurological Stroke Scale (CNS) (250). A retrospective scoring algorithm was used to yield scores from 2 (most severe) to 8.5 (least severe). Severity was classified into four groups: mild with a score greater than 6.5; mild-moderate a score between 5 and 6; moderate a score between 4 and 4.5 and severe with a score below 3.5 (251) (252).

Subjects were interviewed over a 3 to 9 month period after their stroke. As the time of interview since stroke could influence a person's perception of functioning, it was divided into 3 categories: up to 3 months post-stroke, from 3 to 6 months, and 6 to 9 months post-stroke.

Data Analysis

Subjects' ratings of ability on 39 items were available for analysis. The aim was to create a parsimonious list of items to measure the construct functioning as conceptualized by the

ICF that could be used to quantify recovery. To identify the different dimensions within the functioning construct, an exploratory factor analysis was performed through the FACTOR procedure in the statistical analysis software SAS version 9.1 (SAS institute, 100 SAS Campus Dr, Cary NC 27513). The assumptions underlying this procedure were first verified: elimination of outliers, absence of multicollinearity, factorability of the correlation matrix (correlation coefficients exceeding 0.30, and a Kaiser-Meyer-Olkin (KMO) test statistic greater than 0.50 (239) and normality with skewness and kurtosis coefficients not exceeding ± 2.0 for more than 60% of the items (239) (165)). One item, SF-36 PF item 'limitations in walking more than a kilometre' that correlated at 0.90 with another was deleted as redundant prior to the analysis. Although the distribution of the data was highly skewed (Skewness varying from -3.2 to -0.03 and the Shapiro-Wilk statistic for normality from 0.24 to 0.94; $p<.001$) the factorability of the correlation matrix was very good with a KMO measure of sampling adequacy of 0.92 (>0.6 is acceptable) (165).

Next, a Rasch analysis was conducted to construct a measure from the 39 items and further confirm the factor structure, item hierarchy and dimensionality. The Rasch model relates the probability of a person's response to a specific item to the interaction between the amount of functional ability the person has and the level of functioning that item represents (25) (253). Thus the Rasch model is the best method to quantify the amount of recovery a person can achieve based on his or her position in relation to the item's level of difficulty represented in the measure of functioning. The model chosen to fit the data was the extended logistic Rasch model (216) (241) using the Rasch Unidimensional Measurement Model program (RUMM 2020) (215) (231) (228) as the number of item responses and their meaning differed across the various indices.

The first step in a Rasch analysis is to verify that the items are appropriate for or target the people being measured; targeting is gauged by how closely the sample's average measure of functioning approaches "zero", the average item difficulty (207) (226). The Rasch model proceeds by transforming the response to each item onto an interval-like scale using a logit transformation that is then centered on the average item or "zero" in the logit scale. When the item's level of difficulty and the participant's level of functioning match, the individual's probability of succeeding on that item is 50% and that item represents the person's average functional ability (207).

The Rasch model has, as key requirements, unidimensionality and invariance. All the items must measure the same construct and the construct must be invariant across persons with different characteristics. The model's requirements were assessed by fit statistics, their graphical equivalences the item characteristic curves (ICCs), and category characteristic curves (217) (218) (219) (220). Rasch analysis was performed using the Rasch Unidimensional Measurement Model program (254). A criterion of model fit is that the difficulty level of each item's response option must be ordered (215) (228) (229). A disordered category results when people with more ability do not have a greater probability of successfully responding to a more difficult level of a question than those with lower ability. After rescaling the response options for the disordered items, the item fit is re-examined and the worst fitting items are removed iteratively until the best fit of the data to the model is obtained.

For this analysis, the participants were divided into three groups or class intervals by their total item scores. The fit statistics were determined for each class interval based on the difference between the observed and expected mean ability estimate for each group (215) (219). Fit is determined by standardized residuals, χ^2 and F-statistics. To ascertain if the fit is adequate, a test of the power of the fit statistics to detect adequate fit is provided based on the spread of the persons across the continuum being measured. All the statistics are considered in the investigation of item fit. Items are considered not to fit the model when any one of the following criterion are violated: standardized fit residuals greater than 2.0 or less than –2.0; a significant χ^2 or F-statistic.

To evaluate the precision of the measure, Rasch analysis provides a standard error for each item and person estimate and overall reliability and separation indices. The separation index is interpreted as follows: acceptable 1.5, good 2.0, and excellent 3.0, and the closer the reliability index is to 1.0 (range 0.0 to 1.0) the better (219) (214) (255).

Validity

The meaning and interpretation of a measure depends on its validity (21). Three aspects of content validity, relevance, representativeness and item technical quality, and two aspects of construct validity, unidimensionality and item and person hierarchy, were examined.

Content validity

Whether or not the items selected for the measure are relevant and represent the construct functioning was determined through a consensus exercise involving 27 health care professionals with expertise in stroke. The professionals varied in practice setting (tertiary acute care institutions, rehabilitation centers, community clinics) and years of experience ranging from 1-35 years (mean; 13.4: SD; 9). The professionals classified each of the 39 items according to whether, at 6-months post-stroke, the functioning described by that item reflected the theoretical hierarchy of the following: normal recovery, near normal, compensatory or minimal recovery. The definitions used to conceptualize the ordinal categories in the recovery hierarchy are supported by the literature (188) (187) and can be found in the Appendix. When greater than 80% of the professionals agreed an item belonged in a specific category, it was retained to define the category. If they were unable to classify an item, or there was no agreement on the item's category, the item was dropped. Once the hierarchy of items was defined, the professionals reconfirmed each item's place in the hierarchy; agreement was set at 50% to reflect majority opinion. Additionally, the professionals recorded the top 5 to 6 items they considered to be sufficient to define a person as completely recovered, the "normal" recovery category. Based on the score of the chosen items, cut points were determined for each ordinal category of recovery with each item's value standardized on a score from 0-100.

Content validity subsumes the idea of increasing levels of functioning. Thus, the extent or spread of the items and participants along the measure confirms the breadth of the functioning concept and allows the identification of individual differences. The technical quality of the items is addressed by item fit statistics.

Construct validity

The unidimensionality of the "functioning" construct (256) (257) (258) was assessed by examining the distribution of the standardized residuals via a principal component analysis.

To examine whether or not the order of the included items concurred with the theoretical hierarchy of functioning, two hypothesises were put forth 1) that the measure contains a range of items representing functioning that is ordered from easy (Activity items) to hard (Participation items), and 2) that the responses of the persons are ordered with the more functional persons being more likely to answer more questions correctly than the less functional persons. The response patterns of the participants should agree with the difficulty level of the items. The quality of each person's response pattern was evaluated through person standardized residual fit statistics with a critical value of ± 2.0 indicating appropriate fit. In addition, the data were divided into two subsets and the concordance between the person locations on each subset estimated, as if the participants had responded to two different tests of the same construct. The level of agreement between the two person ability locations provides an indication of the internal consistency of person ability (207).

If the tasks represented by the items included in the measure concur with the theory of functioning and the model requirements are met, the items are assumed to form a measure of functioning (259). The total score from the measure representing an individual's functional ability would then quantify recovery (25;216).

Differential Item Functioning

Once the data from items, response categories, and persons were judged to fit the model, a two-way analysis of variance was used to determine whether each item's location was stable (DIF) across the different influencing variables (gender, age, stroke severity, previous health and time of interview) (258) (260). For the DIF analysis the participants were divided into three groups of equal ability, and then by the influencing variable within that group. The difference in the level of difficulty per item was assessed across the groups using a two-way ANOVA (215) (261). The significance level was adjusted for multiple comparisons by a Bonferroni correction (262).

The sample size needed for stable person- and item-estimates (within ± 0.5 logits at the 95% confidence level), based on an expected standard error level of ± 0.03 in the measure was 144 (263)

Results

The baseline characteristics of the Montreal cohort and the sub-sample of 206 participants are presented in Table 3.2. Minor differences between the two groups are evident only in the proportion of males, discharge destination, and the length of stay. The means scores on the QOL, RNL, IADL, PF, and BI were similar.

Despite high mean ADL scores (BI mean: 92; SD: 16), at least 12% of the sample had difficulties in basic functions such as eating, and grooming, while 20% could not bathe, walk fifty yards or climb stairs independently (264). The scores on the OARSIADL (mean: 11.6; SD: 3) demonstrated that 41% of the subjects were able to perform all tasks, but 15% were unable to perform the top three items: housework, shopping and money management (234). The mean score on the Physical Functioning scale (PF) of the SF-36 (mean: 61.4; SD: 30.7) for these subjects was below the Canadian population norms (mean: 75.7; SD: 22.2) (265) with at least 55% of the sample experiencing difficulties with vigorous or moderate activities, carrying heavy groceries, and the more demanding mobility tasks of bending and kneeling and climbing several flights of stairs. In the participation domain (mean RNL score: 4.8; SD: 5), 40% of the subjects were unable to travel in the community or farther afield, participate in recreational activities or be meaningfully occupied during the day. The rating of overall QOL in this group was 6.6 out of a possible 10 (SD: 2.3)

Data structure

The seven-factor solution produced from the factor analysis revealed one major factor and six minor ones; the first factor explained 41% of the variance in the model. Only items with loadings greater than 0.4 were retained (165) for subsequent analysis; this resulted in the elimination of the IADL item 'uses the telephone'. The results of an oblique promax rotation on the remaining items in a four factor solution as suggested by the Eigen values, scree plots, proportion of variance accounted for, factor loading and interpretability of the factors are in Table 3.3 (266) (165) The first two factors explain 64% of the variance and include advanced and basic ADL/IADL tasks at two levels of difficulty. The remaining two factors contain few items, explain 20% of the remaining variance, have lower factor loadings, and either cover a personal relationships concept or are unstable containing two redundant mobility items. The first factor labelled "VIGOROUS ACTIVITIES" incorporates 15 items covering the tasks from performing vigorous activities, to doing housework to bending and kneeling. The second or more "BASIC ADL" factor covers 12 items from getting dressed to eating. The mean internal consistency reliability for the first factor measured with Cronbach's alpha was 0.93 with an average standardized item to scale coefficient of 0.65. All standardized item to scale coefficients were 0.53 or above (267).

The targeting of the items to the subjects in the sample (mean item measure: 0; SD: 1.5; mean person measure: 2.0; SD: 1.6 logits) appears adequate for a Rasch analysis. Convergence to the model was at 0.01. The overall fit of the data to the model was based on the global fit statistics in Table 3.4: an item–trait interaction statistic, a global item and global person fit statistic. The significant interaction seen in the item-trait statistic (χ^2 probability<0.0000) indicates that the level of difficulty of the items along the scale is not consistent across subjects and suggests that the items form neither a linear nor a unidimensional measure. The item fit residuals reinforce these observations (mean fit residuals: -0.5; SD: 1.96).

Disordered thresholds were observed for 9 of the 11 RNL items, five of the SF-36 PF items, and two of the BI items. The category responses were not ordered as expected from high to low; for example from "yes", to "partially", to "no" in the RNL. The category frequencies of these items were adequate suggesting that they should operate in an orderly fashion, but they did not (227;229). The subjects could only discern two response levels not three. All disordered items performed well when scored dichotomously. Rescoring for the RNL and PF scales was achieved by collapsing the category "1" into the lowest category and for the BI items with 4 categories by collapsing the response categories "1" and "2" into the lowest category.

Item Reduction

After rescoring the disordered items, the fit statistics were re-examined to select items for possible deletion. Based on the fit criteria of the model, the worst fitting items were removed iteratively until the best fit of the data to the model was obtained. After each deletion, the targeting between items and persons, the items' fit statistics and response options, were assessed. Deletion of the single item Quality of Life scale, (fit residuals: 0.43; χ^2: 62.35; df: 2; p<0.0000), resulted in a further disordering of the scale response options of two PF items and one RNL. These items were subsequently dichotomized.

A fit of the data to the model was achieved with the removal of 11 items. The order of deletion and fit statistics for each removed item is in Table 3.5. The global fit statistics for the measure with the remaining 28 items are an item–trait interaction χ^2 of 60.1 (df: 56, p > 0.33), and person and item fit residuals of -0.36 (SD: 0.7) and -0.36 (SD: 0.91), respectively. Both the Cronbach's alpha and person reliability index were 0.93 with person and item separation indices of 3.8 and 1.4, respectively (Table 3.4). One hundred and eighty one subjects were analyzed; the 23 subjects with perfect scores were not entered into the analysis.

The fit of the data to the measurement model was further improved by the deletion of a number of multidimensional and redundant items (Table 3.5). The fit residuals of the remaining items and all participants met the critical value of ± 2.0.

Structure of the measure

The distribution of persons and items across the measure of functioning is depicted in the three illustrations in Figure 3.1. The horizontal axes, scaled in logits, denote functioning from least functioning at the left to most functioning at the right. In the top portion of Figure 3.1, the vertical axis denotes the proportion of subjects or items. The bars represent the frequency distribution of subjects and items at each location. The item thresholds range from -7.36 logits for the toileting item to 5.35 logits for the vigorous activities item, while the average item difficulties ranged from -5.20 (SE: 0.37) to + 5.35 logits (SE: 0.37). The measure of individual person ability spans approximately 14 logits from the individual functioning at -8.6l (SE: 2.5) logits of ability to the individual with 6.4 (SE: 2.3) logits of ability. Forty-four percent (44%) of the subjects are centered above "0", the average item difficulty mark. The internal consistency and reliability of the ordering of individuals are Cronbach's alpha 0.87 and Person Reliability Index of 0.91, respectively. The separation index of 3.2 indicated the stroke subjects can be separated into 4 groups whose ability could qualify as: very high, high, moderate or low.

The middle section of Figure 3.1, displays the item map with the location of each response option (0, 1 or 2). The distance between the numbers indicates the spread of difficulty represented by each response option. The difficulty increases from left to right as the numbers increase. The short vertical line indicates the expected half-way point between any two response options, indicating that the person with an ability of that level has a 50% probability of responding either 0 or 1, or 1 or 2. These are the threshold points.

In the bottom portion of Figure 3.1, the relationship between the raw scores on the vertical axis, and the measure of functioning on the horizontal axis, is depicted by the curve. The raw scores are aggregated from the response options of the items and range from 0 to 18. The three vertical lines which extend through all three portions of Figure 3.1, indicate one subject with average functioning ability in logits (middle line), and the lower (left line), and upper (right line) bounds of the 95% confidence interval around that subject's ability. The person depicted on the graph has a mean ability of 1.73 logits (95% CI: 0.33 to 3.0). The raw score for this individual is 14 (out of a maximum of 18) which can be calculated by summing this person's actual responses that fall within the boundary lines and are shown by the star on the horizontal lines. For example, this individual successfully performed all but the last four items (housework, moderate activities, carrying objects and vigorous activities).

At the group level, subjects with abilities above 5.35 logits (n=24) could be considered to have reached the "ceiling" of this measure as they successfully performed even the most vigorous of activities. In contrast, there were only 2 people at the "floor" of this measure with a measure below -5.3 logits indicating difficulty getting to the toilet.

Properties of the measure

The measurement characteristics of the 12 items in Table 3.6, arranged by level of difficulty with the harder items at the top, establish that each item operates well with the others to define a continuum of functioning that can be used to quantify recovery. That is, all the item (mean standardized residuals: -0.43; SD: 0.98) and person (mean standardized residuals:-0.28; SD: 0.38 logits) fit statistics (non significant χ^2 and F-statistics) meet the requirements of the Rasch model. The precision with which the items measure functioning varies from 0.14 logit standard error for the central items to 0.37 logit standard error for the items at the extremes of the measure. Adjacent item thresholds are at least ± 0.2 logits apart indicating an effective spread of items, especially in the center (253). Although the items can be separated into 8 statistically distinct groups, the gaps in the measure (between logits 2 and 5 and between logits -5 and -3) limit the accuracy of determining functional ability between these points. Increasing the number of difficult and easy items would help improve the accuracy.

The least measurable difference (the difference in the measure that corresponds to a one unit increase in the score from 0-18, see Figure 3.1) is 0.4 logits at the center of the scale and 2.3 logits at the extremes (253). The difference in score of 1 or -5.89 logits of functioning and a score of 2 or -4.4 logits of ability is 1.5 logits, while the difference between a score of 10 and 11 is 0.4 logits, as seen on the item map in Figure 3.1. It takes more ability to improve on the measure at the lower and higher ends of the measure than in the middle. The relationship between the raw score and the measure of functioning increases monotonically with a correlation of 0.97 for person ability and 0.95 for the item difficulty.

The difficulty level of the functioning measure was uniform across stroke type, gender, age, health stroke severity and interview time. However, women tended to be more likely than men to endorse higher participation in recreational activities, and people with an ischemic stroke tended to report being occupied during the day more often than those with a hemorrhagic stroke.

Validity

The professionals agreed on a hierarchy of items forming seven ordinal levels of recovery ranging from 'normal recovery' to 'no recovery'. Table 3.7 lists, by level of agreement, the 25 items that at least 80% of the professionals agreed defined the highest category 'normal recovery' and the three items that 50% agreed were sufficient to indicate a person had recovered to 'normal'. The items cover a range of physical abilities and personal relationships. The cut-point for the highest level of recovery, normal recovery, was defined by summing the maximal score on all items in the five indices. Subsequent categories were defined according to the algorithm in Table 3.8.

The shaded items in Tables 3.3, 3.6 and 3.7 are those that are common across methods: factor analysis, Rasch analysis and expert opinion. The professionals included 9 of the 12 Rasch items in their definition of normal recovery, while the first two factors from the Factor Analysis included 11 of the 12 items from the Rasch analysis. The professionals did not agree that three of the items included in the Rasch and Factor Analysis indicated that a person had recovered to a normal level (RNL: Do you move around living quarters as you feel is necessary; RNL: Are you able to participate in recreational activities as you want to, and BI: Can you get to the toilet independently).

The hierarchy of the items in the Rasch Analysis and the factor loadings in the FA support the content validity of the abilities needed to measure functioning. The hierarchy indicates that basic ADL activities such as 'eating', 'bathing', and 'dressing', are easier than the participation item, 'traveling', and are easier than the physically demanding activities 'lifting heavy objects', and doing 'vigorous activities'.

The concepts of 11 of the 12 items contained in the measure of functioning are represented in the Brief ICF Core Set for stroke (walking, toileting, eating, washing and dressing) (197) and the Activities and Participation Comprehensive ICF Core Stroke Set (housework, lifting and carrying objects, moving around in different locations, using transport, recreation and leisure). This information supports the items' relevance for measuring functioning after stroke.

Unidimensionality

A factor analysis of the standardized residuals (238) (268) indicated that the total variance accounted for by the first principal component was 14%. The distribution of the variance was random in nature, though not as uniformly low as would be expected for a perfect unidimensional construct (257). Additionally, inspection of the inter-item correlations and Cronbach's α demonstrated that redundant information was minimal with only one residual inter-item correlation (between vigorous activities and the climb stairs items r: 0.4) above 0.2 and a Cronbach's α of 0.87.

The consistency of the hierarchy of the subjects' response patterns across all the items is supported by the adequate person reliability index (0.91), excellent person separation index (3.2) and the person fit statistics that meet the criterion value of ± 2 (range: 1.03 to -0.92). In addition, when the response pattern of each participant was checked for extreme standardized residuals, only 29% (n=52) of the subjects had values beyond the critical amount (range:-7.0 to 5.0) on any one item. The item to which most (n=22) subjects responded inconsistently was 'limited in vigorous activities' at a location of 5.35 logits. The internal consistency of each person's responses was reinforced by the excellent correlation (0.97) between the ability estimates for the person locations from the two subsets of items. The item reliability (0.97), and separation indices (5.8) are excellent and the fit statistics meet the criterion values. Both the person response pattern and item order are consistent enough to consider the measure valid (259) (214). The interpretability of the measure is increased by the item separation index of 5.8 indicating eight reliable, distinct item difficulty strata.

Discussion

A parsimonious set of items that measures the single construct, functioning, as defined by the ICF, was developed to quantify recovery after stroke. Because items and individuals are situated together on the same interval measure of functioning, the level of recovery of any individual can be established. The level would indicate which tasks an individual could perform and which tasks an individual still needs to accomplish in order to be considered recovered. Once the level of functioning is identified, therapeutic interventions or services can effectively be targeted.

The profile of functioning, as described in Table 3.2b, illustrates the difficulty when multiple indices are used to describe functioning. Summary scores across ordinal categories increase the ambiguity in understanding the exact nature of the lack of functioning or disability of an individual. For example, the average total RNL score (mean: 4.8; SD: 5.1), indicative of participation restrictions, can be obtained from various combinations of responses. Without an item by item analysis it is challenging to determine which tasks are problematic. We can estimate that the subjects, as a group, have restrictions in performing at least 5 community activities; or are unable to perform 2 of them and have difficulties with one. Based on the total score, however, the participation restriction any individual had is unknown. The same can be said for the total scores on the PF, and BI (264). The interpretation of the OARSIADL total scores, developed through Rasch analysis, is more transparent (234). The average score of 11.6 indicates that subjects functioned with enough ability to perform all but the top three tasks (housework, shopping and money management). Nonetheless, the OARSIADL, lacks important measurement properties in the scaling of its items, lacks ability to measure change, and does not cover a broad spectrum of functioning abilities (234).

The intent of our measure was to cover parsimoniously the broad range of functioning needed by stroke survivors, or as defined by the ICF core set for strokes 'what people after stroke need to do to lead productive and meaningful lives' (197). The item difficulty levels and the separation index of the 12 items point out the wide range of tasks (Table 3.4 and Figure 3.1). The items are not concentrated in any portion of the measure, but are spread across the continuum. This increases the capacity of the measure to differentiate levels of functioning. The item separation index reflects that the subjects could distinguish eight distinct levels of item difficulty. The higher the separation index the better the differentiation is between subjects and item difficulty, this in turn helps to improve the quantification of recovery and facilitates the measurement of change (269) (214). Sensitivity to change is an essential quality of any measure (203) and remains to be tested in this measure.

The functioning ability of 60% of the subjects is well defined. The tasks an individual can accomplish are evident from the total score. For example, using the conversion curve depicted in the bottom of Figure 3.1, a person with a score of 10 has a functioning ability of 0.0 logits and would likely complete successfully the 7 items below that location on the item map, would have a 50% chance of passing the 2 items located near zero, but would probably not be able to perform the top three items. The interventions needed to improve recovery in this individual can now be outlined and initiated.

A notable gap exists in the measure of functioning for those with a score above 17 or 2.5 logits; they would successfully complete all but the most vigorous of activities and probably have some difficulty traveling and or carrying heavy objects. The gap between the items 'carrying groceries' and 'vigorous activities' prevents therapists from determining the exact ability required to complete more complex tasks such as 'getting in and out of a car' or 'working' needed by the subjects at that high level. Additionally, as there are no tasks above 5 logits or a score of 18, the true ability of the 13% of subjects above this level can not be assessed. However, the professionals indicated that completion of this item represented normal recovery. It may be that the group able to perform even the most vigorous of activities without limitation should be considered fully recovered physically. They may, however, be disabled in other important areas such as cognition, endurance, or language abilities which would require other measures.

The implications of missing tasks in measuring functioning are more serious for the 25 % of the sample between 2 and 5 logits than for the 1 % at the lowest levels below -4.5 logits. The subjects at the high end are measured inadequately; the lack of items defining functioning at higher levels limits the ability of professionals to intervene to improve recovery for these persons. A definition for recovery of function has been a chronic problem in the measurement of functioning after stroke, especially for the higher functioning individuals. Duncan et al. (175) demonstrated this in a cohort of 459 patients followed for 6 months post-stroke. Recovery categorized as "successfully" or "not successfully" recovered, was assessed across a number of different outcomes. The rate and range of recovery between the various indices differed and the percentage of patients considered recovered depended on the index, and the cut-off point used. All the subjects in this (175) no matter what their level of functioning, valued higher levels of health as they were willing to trade upwards of 5 months to 3 years of their present life to improve their recovery. A categorical index of recovery limits the identification of levels of functioning and recovery that may be important to an individual. Optimal management of an individual's recovery requires the measurement of the full continuum of functioning.

In developing the measure of functioning, the items with disordered responses were rescored dichotomously. Disordered response categories can indicate confusing or poorly worded response choices, multidimensionality, or that an item is not relevant to the population (26) (226). Although dichotomizing response options can decrease the discriminative ability of an item, (270) increasing the number of response options or items does not guarantee improved discrimination, as demonstrated by Hobart et al. (71). They compared the responsiveness of two commonly used indices, the BI (71) (70) and Functional Independence Measure (FIM), via standardized response means (SMR). Despite large differences in the number of response levels (FIM has 7; BI has 3 or 4) and number of items (FIM has 29; BI has 10), the standardized response means were similar (FIM: SRM: 0.56; BI: SRM: 0.54).

Dichotomization of the five most difficult items in the measure of functioning was necessary to improve their fit to the model. The subjects could only discern the response categories 'limited a lot' and 'limited not at all' for these more difficult items. This may be a result of the wording of the items; for instance the hardest item 'vigorous activities' combines a number of tasks, 'running or participation in strenuous sports'. The wording to which the subjects responded is unknown. But the retention of this more difficult item extends the definition of functioning to include the 12 % of subjects who passed the next lowest item (lifting and carrying groceries). If the item were reworded and divided into component tasks, the discriminative ability of the measure could be increased among the most able, and the gap between the item 'carrying objects' and 'vigorous activity' might be bridged.

Rescoring of items did not improve the fit of all disordered items and they were subsequently deleted. The first 11 items deleted from the model for poor fit (Table 3.5) were those that covered the basic activities of daily living and community mobility. The ability of subjects to discern between the responses in some items may be related more to the content of the item than its discriminative ability (271). For example, the item requiring least ability, 'transfer from bed to chair' (difficulty level: -1.54 logits), did not fit the model (χ^2:13.19; p<0000). It could be considered irrelevant for functioning in this group of mobile survivors of whom only 7% were unable to walk independently. Additionally, the results of a study of community dwelling elderly (older than 85 years), demonstrated that feeding oneself and toileting tasks required less ability than transferring, and if unsuccessfully attempted, indicated the need for institutionalization (272) (273) (274).

The seven items with large negative residuals in Table 3.5 over discriminated the survivors' abilities and may have indicated a violation of statistical independence (135)

(275). This signifies subjects will tend to response in a similar manner to the stair and bath items from the BI and PF. The residual inter-item correlations for these items were greater than 0.5 and reinforced the concept of statistical dependency, and the necessity of item deletion.

Many of the basic self-care and mobility tasks in the indices (climbing stairs, walking, bathing and dressing) were similar. Yet, as the wording varied across the indices, the subjects may have perceived these items differently; the BI assessed independence, the IADL ability, the PF limitations, and the RNL satisfaction. The negative standardized fit residuals point more to a dependency in the responses than to a problem of multidimensionality. The high correlation seen in the factor analysis between the first and second factors (r: 0.56) reinforces the idea of statistical dependency between these sets of items as opposed to multidimensionality (Table 3.3) (276). Additionally, the Cronbach's alpha of the first factor is greater than 0.90 which can indicate there is item redundancy or that the scale is too narrowly focused to be a valid measure. Ideally, alpha should be between 0.7 and 0.9 (266).

Fifty percent of the items in the second factor, the 'Basic ADL' factor, were deleted for redundancy. The two BI ADL activities not covered by the other indices, 'feeding oneself' and 'toileting' were retained. They represent the bottom level of functioning and lowered the floor of the measure to include the most disabled of subjects. Deletion of the item 'toileting' would improve the targeting of the measure, but not allow the quantification of functioning in those subjects with the severest disabilities still living in the community.

Few IADL items are included in the measure of functioning (Tables 3.5 and 3.6). The OARSIADL has been Rasch analyzed, but only 3 of the seven items had adequate fit to the model (housework, taking medication and handling finances) (277) (278) (279). The only OARDIADL item retained, 'performing housework', is located in the center at 0.6 (SE: 0.14) logits, but was the most difficult item, at 2.36 (SE: 0.15), successfully completed by 51% of community dwelling elderly in a study validating the OARSIADL (234). The researchers felt the items needed four response categories not three to improve the fit (274). Yet in a recent study on aging, (272) the housework item, defined as heavy, did not fit the Rasch model even when the five levels of responses were dichotomized. It appears that people have trouble discerning more than two response levels in very difficult items. The light house work item in the same study fit the model and was located near the center of the measure of ADL/IADL. Housework is a broadly defined item and could have been perceived as easier in our subjects because of the lack of emphasis on the type of housework, presence of home help or a difference in conceptualization of the type of housework. The SF-36 item 'moderate activities' contains the household chore vacuuming as a moderate activity. This item was not deleted and is located almost 1 logit above housework reinforcing the idea of light house work as a definition here. The response options for items need to be clearly operationalized as a single task to measure the intended construct. The IADL item 'shopping' was deleted (standardized fit residuals: -2.66), as it may represent the cognitive abilities of handling money and the decision process in choosing purchases rather than the construct of functioning developed here. Deletion is supported by the factor analysis results as 'shopping' did not load on any factor (Table 3.3).

The large positive residual of the PF 'bending, kneeling, stooping' item (standardized fit residuals: 2.02), suggests the item is not part of the construct of physical recovery. This item may represent a construct dictated more by age related conditions such as arthritis (280) than abilities lost due to stroke. The unpredictable and variable response patterns of a large sample of Medical Outcome Study patients (n=3445) to this item were felt to be due to individual variations in ability from different chronic conditions (281) and poor wording. The item seems to perform differentially across populations with different disease characteristics and covers three tasks: bend, stoop, and kneel. Subjects may rate their functioning on one or all of these tasks leading to the observed variation in response patterns (281). The fit of the PF items to the Rasch model appears to depend on the sample (95) and how well the items fit the sample (280) (282). Despite this fact, the hierarchy of the PF items has been consistent with the 'vigorous activities' item being the most difficult and the 'bathing and dressing' item the least difficult, which is similar to that in Figure 3.1 (280). The deleted mobility items of the PF found to be redundant and statistically dependent in Table 3.4 were the same as seen by others (281) (282) (280).

All RNL items, except the item 'Do you move around living quarters as you feel is necessary', were dichotomized to fit the model. As was seen with the PF difficult items, the subjects were unable to discern a middle level of difficulty in the rescored items. The deleted items were either not part of the construct or were redundant. This is not unexpected as a factor analysis of the RNL has shown it may be tapping two constructs, an ADL/mobility and social/relationship one (84) (283). The three RNL items retained here were in the first factor with the fourth retained item loading on both factors, the item 'Are you able to participate in recreational activities as you want to?' (283). These three items extend the definition of functioning into the Participation component of the ICF.

Empirical ordering of the items by difficulty in Table 3.6 was consistent with theoretical assumptions supporting internal validity of the measure of functioning. The ordering of the ADLIADL items in Table 3.3 with the first factor containing the more difficult items and the second factor the easier items is similar to that in the literature (272) (284) (234). As the factor analysis reveals only the factor structure underling the pattern of the items, a Rasch analysis was used to provide an accurate estimation of the level of difficulty for each item; this property is required to actually measure functioning and subsequently to quantify recovery (238). Reliability or the reproducibility of the hierarchy is excellent, and both items and person reliability indices are above 0.90. This implies that the order of both the persons and items would be the same if repeated in similar samples. Additionally, the items did not differ across a number of subject characteristics. Self-reported perception of recovery can be affected by a person's level of previous health, age, lifestyle and other factors (86) (285) but, differential functioning across items was not evident in this set of items. Whether the survivors had already taken these factors into account in their self-report of ability on each item is not known, but could be suspected for age (286). Many of the subjects when asked a question responded with, "What do you expect for my age". Thus, they are already accounting for age in their responses. The small sample size may also be a factor. The homogeneity of the subjects in relation to their disabilities and their perceptions of functioning may not have differed across these 12 items, or it could mean that it is possible to develop a concept of recovery that does not differ across gender, stroke severity, or previous health. The time to interview post-stroke did not affect how the items functioned, but the cross sectional nature of the study prevents the testing of whether the perceptions of recovery changed over time with adaptation, and/or changes in ability (89) (287).

Content considerations are important in selecting items to include in a measure of functioning. Capturing a broad range of tasks is critical in the development and evaluation of interventions targeted to improve recovery post-stroke. It is challenging to select a parsimonious group of items that not only covers the components of the ICF, but also maximizes the spread of difficulty and minimizes measurement error. The areas most relevant to persons with a stroke are within the Comprehensive ICF core set for stroke and range from the body structures component of muscle power to participation in recreation and leisure activities. The measure of functioning developed here lacks body structure items. However, the items representing the body functioning component "strength" were found to form a separate construct in another measure assessing functioning (75).

The spread of item difficulty is 5.8 logits and reliably divides the items into 8 distinct strata. The items cover the abilities needed for basic mobility, self-care, hand function, recreation and physically demanding activities, all of which are important for independent community dwelling (234;272).

Limitations

The content of the measure on which the validity is assessed depends on the sample and items used to determine the measure. This sample although representative of a larger cohort of community dwelling survivors at six months (242) does not represent the full spectrum of stroke recovery. By design, all of the survivors were community dwelling, and not in nursing or long term care facilities.

The generalizabililty of the interpretation of the measure would be increased with the addition of items to both ends of the measure. The pool of items within the indices that defined recovery did not cover the full spectrum of the ICF classification of Functioning; missing items are from body structure and body function components. Our measure only contains items from self-report questionnaires. If these items were combined with capacity items, where a person's performance on a task is observed, it could expand the interpretation and difficulty level of this measure (288). The measure formed by combining these two types of items would then relate functioning to the essentials that both healthcare professionals and stroke survivors deem necessary.

The heterogeneous impact of stroke with its limitless number of deficits combines to form a portrait of a stroke survivor that may not be captured in a single unidimensional measure. The items deleted in Table 3.5 (continence, personal relationships, and cognition) require separate sets of measures to delineate the abilities required to define these constructs.

Although the targeting of the persons and items is only fair, the reliability and separation indices and fit statistics are more than adequate. The effect of off-targeting of item difficulty to person ability on the distribution of the fit residuals and the resultant psychometric properties of the measure has only recently being examined (289) and is as yet not fully understood.

The number of indices and data collected were limited and provide only a core set of items for an index measuring functioning. The addition and recalibration with items from other indices would broaden the range. Combining and co-calibrating items from indices that evaluate observed performance on tasks and self-report indices could increase the range of difficulty and ability and improve the measure's ability to assess change (288) (290).

Conclusion

The study has developed a 12-item prototype for measuring functioning that, after further validation, could be used as a prototype to quantify recovery post-stroke. The current prototype was validated qualitatively via expert opinion, and quantitatively with factor analysis and Rasch analysis on a representative sample from a number of clinical sites. The 202 subjects included those with both ischemic and haemorrhagic strokes who had a broad range of stroke severity. It forms the basis of a measure of functioning that needs to be retested to ensure the stability of the response categories and the sensitivity of the measure.

6 Table 3.1 The Index Characteristics, Scoring and Psychometric Properties

ICF Component (24)	Index	Items, responses and total score	Questionnaire content and responses	Psychometric properties
Not part of the ICF	Global quality of life (QOL) VAS (291)	VAS 0-10	How would you rate your overall quality of life?	**Reliability:** Inter-rater Reliability: α = 0.78, inter-rater rho=0.81 **Validity:** Construct Content
Participation	RNL (84)	11 items; 3-point scale; 2-0; Total Score range: 22-0	Participation in community and family activities, roles and relationships **Responses**; Yes, partially, no	**Reliability:** α =0.90 **Validity:** Concurrent Construct Content Predictive
Activity	*OARSIADL* (278) (279)	7 items 3-point scale; 0-2; Total Score range : 0-14	Household management, travel, use of telephone **Responses:** without help, with some help, completely unable	**Reliability:** test-retest 0.71 inter-rater 0.87 α = 0.72 -0.78 **Validity:** Concurrent Construct Content

Table 3.1 continued The Index Characteristics, Scoring and Psychometric Properties

ICF Component	Index	Items, responses and total score	Questionnaire content and responses	Psychometric properties
Activity	MOS SF-36 PF (292)	10 items 3-point scale; 1-3 Total Score range : 0-100	Vigorous, moderate, carrying, bending, stairs, walking, bathe and dressing activities. **Responses:** Not limited, limited a little, limited a lot	**Reliability:** α =0.92 Test-retest r=0.81 **Validity:** Concurrent Construct Content Predictive
Activity	Basic ADL BI (211) (264)	10 items: 2 items: 2-point scale 0,5; 6 items: 3 point scale 0,5,10; 2 items; 4-point scale; 0,5,10,15; Total Score range 0 -100	Feeding, hygiene, bathing, getting dressed, continence of bowel and bladder, transferring bed to chair and off the toilet, walk 50 yards, climb stairs. **Responses** Independent, needs assistance, (major or minor), unable.	**Reliability:** Inter-rater r = 0.88 – 0.99; α = 0.96 SRM = 0.99 **Validity:** Concurrent Construct Content Predictive

Abbreviations: BI, (Barthel Index of basic activities of daily living); IADL, (OARS), (Older Americans Resources and Services Questionnaire, Instrumental Activities of Daily Living); ICF, (International Classification of Functioning, health and Disease); MOS SF-36, PF, (Physical Function Scale of the Medical Outcomes Study Short Form-36 questionnaire); QOL, (Quality of life); RNL, (Reintegration in to Normal Living); SRM (standardized response mean).

7 **Table 3.2a Baseline Characteristics of the Subset and the Montreal Cohort Subjects**

	Subset (n=206)	Cohort (n=434)
Age at stroke onset, years		
Mean age ± SD	68.1 ± 11.9	69.2 ± 12.5
20-54 / 55-64 / 65-79 / ≥ 80 (%)	24 / 28 / 29 /19	14 / 18 / 47 /21
Men/Women	63 / 37	57 / 43
Discharge destination (%)		
Home / Rehab / Transferred	59 / 3 / 2	54 / 44 / 2
Ischemic/Hemorrhagic (%)	86 / 14	83 / 17
Length of stay in acute care (days)		
Mean ± SD	13.4 ± 10.5	15.8 ± 14.8
Stroke severity		
*Retrospective admission CNS		
Mean ± SD	4.8 ± 1.7	5.3 ±1.8
Mild/Mild-moderate/Moderate/Severe (%)	21 / 25 / 26 / 28	
Time of interview (%)		
3 months / 3 to 6 months / 6 to 9 months	36 / 35 / 29	
No. Comorbid conditions (%)		
0 / 1 / 2 / >2	8 / 23 / 19 / 50	

8 **Table 3.2b First Interview Results for the Subset and Montreal Cohort Subjects**

Indices	Mean scores ± SD	Subset (n=206)	Cohort (n=434)
QOL (VAS)	0-10	6.6 ± 2.3	6.8 ± 2.0
RNL	22-0	4.8 ± 5.1	4.4 ± 4.8
IADL (OARS)	0-14	11.6 ± 3.0	11.6 ± 3.2
PF	0-100	61.4 ± 30.7	63.4 ± 29.9
BI	0-100	92.2 ± 16.0	90.6 ± 17.5

* estimated from chart review according to scoring algorithm; best score: 8.5 and categorized as: mild: ≥6.5-8.5; 5≤mild-moderate <6.5; 4≤moderate <5; and severe <4. Abbreviations: BI, (Barthel Index of basic activities of daily living); CNS, (Canadian Neurological Stroke scale); IADL(OARS), (Older Americans Resources and Services Questionnaire, Instrumental Activities of Daily Living); PF (Physical Function scale of the Medical Outcomes Trust Short Form SF-36 questionnaire); QOL (VAS), (Quality of life, visual analog scale); RNL, (Reintegration to Normal Living); SD, (standard deviation).

9 Table 3.3 Factor Solution for the QOL, RNL, IADL, PF and Bl Items

Index	Items (39)	h2*	Factor loadings 4-factor solution			
			Vigorous activity	Basic ADL	Personal	Mob-ility
RNL	Are you able to take trips out of town	0.5	0.74			
IADL	Can you do your own house work without help (scrub floors etc)	0.7	0.68			
RNL	Are you able to participate in recreational activities as you want to	0.4	0.66			
IADL	Can you go shopping for groceries or clothes without help (assuming has transportation)	0.8	0.65			
PF	Does your health limit you in walking several blocks	0.7	0.64			
RNL	Do you move around your community as you feel is necessary (shopping banking)	0.6	0.64			
PF	Does your health limit you in lifting or carrying groceries	0.6	0.63			
RNL	Are you participating in social activities with family or friends as necessary or desirable	0.4	0.63			
PF	Does your health limit you in performing vigorous activities	0.3	0.59			
RNL	Do you spend most of your day occupied in activities that are necessary or important to you	0.4	0.57			
PF	Does your health limit you in climbing several flights of stairs	0.5	0.56			
QOL	Today how would you rate your quality of life	0.4	0.55			
IADL	Can you get to places out of walking distance	0.7	0.53			
PF	Does your health limit you in performing moderate activities	0.4	0.50			
PF	Does your health limit you in bending, kneeling or stooping	0.5	0.44			

Table 3.3 continued. Factor Solution for the QOL, RNL, IADL, PF and BI items

Index	Items (39)	h2	Factor loadings 4-factor solution			
			Vig-orous activity	Basic ADL	Personal	Mob-ility
BI	Could you Transfer from a bed to a chair independently	0.6		0.81		
BI	Can you go up and down stairs independently	0.8		0.79		
BI	Can you get to the toilet independently	0.6		0.78		
BI	If there was no one to help you with your personal hygiene, could you do it alone	0.6		0.73		
BI	If there was no one to help you with your feeding, could you do it alone	0.5		0.73		
BI	If there was no one to help you with dressing , could you do it alone	0.6		0.71		
BI	Can you walk 50 yards independently	0.6		0.68		
RNL	Do you move around living quarters as you feel is necessary	0.6		0.63		
BI	Can you Bath or shower independently	0.6		0.59		
PF	Does your health limit you in bathing or dressing yourself	0.7		0.59		
IADL	Can you take your medicine without help correct time and amount	0.5		0.56		
IADL	Can you prepare your own meals without help (plan and cook)	0.6		0.47		
RNL	In general, are you comfortable with your personal relationships	0.5			0.66	
RNL	In general, are you comfortable with yourself when you are in the company of others	0.5			0.65	
RNL	Do you feel you can deal with events when they happen	0.4			0.49	
RNL	Are you assuming a role in your family which meets your needs and those of your family members	0.5			0.47	
PF	Does your health limit you in climbing one flight of stairs	0.7				0.50
PF	Does your health limit you in walking one block	0.8				0.45
BI	Do you have trouble with bowel control	0.3				
RNL	In general, are you Comfortable with how your self-care needs are met	0.4				
BI	Do you have trouble with bladder control	0.3				
IADL	Can you handle money without help including handling check book	0.3				
PF	Does your health limit you in walking more than a kilo meter	del				
IADL	Can you use the telephone without help including looking up the number	del				
	Inter factor correlation (1,2)		0.56			
	Percent of variance explained		30.6	33.5	9.7	9.8

Abbreviations: BI, (Barthel Index of basic activities of daily living); del, (deleted); h2, (item commonalities); IADL, (Instrumental Activities of Daily Living); PF, (Physical Function Index of the Medical Outcomes Trust Short Form-36 questionnaire); QOL, (Quality of life); RNL, (Reintegration to Normal Living). The shaded items are those common across methods: factor analysis, Rasch analysis and expert opinion.

10 **Table 3.4 Summary of Global Fit Statistics for the Rasch Models**

	Full-item model (n=193)	28-item model (n=183)	12-item model (n=179)
ITEM-TRAIT INTERACTION			
Total Item Chi Square	243.27	60.10	27.77
Total Deg of Freedom	78	56	24
Total Chi Square Probability	0.00000	0.33	0.27
ITEM-PERSON INTERACTION			
ITEMS			
Difficulty	0.0 ± 1.55	0.0 ± 2.15	0.0 ± 2.76
Fit Residual	-0.50 ± 1.96	-0.36 ± 0.91	-0.43 ± 0.98
PERSONS			
Measure	2.04 ± 1.62	2.31 ± 2.25	1.73 ± 2.61
Fit Residual	-0.32 ± 1.04	-0.35 ± 0.75	-0.28 ± 0.38
RELIABILITY INDICES			
PERSONS			
Reliability Index	0.95	0.94	0.91
Cronbach's Alpha	Not applicable with missing data	0.93	0.87
Separation index	4.2	3.9	3.2
Strata	6.1	5.6	4.5
ITEMS			
Reliability Index	0.93	0.95	0.97
Separation Index	3.8	3.9	5.8
Strata	5.1	6.1	7.9
Power of Test- of- Fit	Excellent based on a Person reliability of 0.95	Excellent based on a Person reliability of 0.94	Excellent based on a Person reliability of 0.91

11 **Table 3.5 The Deleted Items, Order of Deletion and Reason For Deletion.**

Index	Item	Difficulty	SE	Fit Res	χ^2 (F)	Prob χ^2 (F)	Reason deleted
QOL*	Today how would you rate your quality of life	0.63	0.07	8.43	44.7	0.00	Fit
PF	Does your health limit you in bending, kneeling or stooping	1.33	0.13	2.02	18.32	0.00	Fit
IADL	Go shopping for groceries or clothes without help (assuming transportation)	0.37	0.15	-2.66	9.78	0.00	Fit
BI*	Can you walk 50 yards independently	-0.10	0.22	-2.44	5.4 (7.42)	0.06 (0.00)	Fit redundant
BI	Can you go up and down stairs independently	-0.89	0.18	-2.21	3.80 (4.3)	0.14 (0.01)	Fit/ redundant
BI	Can you Bath or shower independently	0.13	0.21	-2.13	11.02	0.00	Fit redundant
RNL*	Do you move around your community as you feel is necessary (shopping banking)	1.13	0.19	-2.22	4.5 (4.2)	0.11 (0.01)	Fit
BI	If there was no one to help you with your personal hygiene, could you do it alone	-1.02	0.26	-1.92	5.84	0.05	Fit
PF*	Does your health limit you in walking several blocs	2.06	0.18	-1.37	7.56	0.02	Fit
IADL	Can you prepare your own meals without help (plan and cook)	-0.07	0.16	-2.08	3.98 (2.7)	0.13 (0.06)	Fit
BI*	Could you Transfer from a bed to a chair independently	-1.54	0.30	1.34	13.19	0.00	Fit

Table 3.5 continued. Second Set of Deletions, Order of Deletion and Individual Fit.

Index	Item	Difficulty	SE	Fit Res	χ^2	Prob χ^2 (F)	Reason deleted
IADL	Can you take your medicine without help	2.46	0.23	-1.51	4.19	0.12 (0.02)	Fit
IADL	Can you get to places out of walking distance	-0.08	0.15	-1.82	4.23	0.12 (0.05)	Fit
PF*	Does your health limit you in walking one block	0.54	0.19	-1.80	3.87	0.14 (0.03)	Fit/ redundant
RNL*	In general, are you comfortable with how your self-care needs are met	-0.45	0.22	-1.64	3.70	0.15 (0.03)	Fit
PF*	Does your health limit you in climbing several flights of stairs	2.64	0.19	-0.85	5.73	0.05 (0.03)	Fit
IADL	Can you use the telephone without help	-2.04	0.27	0.34	6.26	0.04	Fit
BI	Do you have trouble with bladder control	-1.88	0.22	0.23	5.04	0.08	Fit
BI	Do you have trouble with bowel control	-4.19	0.33	-0.09	0.70	0.71	Discrim-
BI	If there was no one to help you with dressing, could you do it alone	-3.33	0.24	1.30	3.29	0.19	Discrim-
RNL*	Are you assuming a role in your family which meets your needs and those of your family members	-0.39	0.21	-1.34	3.72	0.15 (0.05)	Dim
RNL*	In general, are you comfortable with your personal relationships	-1.82	0.27	0.60	1.50	0.5	Dim
RNL*	In general, are you comfortable with yourself when you are in the company of others	-1.77	0.26	-0.11	6.21	0.04	Fit Dim
PF*	Does your health limit you in walking more than a kilo meter	1.72	0.18	-0.25	0.751	0.67	redundant
RNL*	Do you feel you can deal with events when they happen	-0.807	0.21	0.11	1.62	0.45	Dim
RNL*	Are you participating in social activities with family or friends as necessary or desirable	1.19	0.18	0.96	2.311	0.31	redundant
IADL	Can you handle money without help including handling check book	-1.82	0.19	0.33	3.84	0.15 (0.07)	Dim

*Items rescored dichotomously 0, 1.

12 Table 3.6 Characteristics of the Items in the Prototype Measure of Functioning

Index	Item	Difficulty	SE	Fit Residual	+ χ^2	F-statistic
PF	*Does your health limit you in performing vigorous activities	5.35	0.37	-0.43	0.84	0.35
PF	*Does your health limit you in lifting or carrying groceries	1.91	0.19	-1.18	4.18	2.96
RNL	*Are you able to take trips out of town	1.70	0.19	-1.08	0.94	1.25
PF	*Does your health limit you in performing moderate activities	1.41	0.19	1.20	0.44	0.05
RNL	*Are you able to participate in recreational activities as you want to	1.09	0.19	1.60	6.69	2.94
IADL	Can you do your own house work without help (scrub floors etc)	0.60	0.14	-1.49	4.34	2.71
RNL	*Do you spend most of your day occupied in activities that are necessary or important to you	0.50	0.19	-0.32	3.02	1.59
PF	Does your health limit you in climbing one flight of stairs	-0.28	0.15	0.28	0.93	0.05
PF	Does your health limit you in bathing or dressing yourself	-1.42	0.18	-1.20	3.39	1.66
BI	If there was no one to help you with your feeding, could you do it alone	-2.58	0.23	-1.05	1.43	0.29
RNL	Do you move around living quarters as you feel is necessary	-3.06	0.25	-0.87	0.64	0.00
BI	Can you get to the toilet independently	-5.22	0.39	-0.70	0.92	0.52

Items are listed in order of difficulty and shaded items are common across methods: factor analysis, Rasch analysis and expert opinion. * Items scored 0, 1 SE, (standard error). Degrees of freedom for: Fit residuals: 162.7; χ^2 (Chi-square):2; F-statistic: 176. +Bonferroni corrected significance level $p < .002$. Index abbreviations as in other tables

13 **Table 3.7 The Items Chosen by Health Care Professionals**

Item	statement	score	agreement
*PF	*Does your health limit you in performing vigorous activities*	3/3	100
*PF	*Does your health limit you in climbing several flights of stairs*	3/3	100
PF	*Does your health limit you in walk more than a kilo meter*	3/3	100
IADL	*Get to places out of walking distance*	2/2	96.3
PF	*Does your health limit you in performing moderate activities*	3/3	96.3
PF	*Does your health limit you in lifting or carrying groceries*	3/3	96.3
PF	*Does your health limit you in bending, kneeling or stooping several blocks*	3/3	96.3
PF	*Does your health limit you in walking*	3/3	96.3
*RNL	*Do you spend most of your day occupied in activities that are necessary or important to you*	2/2	92.6
PF	*Does your health limit you in climbing one flight of stairs*	3/3	92.6
PF	*Does your health limit you in walk one block*	3/3	92.6
PF	*Does your health limit you in bathing or dressing yourself*	3/3	92.6
RNL	*In general, are you comfortable with your personal relationships*	2/2	88.9
IADL	*Can you use the telephone without help including looking up the Number*	2/2	88.9
IADL	*Can you do your own house work without help (scrub floors etc)*	2/2	88.9
RNL	*Do you move around your community as you feel is necessary*	2/2	85.2
RNL	*Are you able to take trips out of town as you feel is necessary*	2/2	85.2
RNL	*In general, are you comfortable with yourself in the company of others*	2/2	85.2
IADL	*Can you go shopping for groceries or clothes without help (assuming has transportation)*	2/2	85.2
IADL	*Can you prepare your own meals without help (plan and cook)*	2/2	85.2
BI	*Do you have trouble with bladder or bowel control*	10/10	85.2
RNL	*Are you assuming a role in your family which meets your needs and those of your family members*	2/2	81.5
BI	*If there was no one to help you with your feeding, could you do it alone*	10/10	81.5
BI	*If there was no one to help you with your personal hygiene, could you do it alone*	5/5	81.5
BI	*Can you go up and down stairs independently*	10/10	81.5

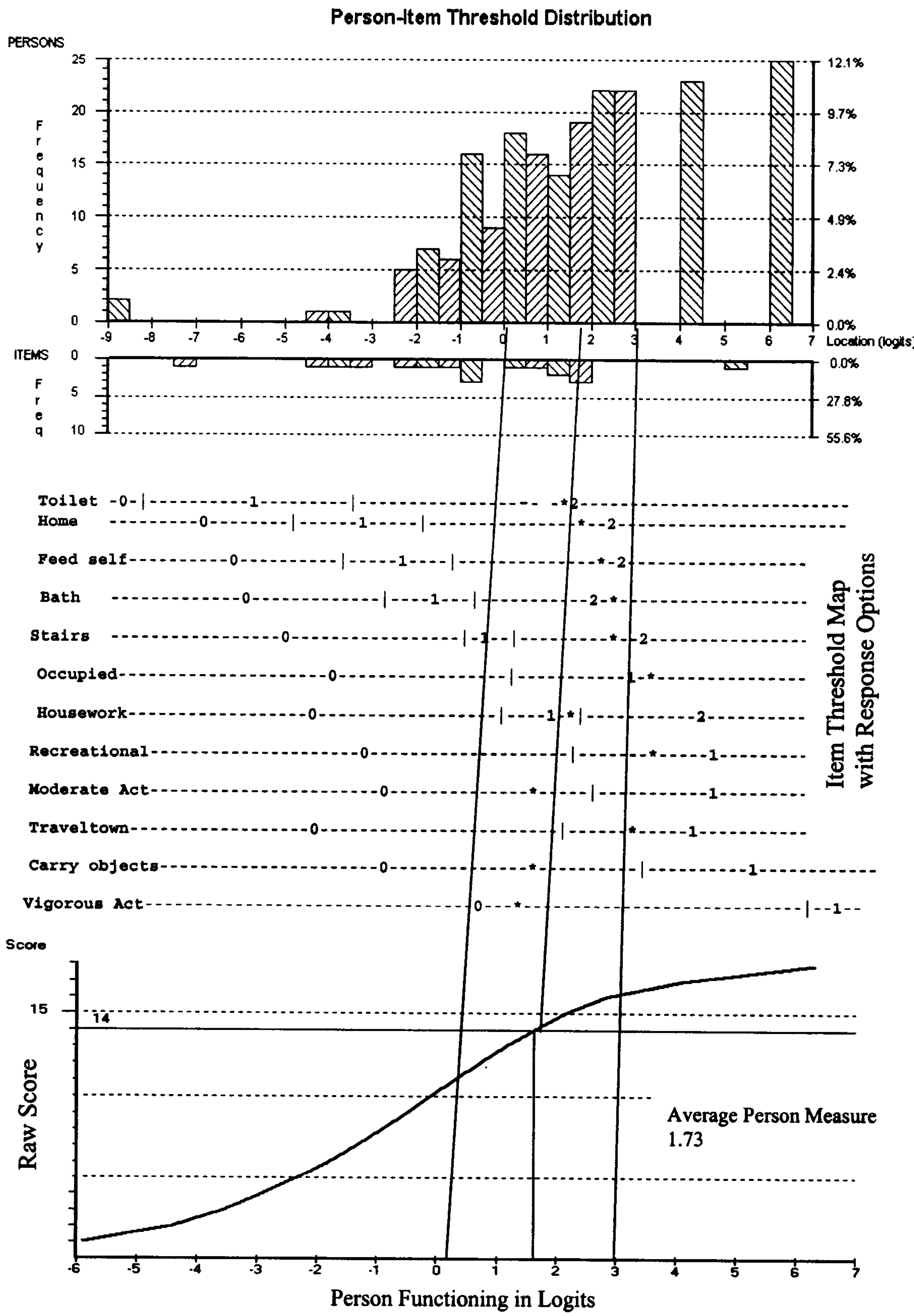
*Items chosen as sufficient to define normal recovery. The shaded items are those common across methods: factor analysis, Rasch analysis and expert opinion. Abbreviations are as in other tables.

14 **Table 3.8 Cut Point Algorithm**

FUNCTIONAL OUTCOME*	*0*	*1*	*2*	*3*	*4*	*5*	*6*
	BEST	→					WORST
N (%)	7 (3)	26 (12)	55 (27)	55 (27)	32 (16)	19(9)	11(5)
VARIABLES							
QOL (VAS)	10	<10	<10	<10	<10	<10	<10
RNL	0	1-2	3-4	5-7	8-11	12-15	16-22
IADL	14	13	12-11	10-9	8-7	6-5	4-0
PF	100	99-95	94-78	77-68	67-55	54-30	29-0
BI	100	99-95	94-78	77-68	67-55	54-30	29-0

*Cut points were determined defining the ordinal categories of recovery based on the standardized value (from 0-100) of the items per index chosen by the professionals.

Abbreviation: BI, (Barthel Index of basic activities of daily living); IADL, (Instrumental Activities of Daily Living); N, (number); PF (Physical Function scale of the Medical Outcomes Trust Short Form-36 questionnaire); QOL (VAS) (Quality of life, visual analog scale); RNL (Reintegration to Normal Living).



4 Figure 3.1 The Distribution of Persons and Items in the Measure of Functioning.

Figure 3.1 Legend The horizontal axes, scaled in logits, denote functioning from least functioning at the left to most functioning at the right.

In the top portion of Figure 3.1, the vertical axis denotes the proportion of subjects or items. The bars represent the distribution of subjects and items at each location.

The middle section of Figure 3.1, displays the item map with the location of each response option (0, 1 or 2). The items are ordered from top down by difficulty with the most difficult at the bottom. The stars represent the responses on an item by a subject with an average ability of 1.73 (SE: 0.28) logits

In the bottom portion of Figure 3.1, the relationship between the raw scores on the vertical axis, and the measure of functioning on the horizontal axis, is depicted by the curve. The raw scores are aggregated from the response options of the items and range from 0 to 18. The three vertical lines which extend through all three portions of Figure 3.1, indicate one subject with average functioning ability in logits (middle line), and the lower (left line), and upper (right line) bounds of the 95% confidence interval around that subject's ability.

Chapter 4 Manuscript 2: *A Measure of Functioning to Define Stroke Recovery at Three Months.*

Preface to Manuscript 2

The first manuscript determined if items from the activity and participation component of the ICF could be combined through a Rasch analysis to form a single interval measure of functioning to quantify recovery. The prototype measure of functioning combined ADL, IADL and participation indices, but, by not including the impairment component of the ICF, it was limited in scope. Additionally, all the items were from patient self-report questionnaires, where an individual rates his or her own performance. Self-report items add value to any measure, but when complemented by indices with items that rate observed performance (called capacity in the ICF model) this can improve the measurement of a construct. Although self-report and observed performance items evaluate similar constructs, the correlations between these two different forms of assessment vary from 0.38 to 0.61 (288).

Recent research has indicated that by combining the two forms of evaluation the categorization of physical function is improved (293). In a large cohort of community dwelling elderly (n= 4611), self-report measures demonstrated a ceiling effect in the higher functioning subjects. But cross categorized, using both self-report items from ADL indices, and observed performance on four impairment measures, allowed better classifying of the high level individuals and refined the prognostic information on mortality (293).

In another study, recovery varied considerably when the change in functioning over time in 93 subjects, post-joint replacement, was compared using the two types of assessments. The difference was thought to be related to the information provided from self-report indices. The self-report indices provided information about the patient's experience with the task, while the information provided from the observed performance indices reflected on how the task was completed (290).

Clinicians usually gauge recovery from observation of specific tasks mainly at the impairment level such as: gait speed, grip strength, and return of voluntary movement or by forming a global impression largely based on their clinical experience (294) (295) (296). If health care providers are to judge what recovery is and what stroke survivors report as meaningful recovery, both types of information will be needed.

This sets the stage for manuscript 2, where the objective is to develop a comprehensive, parsimonious measure of functioning quantified through interval scaling properties that incorporates all the concepts of functioning within the ICF framework; a measure that can be used to define recovery three months after stroke.

A longitudinal prognostic study was carried out with the subjects evaluated on both types of indices within three days of their stroke and again at three months.The manuscript defines the development, through Rasch analysis, of a 44-item measure of functioning at three months, the F3m. Based on the total score from this measure recovery could be determined at three months across the full spectrum of functioning as outlined by the ICF. The following manuscript is to be submitted to the *Archives of Physical Medicine and Rehabilitation.*

Title Page

Title: A Measure of Functioning to Define Stroke Recovery at Three Months.

For submission to: Archives of Physical Medicine and Rehabilitation.

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Keywords: Rasch analysis, Functioning, Stroke recovery, ICF

Abstract

Measuring a person's ability to function independently is part of a standard evaluation for stroke. More than 100 indices measuring functioning exist; few capture the spectrum from basic activities to participation. Additionally, items can be irrelevant, redundant, or exhibit floor and ceiling effects. Rasch analysis has been used to develop and combine items from functioning indices into one measure.

Purpose: To develop a parsimonious measure of functioning for persons with stroke using Rasch analysis.

Methods: A study involving 235 people with stroke was performed with assessments at three days and three months post-stroke using 14 indices with 264 items. Data on influencing variables were also collected. For this study, the data at three months post-stroke were used.

Analysis: Two statistical methods; Factor analysis and Rasch analysis confirmed the factor structure, and dimensionality of the measure. Items were deleted iteratively based on fit and relationship to the construct. Fit statistics confirmed the fit to the model: reliability was also assessed.

Results: A 44-item unidimensional functioning measure, the F3m, resulted. All items and persons fit the model with a reliability of 0.96 indicating a stable person-item hierarchy, and standard errors of 0.51 and 1.2 logits per item and person, respectively.

Conclusion: A reliable functioning measure was developed that can assist in directing and assessing interventions.

Introduction

Functioning or the ability to perform tasks necessary for daily living, leisure, vocational and societal interactions (93) is the predominant area of concern in rehabilitation (192) (193) (194) (22) (195). The assessment of an individual's level of functioning provides a portrait of the whole person and acts as the starting point in the evaluation of that individual's needs. A functional assessment is especially meaningful for a person who has had a stroke, as once assessed, the necessary interventions that aid in returning functioning to its former level can be put in place. What constitutes functioning differs across patients, professionals, families, and caregivers (183) (184) (297) (185) (186) (240). Professionals and caregivers gauge functioning by observing how a stroke survivor accomplishes specific tasks. Stroke survivors measure functioning compared to what they did in their pre-stroke life (18), hence equating functioning and recovery. Recovery means getting back to a previous level and is considered a dynamic process. Quantifying recovery requires a mathematical comparison of a stroke survivor's current and pre-stroke state.

Not all tests or indices used to assess functioning are capable of quantifying recovery. A change in the capacity to perform a test such as a "walking test" is easily quantified as the units of measurement are meaningful. These tests often reflect the health professional's perspective of recovery more than the individual stroke survivor's perspective. While stroke survivors are happy to walk faster, they want their perspectives of their performance captured in a way that reflects their functioning and recovery measured in units that are interpretable and meaningful (298).

An additional problem arises because functioning being such a vast concept requires numerous tests and indices to define (195) (93). The scope of functioning has been outlined by The World Health Organization (WHO) International Classification of Functioning, Disability and Health (24). The ICF framework describes functioning and its antithesis, disability. Functioning includes two components, 1) body functions and structures, and 2) activities and participation, while disability refers to impairments of body structures and functions, limitations of activities and restrictions to participation. Body functions are the physiological expressions of body systems, body structures are anatomical parts of the body, organs limbs etc while impairments are deviations in either.

Activities are tasks or actions an individual performs. Involvement in life situations is considered participation. The ICF qualifies functioning based on environmental context, with capacity qualifying tasks done in a standard environment without assistance, and performance qualifying tasks in the person's natural environment. What is needed is a measure that synthesises functioning from both perspectives, the health care professional and the person with the stroke that covers all the ICF components suitable to quantify change(92) (18).

A method of combining items from different indices is Rasch analysis. This analysis is focused at the item level and provides criteria by which to judge whether items from different sources fit together to define a unidimensional construct, such as functioning. In addition, it transforms ordinal observations onto an interval scale with the logit, or the log odds ratio of the probability of success relative to the probability of failure, as the unit of measurement (253). This property allows for the addition of item responses into a summary score that is sufficient to define functioning for a person (206) (26).

Numerous measures, (299) (300) both disease specific (301) and generic (234) (302) (272), have combined items from basic and more advanced activities of daily living indices, but (303)few have incorporated items that score observational tasks such as tests of capacity(134). A measure that combines observational and self-report sets of items across the ICF domains is needed to incorporate both the reality of performance and the perceptions of the person.

Objective

The object of this study is to develop a comprehensive, parsimonious measure of functioning quantified through interval scaling properties and conceptualized by incorporating the concepts of functioning within the ICF framework- a measure that can be used to define recovery three months after stroke.

Methods

This is a longitudinal prognostic study of patients admitted to an acute hospital following a cerebrovascular accident using the World Health Organization definition: "rapidly developing clinical signs of focal (or sometimes global) disturbances of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin"(33). Subjects were evaluated within three days of their stroke by observing their performance on tasks and by the self-ratings of their own performance on the Stroke Impact Scale (209). They were reassessed at three months using the same tasks complemented by self-report indices gauging their perceptions of their own activities and participation.

Persons were excluded if a diagnosis of stroke was not confirmed by imaging or clinical examination within 24 to 72 hours. Additionally, persons were excluded with the following: transient ischemic attacks, admission to hospital more than 72 hours after stroke, hemiplegia resulting from non-vascular causes, subdural hematoma, or subarachnoid haemorrhage, those with severe illness, such as end-stage cancer, pulmonary, cardiac or renal disease, those with severe cognitive or severe comprehension impairments and those persons in an altered state of consciousness at 72 hours as a result of their stroke.

For this study, only the data from subjects that responded to both set of items at three months were used in the analysis. The study had ethical approval from McGill University Institutional Review Board and from the Research Ethics committees of all participating hospitals

Indices of Functioning

The measure of functioning, the F3m, at three months was created from the items from 14 multiple tests and indices commonly used to assess the impact of stroke, as well as interviews on health related quality of life. The indices and their characteristics are found in Table 4.1a. Continuous measurement scales were used in 4 (grip strength, Box and Block, walking speed, and the Two Minute Walk test) of the 14 indices. These had to be converted to ordinal scales for incorporation into the Rasch Model. The categories based on age and gender norms and the relationship of the specific category to every day tasks are shown in Table 4.1b.

Trained healthcare professionals carried out all evaluations at three days and three months after stroke. The evaluation procedure lasted 1.5 to 2 hours.

Socioeconomic data and information on potential influencing factors were also collected via interview and included: age, gender, level of education, living arrangements, comorbid conditions(304), type of stroke, and cognition (305) (306). Data on the type of stroke were obtained from the neurological and radiological reports. The previous level of health of individuals was categorized into four groups based on the weights in the Charlson Comorbidity Index: 0; 1; 2 or 3; >3. The index weights are determined by the severity and number of comorbid diseases (304). Age was categorized into 4 groups (< 65 between 66 and 75, between 76 and 85, and > 86 years).

The strokes were classified as ischemic or hemorrhagic. Stroke severity was classified, based on the Canadian Neurological Stroke Scale (CNS) (250) scored from 1.5 (most severe) to 11.5 (least severe), into four groups: Very Mild with a score > 11; Mild a score between 9.5 and 11; Moderate a score between 9.5 and 5; and Severe < 5 (251) (252).

Analysis

Ratings from 235 subjects on 112 self-report items and observations on 155 tasks were available for analysis. Two methods, principal component analysis (PCA) and Rasch analysis, were used to combine the items. The aim was to create a parsimonious list of items to measure functioning, as conceptualized by the ICF, ultimately to be used to quantify levels of functioning for recovery. Descriptive statistics were used to characterize the population, and analysis of variance, χ^2 and t-tests tested the differences between groups as necessary.

Due to an administrative error, data from 12 subjects on the EQ-5D were missing. The data were replaced by imputed values using a logistic regression model with the monotone predicted mean matching method (SAS v9.1). This method imputes values randomly from data whose predicted values are close to the predicted values for the missing variable (307) (308). The two EQ-5D means, one without replacements and one with the imputed data for the EQ-5D, did not differ significantly (n=223: mean: 63.08; 95% CI: 60.2-65.9; n=235: mean: 62.4; CI: 60.1-65.5). Although the benefits of a Rasch analysis are that any item's response can be estimated for any person (253) (231), missing data in a PCA are problematic.

To identify the number of dimensions within the physical construct of functioning, a PCA was performed through the FACTOR procedure in the statistical analysis software, SAS 9.1 (SAS institute, 100 SAS Campus Dr, Cary NC 27513) (205). As would be expected from indices with items covering the same constructs there were 30 pairs of items with inter-item correlations greater than 0.80. Although the assumptions underlying the PCA (normality, presence of outliers, multicollinearity, and factorability of the correlation matrix) were not met, and the number of items, type of data (ordinal) and sample size were inadequate, this approach helped to identify and understand the number of dimensions underlying the construct (165).

We used the PCA approach to triage items clearly not related to functioning or that were correlated at greater than 0.95 with other items: 9-items from the SIS emotion domain, and from the SF-36, five mental health items, four vitality items, four general health items, the past ratings of health item as well as four of the nine sensory items, and the seven CMSA shoulder pain items. These items were deleted and not carried forward to the Rasch analysis.

A Rasch analysis was conducted next to combine the remaining 233 items into a single measure and further confirm the factor structure, item hierarchy and dimensionality. The outcome of a Rasch analysis, when the data fit the model, is a unidimensional measure in which items and people are organized hierarchically, by difficulty and ability respectively, on the same measurement scale in natural logarithm linear units or logits. An extended logistic Rasch model (26) using the Rasch Unidimensional Measurement Model program (RUMM 2020) (254) was judged the most appropriate for fitting the data, as the number of item responses and their meaning differed across the various indices (228) (231).

Two CMSA items that no one responded to were deleted (253) because a Rasch analysis does not use items to which all or none of the subjects respond or persons that successfully pass or fail all the items, as neither provide information about difficulty or ability, respectively. The remaining 231 items were co-calibrated using the concurrent calibration method (195). The Rasch model's key requirements of unidimensionality and invariance, meaning that all the items must measure the same construct and in a similar manner across persons with different characteristics, were assessed by fit statistics, item characteristic curves (ICCs), a PCA analysis of the Rasch model item residuals, and category characteristic curves (268) (217) (309) (219) (220). An additional criterion for model precision is that the difficulty level of each item's response option should be ordered; (229) (208) (217) the items that were disordered were thus, rescored. After rescoring of items (as necessary), all fit statistics, the standardized residuals, χ^2 and F-statistic, were considered in the investigation of item fit (215) (219). Fit statistics are available for overall model fit, and for each item and person. Item fit criteria were set as follows: standardized fit residuals between the boundaries of + 2.0 and –2.0 and a non significant χ^2 or F-statistic. Person fit is judged by standardized fit residuals between the boundaries of + 2.0 and –2.0 and global model fit by a non significant χ^2 item-trait interaction. Precision of the items and persons as well as reliability, separation indices and the number of distinct measurable strata separated by 3 standard errors defined by the data for items and persons were calculated (214) (257).

How precisely an item can estimate a person's ability is measured by the item's information function, derived as the inverse of the item standard error squared. The information function delineates the range over which an item is most useful for defining person ability and when all item information functions are summed a Test Information Function results (235) (310) (311).

The response patterns of the participants should agree with the difficulty level of the items. The quality of each person's response pattern was evaluated through person standardized residual fit statistics with a critical value of ± 2.0 indicating appropriate fit. In addition, the data were divided into two subsets and the concordance between the person locations on each subset estimated, as if the participants had responded to two different tests of the same construct. The level of agreement between the two person ability locations provides an indication of the internal consistency of person ability (25) (208).

The statistical independence of the items, that is, the concept that the responses are based solely on ability and not on the person's response to other items, was assessed by inspection of Rasch residuals inter-item correlations. Statistical independence is defined by a residual inter-item correlation less than 0.3, items that correlate with each other greater than >0.3 are often redundant. The removal of redundant items, those with same difficulty level and content, was based on their association to the construct and their precision.

Differential Item Functioning

Once the data from items, response categories, and persons were judged to fit the model, a two-way analysis of variance was used to determine whether the items' location were stable (DIF) across the different influencing variables (gender, age, stroke severity, and previous health) (258) (260). For the DIF analysis the participants were divided into four groups of roughly equal ability and then by the influencing variable within that group. The difference in the level of difficulty per item was assessed across the groups using a two-way ANOVA (215) (261). The significance level was adjusted for multiple comparisons by a Bonferroni correction (262) (26) (226).

To further test the stability of the person measures, the items were randomly divided into 2 separate instruments and the correlation of the measures examined; a high correlation between the two would indicate the invariance of the measure.

The sample size needed for stable person and item estimates (within ± 0.5 logits at the 95% confidence level), based on an expected standard error level of ± 0.1 in the measure is 200 (263) taking into consideration a fair targeting of items to persons (309).

Validity

Content validity

Content validity subsumes the idea of increasing levels of functioning. Thus, the extent or spread of the items and participants along the measure confirms the breadth of the functioning concept and allows the identification of individual differences.

Construct validity

Measures developed with Rasch methodology are considered valid if the data fit the model (214). Validity is reinforced by a stable hierarchy of items and persons consistent with the theory of the underlying construct. The theoretical model here is the ICF construct of functioning: that is, the items capturing observed performance and self-ratings of performance should proceed from easier to harder tasks; from easier body function items to basic activities items to advanced activities and to harder participation items; from simple to complex tasks and from tasks requiring increasing strength, motor control and integration of body functions. An example follows, bending the knee while lying is easier than in sitting, which is easier than walking in the house, which is easier than walking in the community. Finally, participation is facilitated by walking in the community that requires strength, motor control, and balance and is often a person's goal (34).

As a gold standard does not exists against which to compare this measure of functioning, divergent and discriminative approaches were used. For convergent and divergent validity, it was hypothesised that the correlations between the raw total F3m scores and the total scores from the indices measuring the more physical aspects of functioning, set out in Table 4.3a and 4.3b, would be higher (0.7 or greater) than the correlations between the emotional aspects of functioning measured by the SIS domains of emotion, and memory or the Mental Health Index of the SF-36 (0.4 or less). As the measure of functioning could incorporate items from the measures, the correlations were expected to be much greater between functioning and the indices or domains assessing the physical aspects of functioning

The recovery of functioning ability is known to vary across levels of stroke severity (304). A general linear model with post hoc t-tests examined if the Rasch measure of functioning could discriminate between subjects across the four levels of stroke severity as measured by the CNS (251) (252).

Results

A total of 1216 patients was screened at three days post-stroke for entry into the study, of these 262 accepted to participate, 77 refused and 877 were excluded; 89% of eligible participants were assessed at 3 months (10 died, 10 refused, 4 moved, 1 was lost to follow up and 2 had an accident). Figure 4.1 illustrates the screening process, participants and reasons for exclusion. Of the 235 evaluated at 3 months, 89% were assessed within 3 months ± 10 days, and 11% were evaluated at 4 months. There were no differences between the groups, the one assessed on time and the other later, and the data were merged.

Table 4.2 lists the baseline characteristics of the participants. The average age of the subjects was 71.6 (SD: 12.5); they were predominately male (62%), and lived at home (94%) with their families (59%) prior to their stroke. Seventy nine percent sustained a first stroke, 86% of which were ischemic and 41% of the subjects had a moderately severe stroke. Their median hospital length of stay was 11 days (mean: 15.9; SD: 20.9), the majority were discharged to rehabilitation (53%) or home (39%) and at the time of the three month interview, 75% were at home, 9% still in rehabilitation, 2% in a residence, and 13% in long term care.

Table 4.3a presents the results of the observed performance on tasks at 3 months. The overall impairment of movement is seen in the total STREAM (mean: 83.5; SD: 22.9) and CMSA scores (mean: 34.3; SD: 7.6). Impairment in lower extremity movement is illustrated by the average lower extremity STREAM score of 85 (SD: 24). The leg appears more recovered at CSMA stage 6 out of 7, than the foot at stage 5. The subjects varied greatly, yet close to 30% of the subjects reached the top leg CSMA stage, considered normal for the leg and foot and 45% achieved the top STREAM leg score; less than 3% had no movement. Impairments beyond movement are seen in the distance walked for two minutes, 91 meters (SD: 8.1) (approximately 40% of expected age and gender norms (312)), and average walking speed of 0.76 m/s (SD: 0.5) (6% of normal for this age group (313) (314)). Further indications of impaired mobility are reflected in the number of subjects using walking aids (28%), the STREAM mobility score (mean: 77.7; SD: 26.1) and balance score (mean: 43.4; SD: 16). The self-report of mobility performance was 71 (SD: 28.8) out of 100 on the SIS mobility domain score.

The impairments of upper extremity movement are reflected in the upper extremity STREAM score (mean: 87; SD: 25.6), and CSMA arm and hand stages. Shoulder pain was absent in 69% of the subjects and 2% had 'constant shoulder and hand pain'; sensation was poor in 41% of the sample. Functioning of the arm and hand appear similar at CSMA stage 6. Although upper extremity impairments varied, fewer than 3% were without hand or arm movement. Better upper extremity ability is seen in hand strength and dexterity. While 92% of the subjects were below the dexterity norms of 67 blocks in the B&B test (less affected hand: mean: 46; SD: 14 blocks) (315) (316), hand strength was close to the norms for persons older than 75 (317) (less affected hand: mean: 26.6; SD: 1.1

kg) (318). The degree of impairment is related to hand use, (319) (320) but a decrease in impairment does not always translate into better perceived or real performance on tasks. The impairment items may not have been hard enough to match the ability required by the hand use items. The subjects rated their ability to use their hands in activities such as cutting, lacing shoes, picking up a dime or carrying objects as 63.8 out of 100 (SD: 37.5) in the SIS hand domain(209). The ceiling and floor effects in the hand measures in Tables 4.3a and 4.3b make it difficult to discern the capacity and performance of the best or worst performers.

Also shown in Table 4.3a are impairments beyond voluntary movement. For example, perceptual neglect is present in 6% of the subjects. Few subjects had difficulties with basic cognitive functions (MMSE: mean: 19.1; SD: 3.3) and most rated their memory (mean: 87.3; SD: 18.1), communication and thinking (mean: 91; SD: 15.3) performance highly in those SIS domains. This reflects the study's inclusion criteria of mental competency.

Table 4.3b points out the integration of complex capacities required to perform activities and to participate in the community as reflected in the subjects ratings in the PBSI total score (mean: 67.7; SD: 21) and the SF-36 social functioning domain (mean: 62.1; SD: 31.2). The overall health-related quality of life of these subjects is significantly below Canadian norms in all SF-36 domains except pain (265). The persistent effects of stroke, similar to other studies (88), are reflected in the SIS domains of strength, hand function, participation (mean 56.6: SD; 31.9), and the physical function domain. Society's perception of the health state of these subjects is in the EQ-5D index score in Table 4.3b, while the PBSI and EQ-5D VAS reflect the subjects' perceptions; as to be expected, the subjects value their health state more than society does.

Data structure

The first principal component of the PCA was responsible for 40% of the variance (276) and is indicative of an underlying non linear unidimensional factor structure (165) (268).

Before a full Rasch analysis was carried out, disordered response thresholds in the majority of the polytomous items revealed by the analysis were rescored. Inadequate low category frequencies, less than 10 subjects, in a number of response options were evident in the following: EQ-5D and SIS recovery VAS items, the majority of the SIS items, SF-

36, Balance Scale, and STREAM, walking speed, Two Minute Walk test, grip strength and the B&B test. The subjects were unable to discern the difference in difficulty coded by the numerous response options. The persons with low ability were not consistently rated in the lower response options of the items, nor were those of high ability consistently rated with higher ability; this makes discrimination difficult and lead to misclassification. In all, 95 polytomous items were rescored based on the criteria for optimizing category effectiveness by Linacre (227). This included inspection of category characteristic curves as well as item fit and standard errors (229) (228).

Item Reduction

After rescoring the disordered items, the fit statistics were re-examined and the worst fitting items were removed iteratively until the best fit of the data to the model was obtained. After each deletion, the matching between item difficulty and person ability, the fit statistics and response options were reassessed. A fit of the data to the model was achieved with the removal of 142 items leaving 89 items. The standardized residual fit statistics of the first set of deleted items ranged from 13.0 to 2.2. These items represented constructs divergent from physical abilities such as: communication (SIS: 7-items), memory and thinking (SIS: 7-items), and emotions (PBSI and EQ-5D: 5-items). Also deleted were items assessing physical abilities from the capacity indices of sensation and pain (7-items), STREAM low level mobility items (2-itmes), and performance items assessing: strength (SIS: 4-items), interference in social or regular activities (SF-36: 6-items), the two items evaluating global perceptions of recovery (SIS, VAS) and health (EQ-5D, VAS). Subsequent items were deleted for fit or relevance to the population (CMSA: 'hop on one foot', Balance Scale 'transfer from bed to a chair'), and redundancy (STREAM, SF-36, SIS, items on "walking", and B&B), or because conceptually they seemed to evaluate more than one concept (SIS 'get into and out of a car', SF-36 'bend, kneel or stoop').

Structure of the Item Pool

The 89 items formed a pool of capacity and self-rating items for the final measure. (These items and their characteristics are found in the Appendix.) The model global fit statistics and quality indicators of person and item reliability, separation and fit statistics indicated the quality of the item pool was adequate (item–trait interaction X^2 of 237.89 (df: 267, p>0.899), and person and item fit residuals of -0.30 (SD: 0.53) and -0.27 (SD: 0.67), respectively (Table 4.4)). The spread of functioning measured by person ability and item difficulty was 10 and 14 logits respectively, but the items appear too easy for the sample whose mean logit ability was 1.95 (SD: 2.55) above the average item difficulty of 0.0 logits. Unidimensionality of the item pool was confirmed by overall model fit and by the amount of variance, 9%, explained by the first component of the Rasch residuals from a PCA. However, 30% of the residual inter-item correlations were greater than 0.5 indicating item redundancies (26) (226).The items for the final F3m were chosen iteratively from the item pool based on their relationship to the ICF constructs of functioning, targeting to the subjects, content coverage, and precision of measurement. The reduction in items from the pool from 89 to 44 in the final functioning measure resulted in a slight decrease in person reliability; the item reliability was not compromised.

Structure and Properties of the F3m

The global fit statistics in Table 4.4 confirm that the 44 items chosen from the item pool are adequate to define functioning. Each of the 44 items operates well, defines the continuum of functioning and can be used to quantify recovery; that is, all item (mean standardized residuals:-0.32; SD: 0.58) and person (mean standardized residuals:-0.26; SD: 0.53 logits) fit statistics meet the requirements of the Rasch model. The items can be separated into 30 statistically distinct groups and their level of precision varies from 0.12 logit standard errors for the hardest items to 0.51 logit standard errors for the easiest items.

The distribution of the 235 persons and 44 items across the F3m is depicted in Figures 4.2 and 4.3. The horizontal axes in both figures scaled in logits symbolize functioning from least functioning at the left to most functioning at the right. In Figure 4.2, the vertical axis denotes the proportions. The bars represent the frequency distribution of subjects and items at each location. The item thresholds range from -5.18 logits for the item 'facilitate finger flexion' to 4.86 logits for a 'walking speed' of >1.3 m/s, while the average item difficulty ranged from -5.18 (SE: 0.51) to + 3.81 logits (SE: 0.20). The measure of individual person ability spans approximately 12 logits from -5.99 (SE: 0.95) to 6.59 (SE: 1.3) logits of ability. Seventy percent of the subjects are located above "0", the average item difficulty mark. The average person measure of 1.32 logits (average SE: 0.23) is above the item mean of "0"; a difference of 1.0 logits between person and item average measure is considered mismatched (209). Despite the apparent mismatch, the person measures fall nicely between the items, and the Test Information Function (TIF) in Figure 4.2 is centered at 2 logits (310). The TIF indicates that information provided on the ability of all subjects matches the sample, but drops off sharply at 2.5 logits where a decrease in the precision of measurement would occur. The reliability of the ordering of persons by ability and items by difficulty is 0.96 and 0.98, respectively. Based on this reliability, the standard error of this measure (SEM) is approximately 0.4, or there is a 95% chance the subjects true scores are within 0.8 logits (321) of the measured value. The separation index of 5.1 indicated the items can separate the stroke subjects into 7 distinct strata that could qualify as recovery categories of: normal, nearly normal, good, fair, poor, minimal and no recovery.

Figure 4.3, displays the threshold item map with the location of each response option (0, 1 or 2). The distance between the numbers indicates the spread of various levels of difficulty represented by each response option. The difficulty increases from left to right. The short vertical line indicates the expected half-way point between any two response options indicating that the person with an ability at that level has a 50% probability of responding either 0 or 1; or, 1 or 2.

The responses of a specific individual subject with a mean ability of 1.32 logits (SE: 0.39) are depicted in Figure 4.3. The 95% confidence interval around his ability is 0.56 to 2.00; that is, 95 % of the time his average logit ability will be between 0.56 and 2 logits. The equivalent raw score for the subject is 34 (out of a maximum of 52) which can be calculated by summing this person's actual responses that are shown by the stars on the horizontal lines in Figure 4.3. The probability that this person will successfully complete the tasks below his ability level is 100% for the item farthest from his ability, but decreases as the item difficulty approaches his ability; for example, 'walk several blocks' probability of success was; 66%. He is less likely to successfully complete the tasks above his ability level (1.32 logits: SE; 0.39), for example, the item 'stand with one foot in front 30 sec' (difficulty 1.94 logits: SE; 0.17) where his probability of success was 35% and for the item 'tandem walk 2 meters' (difficulty 3.81 logits: SE; 0.20) his probability of success was only 7%.

At the group level, all the subjects in Figure 4.2 at 6.57 logits of ability can walk at a speed greater than 1.3 m/sec and stated that they can perform physically demanding activities as before their stroke; the subjects at the lower end at -5.99 logits are totally dependent and unable to move.

Table 4.6 arranges the items and person by ability and difficulty with their logits and equivalent expected scores from 0-52. It demonstrates that the least measurable difference (the difference in the measure that corresponds to a one unit increase in the score from 0 to 52, see Figure 4.3 and Table 4.6, forms a "U" shaped distribution from 0.7 logits equivalent to 5 points between items at the ends to 0.1 logit or 1 point for items at the center (207). The difference in a score of 1 or -5.99 logits of functioning and a score of 2 or -5.32 logits of ability is 0.67 logits, while the difference between a person score of 33 and 34 is 0.15 logits (Table 4.6). More ability is required by a person to improve functionally at the lower end of the measure than in the middle. The raw total score and the logit scores correlate at 0.98.

This measure has a ceiling effect of 1%, four subjects are above 4.86 logits, and there is no floor effect.

The unidimensionality of the measure was confirmed by first, a PCA analysis of the Rasch item raw scores that yielded a first principal component explaining 41% of the variance and second, by the first principal component of the Rasch item residuals that explained 9% of the remaining variance (268). Cronbach's alpha, a measure of internal consistency reliability of the Rasch items scores, was 0.96. The standardized item to scale coefficients were between 0.45 and 0.81 (mean: 0.61; SD 0.11), except for one CMSA item (r: 0.20) (267). Given the high reliability the correlation between the measures when the items were split was, as expected, high (0.93), reinforcing the invariance of the person measures.

Differential Item Functioning

The difficulty level of the functioning measure was uniform across stroke type, gender, age, previous health, and stroke severity. The 2nd easiest item exhibited an interaction between ability and age. The number of subjects in the higher ability levels in the oldest age group was too few (4) to adequately test whether DIF was present. Men were more likely than women to drive a car as before their stroke and older subjects tended to have more hand ability than expected.

Validity

Content

The content of the F3m crosses all ICF domains; 24 body function items related to movement in the upper (15 items) and lower extremity (9 items); 14 activity items related to basic self-care (3 items), mobility (10 items, including 3 for the hand) and domestic life (1 item) and 3 participation items related to community (2 items) and major life areas (1 item). In addition, items covering balance (3), a construct not covered by the ICF but of importance to a person after a stroke, are also included. The items cover a broad spectrum of difficulty (see Figure 4.2 and Table 4.5) and comprise 20% of the components in the comprehensive ICF core set for stroke (197) that defines "what people after stroke need to do to lead productive and meaningful lives" (322).

The 31 items requiring observation of the performance of persons on specific tasks represent a core set of capacities therapists would normally assess to determine recovery at 3 months, while the 13 self-report items contain the major areas important to a person's functioning from toileting to being able to work and /or perform strenuous physical activities.

Construct

Construct validity is assured by the fit of the data to the model, its invariance and unidimensionality. The consistency of the hierarchy of the subjects' response patterns across all the items is supported by the adequate person reliability index (0.96), excellent person separation index (5.1) and the person fit statistics that meet the criterion value of ± 2 (range -1.6 to 2.0). The response pattern of each subject was checked for extreme standardized residuals on each item. Less than 9% (mean: 5%; SD: 1.5%) of the subjects had residuals greater than + 2 or less than -2 on any item. The item that the most subjects (9 %) responded to inconsistently was 'hip flexion with knee extension' at a location of

-0.13 logits. The internal consistency of the person's responses was excellent as the ability estimates for the person locations from the two subsets of items correlated at 0.94.

Convergent

As hypothesised, the correlations, in Table 4.7, between the total scores of the F3m and the indices assessing the physical aspects of functioning were stronger (>0.70) than those between sensation and the physical indices, confirming convergent and divergent validity.

Discriminative

The scores differed significantly across the four levels of stroke severity from very mild with a functioning score of 42.4 (95% CI: 39.8 to 45.0), to mild (score: 38.1; 95% CI: 35.6 to 40.5), to moderate (score: 32.9; 95% CI: 30.7 to 35.2), to severe (score: 17.9; 95% CI: 14.11 to 21.5). The F3m was able to discriminate between four levels of stroke severity, including between very mild and mild that were only 4 functioning points apart.

Although the responsiveness of this measure needs to be tested, the reliability of the hierarchy, content of the measure and the distance between the items indicates that the measure would be responsive.

Discussion

A comprehensive 44-item F3m with a reliable and valid total score was developed from observational and self-report indices to gauge recovery three months post-stroke. The quality of the F3m is seen in the fit of the data to the model and its psychometric indicators. Unidimensionality is reflected by the fit of the data to the Rasch model in Table 4.4 and the residual variance of 9% accounted for by the PCA of the item-person residuals, after the Rasch factor has been removed(323) (268) (238). The result of a Rasch analysis when the data fit the model is a total score that is sufficient to describe an individual's functioning and transparent enough to define both the tasks the person can do and the rating of his own performance. The psychometric properties indicate that it may be possible to detect improvements in functioning, defined as recovery, across the continuum from impairments to participation restriction. If interventions are to be judged effective in facilitating recovery, evaluation measures must be able to detect a change in functioning that is important to health professionals and, more importantly, to stroke survivors. The precision of the F3m could provide such indications of change and is one of the first measures to include items of import to both parties.

The sample, as characterized by the data in Tables 4.3a and 4.3b, is similar to stroke populations described in the literature (1) (34) (56) (324). The subjects exhibit a broad range of stroke characteristics including type of stroke, number of stroke and living arrangements. The subjects demonstrate major impairments in the complex tasks requiring integrated movements, speed, and endurance, while they report limitations and restrictions in activities and participating in the community as seen in the scores of the SF-36, SIS, PBSI and EQ-5D. Tables 4.3a and 4.3b illustrate the difficulties in defining and tracking recovery post-stroke at an individual or even the group level. Little information on the specific tasks needed to function is provided in the total scores. An item by item analysis is required to define the functioning of these subjects. The F3m provides a transparent indication of what the person can do through the total score; the hierarchy of the items indicates on the continuum just what the person is capable of performing or how he rates his performance.

It is not surprising that a number of items needed to be rescaled as response scaling is rarely addressed in the development of measures. Disordered response categories can indicate confusing or poorly worded response choices, multidimensionality or that an item is not relevant to the population (26) (226). The SF-36 items (325) (326) (281) (282) (280) and the Balance Scale (327) have been rescored by other researchers, and the developers of the SIS stated that the five category scoring system was inappropriate. They felt that the middle categories of the SIS should be combined, as was done here (209) (75). Interestingly most of the rescaled items, with a few exceptions, were the harder ones (e.g. 'climb several flights of stairs'). It may be that stroke survivors have problems rating their performance at more than two levels 'able' and 'not able' for the most difficult tasks. This was also seen in a study of community dwelling elderly by McHoney et al. (195), where the subjects found the dichotomous response categories restrictive, yet only used two of the six response categories on the difficult mobility items.

The response options of the STREAM and CMSA indices were developed based on the theory of motor recovery as proposed by Twitchell (45) and Brunstruum (111) and to reflect the quality of limb movement (210) (54) (50) (52). The CMSA assessed quality of movement by increasing numbers of items and the STREAM through increased response categories. Neither method proved beneficial. The original rating scale categories of the STREAM were disordered and showed poor item fit.

Additionally, both measures have numerous high inter-item correlations (range: r: 0.80-0.99), especially in the moderately difficulty hand and arm items. The CMSA and STREAM items are arranged hierarchically according to the stages of motor recovery from proximal to distal portions of the limbs and from simple to complex tasks. Yet, the number of items in the CMSA defining the hierarchy is burdensome and the STREAM scores provide little information on the tasks a person can perform.

Rescaling of the continuous variables reflects the difficulties in defining the categories for continuous variables in a Rasch analysis. Despite defining the categories in response to clinically meaningful values, all the continuous variables were rescored by collapsing the lowest three categories into one category. The increase in categories to better differentiate the least able persons was not necessary, as fewer than 21% of the subjects (n=50) responded in the lowest category. Collapsing the categories strengthened the items and makes the categories for gait speed more relevant and interpretable. A gait speed score of 1 is the threshold point between the persons with a walking speed of 0.5 m/s or less that tend to be non ambulatory (score of 0) and those with a score of 1 with a walking speed of 0.6 to 0.8 m/s (67) needed for adequate indoor mobility (328). While a score of 2 differentiates indoor walkers from community walkers as a 2 is equivalent to the walking speed needed to cross most streets and move about in the community (0.9 to 1.3m/s), (329) (330) and a score of 3 indicates a walking speed greater than the 1.3 m/s considered as normal (331).

Further indicators of the quality of the F3m are seen in Table 4.4. Although the item and person reliability and separation indices are very good, they could be enhanced by improving the match between item difficulty and person ability. Adding self-rating of performance items, rather than capacity items, is suggested. The capacity items are spread evenly throughout the measure, while the rating of performance items are clustered at the extremes of the measure and are out-numbered four to one by the capacity items. Four of the 11 self-rating items are located above 2.0 logits while the rest are at or below 0.0 logits. Additional harder IADL items and participation items, such as doing laundry, estimated at 1.87 logits (235) and taking things out of a cupboard estimated at 2.44 logits (195) are needed.

The 44 items encompass the content in the ICF: body functions; movement of the upper and lower extremities, and balance; activities from basic ADL to IADL and mobility; and finally participation in life roles, all recognized as meaningful to persons after a stroke (200). The importance of distinguishing recovery post-stroke at all levels of the ICF and all levels of difficulty even those with minor residual deficits should not be underestimated.

The inclusion of a number of items measuring hand ability is note-worthy. Recovery of the upper limb ability is perceived as important by stroke survivors (1) (58) (75). The lack of hand functioning is a significant deficit even in those persons with mild stroke (82) and remains a difficulty in upwards of 50% of persons even 3 months after stroke(1) (88). The inclusion of 15 items observing the functioning of the hand as well as self-report items on the hand allows for the definition of recovery without problems of other measures thought to measure compensation ability (59)and not true hand ability.

The standard deviations of the items and persons demonstrate the breath of item difficulty and person ability across the continuum of functioning and help validate the rescaling of the items (see Figure 4.2 and Table 4.5). Decreasing the number of response categories did not limit the scope of the measure. The lack of ceiling and floor effects in the F3m is in contrast to that seen in the indices in Tables 4.3a and 4.3b, especially in the indices with ordinal scores, where all but a few exhibit a ceiling effect. Rehabilitation instruments (STREAM, CMSA, Balance) with items used to observe performance of tasks are known for their ceiling effects and inability to adequately measure the more able subjects (332) (72) (333), particularly later in the evolution of stroke (34). Other indices, more often self-report indices, are known more for floor than ceiling effects, but have both (71) (209). The SIS domains related to emotion, communication, and hand function and the SF-36 domains of pain, mental health and emotion demonstrate the known ceiling in these instruments for stroke evaluations (209), while the SF-36 PF demonstrates the floor effect

(71). It is interesting that the PBSI item 'physically demanding activities', conceptually a combination of two SF-36 items 'vigorous and moderate activities' fits very well in this measure without a floor effect.

The construct validity of the measure is assured by the fit of the data to the model and is reinforced by the hierarchy of items and persons aligned by difficulty and ability along the functioning metric. As theorized, the items are organized from body functions (1/2 range of wrist flexion movement:-3.3 logits) to activities (dressing:-1.32 logits) to participation (working: 2.2 logits) items and from simple tasks such as 'hip flexion while in lying' at -3.46 logits to more complex tasks of 'standing on weak leg 5 sec', 2.56 logits, or 'walking on one's toes quickly' 3.85 logits (Table 4.6). The ordering of the Balance Scale items and the activity items of the SIS within the measure are the same as other researchers. The Balance Scale items are ordered from 'sitting unsupported' to 'tandem stance' to 'standing on the affected leg for 5 sec' (from the CMSA) as suggested by Berg et al. (334) (335). Although the scoring options (original 0-4, rescored 0, 1) and populations differ (elderly versus stroke survivors) the hierarchy is the same. The seven SIS items are ordered as perceived by Duncan et al. (209) in their cohort of mild and moderate stroke survivors. This hierarchy will aid in understanding the process of recovery of functioning, that is, what is needed to successfully complete each successive stage. And, unlike a number of measures (211) (336) (337) it is not restricted to ADL or IADL items but goes beyond them, above to include participation and below to include the body function components of functioning.

Convergent and divergent validity were demonstrated by the correlations between functioning and the other indices presented in Table 4.7 both those greater than 0.7 and those less than 0.3. The moderate correlations seen between functioning and the SF-36, SF domain (r: 0.52) and the SIS recovery VAS scale (r: 0.54) may indicate that the F3m has some social content and is related to recovery as reported by the subjects. A very high correlation between indices usually indicates redundancy and that only one index is required. The high correlation between the CMSA and functioning is as expected and reflects the content of the measure where 54% of the items are from the CMSA. The F3m has greater breadth of content that the CMSA that only assesses impairment level tasks

(200). The F3m includes items at all levels of the ICF as well as subjects' self-ratings of their own performance.

A valid measure should be interpretable and meaningful. Figure 4.3 illustrates the difficulty using Rasch logit scores, probabilities, or odds ratios rather than actual item numerals. The strength of the Rasch model is also its weakness: it is a probabilistic model not a deterministic one and probability scores are not actual scores. Although the logit scores can be converted to any convenient linear scale, the new scale does not correspond always to the actual item numerals (321). Anyone using the F3m will score the item tasks as a 0, 1, or 2 and subjects will rate their performance using the same numbers, as the numeric scores for each item correlate with the logits at 0.98, they can be used interchangeably (338), for example, the raw score equivalents given the average person has a score of 34 (95% CI: 32-36) rather than 1.3 logits (95% CI: 0.52-2.1). The hierarchy of the items allows for the linking of the items to the total score and thus describes in functional terms what a person with a score of 34 can do. This total score is sufficient to provide all the information necessary for health care professionals to determine the appropriate therapy for our average person.

While interviewing our average subject, subject #30074, he stated that his goal was to be able to walk 4 blocks down the street to get his groceries. The type of therapy required to achieve this goal would be based on the items in the list in Table 4.6 from 2 points below to 2 points above his score of 34 (the 95% CI on the item estimate). The therapy would include foot exercises, balance (standing on one leg), endurance exercises, and arm strengthening activities. If the goal proved unattainable the necessary services can be put in place. This leads one to ponder what the potential is for improvement in subject #30074 at three months?

This is where logits and probabilities have a place; what is the probability our person will achieve his goal. In the Rasch model, the probability of successfully completing the next item is a conditional probability, that is, the probability of success is conditional on the fact that he achieved a score of 34. Presently, based on his ability score of 1.32 logits (equivalent score of 34), and his goal of successfully completing the item "walk in the community" with a difficulty of 1.42 logits, he requires an increased ability of 1.1 logits or a total score of 37. Adding 2 points for measurement error (derived from the standard error), or an increase of 5 points. His probability of successfully completing the item is then 47%. This probability is 3% above his ability to successfully complete the task at his ability level (50%), the 'tap foot quickly' item. Once we understand the physical levels subjects can attain or are supposed to attain, we can improve our interventions, both the targeting and timeliness. We can also begin to understand the interplay between physical performance and other factors indicative of performance such as cognition, motivation or self efficacy (339).

The Rasch analysis produced a measure that defined functioning with a reliable and valid score to be used to determine recovery. Traditionally, post-stroke recovery has been defined dichotomously as "recovered" or "not recovered" , "independent" or "dependent" based on somewhat arbitrary cut points on a single index or by a group of indices and scores such as those listed in Tables 4.3a and 4.3b (12). With the F3m it is possible to evaluate and define any increment of recovery, not just "independent" or "dependent" (175) (68). All the data collected can be used in the determination of recovery. Quantifying recovery can be based on goals or the tasks a person wishes to achieve and measured against attained goals, or the percent increase in the functioning score or even cut points. An additional strength of this measure for the quantification of recovery is that it combines both capacity and performance items which may help professionals define the requirements or thresholds of ability needed to perform tasks. Health care professionals can then begin to define the limits of recovery for a specific person. The knowledge obtained can provide an understanding into the relationship between physical ability and other abilities necessary to complete a specific task. The person's rating of his performance, combined with his capacity to perform a task provides insight into what a person can or wants to do and what he actually does or what he feels is important to do.

As no measure satisfies the needs of all parties (200), the difficulties in the selection of an index to evaluate patients is increased, the measure of "functioning" overcomes this difficulty by including items from both perspectives across the ICF components

Limitations

Every study has limitations and this one is no exception. Although the subjects covered a broad spectrum of age and severity, from those totally dependent and living in long term care facilities, to those working in the community, the ability to measure functioning in aphasic or cognitively impaired subjects was limited. These subjects are often unable to respond adequately to all items. Yet, Rasch analysis with its ability to impute missing values would be invaluable in this instance (231). To adequately test DIF for the easier items requires more subjects over 85 years of age. Additionally, the data considered are cross sectional at three months. Data at additional time points would provide the opportunity to define recovery by calibrating the items across the time continuum.

The inclusion of harder IADL and participation items such as those from the Older American Resource Scale IADL measure (234) and the Reintegration to Normal Living index (84) (249) could provide a better picture of self-report performance abilities of functioning for recovery.

In addition, the rescoring of the items needs to be tested for comprehension, and stability, and the responsiveness the measure needs to be assessed.

Conclusions

The development of an internally consistent and reliable F3m that shows promise in defining recovery post-stroke has been proposed. The person and items aligned on a single measure with a sufficient total score allows for the quantification of a person in terms of their functioning, of what a person should be able to do, given their total score. It has the capacity to assist in directing and assessing therapeutic interventions and defining the services needed to meet the needs of stroke survivors three months post-stroke.

15 Table 4.1a Index Characteristics in the Measure of Functioning at Three Months (F3m)

Construct	Instrument	**Validity**	**Reliability**	**Responsiveness**	**Units, items /Scaling**
Body Function	Activity Movement mobility STREAM (53) (54) (332)	Content Convergent Divergent	Inter-rater: r: 0.99; Cronbach's α : 0.98; κ : 0.8 – 1.0	SRM: 0.89	Scale: 0–100; 30 items: 10 upper, 10 lower, responses: 0,1,2; 10 mobility: responses: 0,1,2,3.
Body Function Movement balance pain	Chedoke-McMaster Stroke Assessment Impairment, Inventory (CMSA) (50) (51) (52)	Construct Concurrent Predictive	Varies by domain Intra-rater: ICC :0.94-0.96 Inter-rater-: ICC:0.88-97 Test retest: ICC:0.75-94	Not determined	Scale: 1-7; 19 items each in 5 domains: posture, arm, hand, leg, and foot. Shoulder pain 7 items. Responses; 0,1
Body Function Balance	Balance scale (340) (334) (335)	Content Construct Discrimin-ative	Intra-rater: ICC : 0 .99 Inter-rater : 0.99	Yes	Scale: 0-56: 14 items; responses: 0-4
Body Function	Sensation: Sensation portion of the Fugl-Meyer (46) measure of sensori-motor recovery after stroke	Content Criterion	Sensation inter-rater: 0.85	SEM: 2.9	Scale: 0-24 12 Items: Light touch on arm and leg and position sense 8 joints. Only the 4 light touch and 1 joint items used scale: 0-9; responses: 0-2

Table 4.1a cont Index Characteristics in the F3m

Construct	Instrument	Validity	Reliability	Responsiveness	Units, items /Scaling
Body Function	Cognition: MMSE telephone version (305) (306)	Content Construct	Not reported	Not reported	Scale: 0-22 6 items responses vary by item
Body Function	Perceptual neglect: Albert's test (341) (342)	Content Construct	Test-retest r: 0.79	Not reported	Lateralized neglect is present when > 70 % of the lines are uncrossed on the same side as the motor deficit.
Activity and Participation	Health states EQ-5D (343) (344)	Construct Content	Internal consistency α :0.89, Inter-rater Reliability: κ varies between 0.38-0.62 depending on the item, ICC 0.53, Test-retest 0.83	Unknown due to bimodal distribution	Scale:0-100, 5 Items, responses: 3-1 Thermometer 0-100
Activity and Participation	PBSI (345)	Construct	Internal consistency α: 0.89	Unknown	Scale 0-100; 10 items; Responses: 3-1

Table 4.1a cont Index Characteristics in the F3m

Construct	Instrument	**Validity**	**Reliability**	**Responsiveness**	**Units, items /Scaling**
Activity and Participation	SIS, Recovery VAS and SIS-16 (87) (209) (75) Proxy version (83)	Construct Convergent Known groups	Test-retest: ICC : 0.70-0.92 for domains except emotion 0.57 Internal consistency α: 0.93-1.00	Estimated Clinically important change 10-15 points	Scale: 0-100; 59 items. 8 domains Responses: 1-5, VAS 0-100
Activity and Participation	SF-36 (346) (347) (348) (349).	Content, Criterion Construct Predictive (348) (346)	Varies by sample internal Internal consistency α >60 in all scales for stroke; test retest from 0.30-0.93	Not available: PCS, MCS estimated to be 10 points	Scale: 0-100; 36 items; 8 domains; 2 summaries: PCS, MCS transformed to a scale with mean of 50 and standard deviation of 10

Abbreviations: ADL, (Activities of daily living); BI, (Barthel Index); CMSA, (Chedoke-McMaster Stroke Assessment Impairment Inventory); α, (Cronbach's alpha reliability coefficient); EQ-5D, (EuroQol instrument); ICC, (inter-correlation coefficient), κ, (Kappa reliability coefficient); SF-36, (Medical Outcomes Trust Short Form, Sf-36); SF-36, PCS, (physical composite score); SF-36 MCS, (mental composite score); MMSE, (Telephone Version of the Mini-Mental State Examination); PBSI, (Preference based Stroke Index); SEM, (standard error of the measure); STREAM, (Stroke Rehabilitation Assessment of Movement); SIS, (Stroke Impact scale); SIS-16 (Stroke Impact scale-16 items); SRM, (Standardized response mean), VAS, (visual analog scale).

Table 4.1b Continuous Measure Characteristics and Categorization for Items in the F3m

Construct	Instrument	Validity	Reliability	Responsiveness	Units, items /Scaling
Body	Strength: †Grip Strength (350) (318) (351) (352)	Not Applicable	Test retest ICC Right:0.93 Left:0.90	Not reported	kg of force Norms available
Body Function	Walking Speed: 5 meters (332) (313) (314)	Not Applicable	Test-rest: r : 0.89 – 1.0	SRM : 1.19m/s	Meters per second Norms available
Activity	Two Minute Walk test (353) (354) (355) (52)	Construct	95% Confidence Interval for repeatability -27% to +38% Inter-rater ICC .92	Minimal detectible change in stroke (90%CI) 19.8 meters	Distance in meters walked in two minutes Norms available
Activity	Dexterity: †Box and Block test (315) (316) (352) (356)	Construct	Inter-Rater r : 1.0 both hands Test-Retest: ICC:0.97-0.89 dependent on population	Estimated as 7 blocks	Norms available Number of Blocks per 60 sec

Table 4.1b Continued. Categorization of Continuous Measures for Items in the F3m

Categories	0	1	2	3	4	5	6
Measure							
Walking speed category: meters per second (332) (313) (314)	0	0.12	0.25	0.5	0.8	1.3	>1.3
Two Minute Walk test: category distances in meters (353) (354) (355)	<7	15	30	60	110	199	>199
Grip strength category: kilograms of force (317)	0	8	15	28	40	>40	-
Box and Blocks category: number of blocks per second (315) (316) (352)	0	10	25	40	66	>66	-

[†]As the effects of gender and handedness on grip strength and dexterity as measured by the B&B test are minimal, the data for males and females, and for the left hand dominant (n=4), and right hand dominant subjects were combined (316) (352). Grip strength and hand dexterity were classified by whether the hand was the affected or less affected hand.

16 **Table 4.2 Baseline Characteristics of the Subjects**

Characteristic	Participants (n=235)	Refusals (n=77)
Age at stroke onset (years)		
Mean ± SD	71.6 ± 20.7	75.2 ± 10.5*
64>/ 65-74/ 75-84/ ≥85 (%)	29 / 25 / 35 / 11	13 / 36 / 33 / 18
Men/Women (%)	62 / 38	51 / 49
Level of Education Finished (%)		
None / Grade school / High school / College	18 / 39 / 14 / 29	N/A
Living where before stroke (%)		
Home / Residence / Other	94 / 5 / 1	90 / 9 /1
Living with whom before stroke (%)		
Family / Alone /Other	59 / 34 / 6	66 / 31 / 3
Discharge Destination (%)		
Rehab / Home / Trans / LTC / Died	53 / 39 / 2 / 6 / 0	53 / 35 / 3 / 5 / 3
Ischemic/Hemorrhagic/Other (%)	86 / 14 /<0.1	87 / 13 / 0
First stroke (%)	79	78
Side of hemiplegia %		
Right / Left / bilateral / none	36 / 53 / 0 / 11	
Length of stay in acute care (days)		
Mean ± SD	16.9 ± 20.9	13.5 ± 9.7
Stroke severity CNS score at admission †		
Mean ± SD	8.2 ± 2.6	7.7 ±3 .5
Very Mild / Mild / Moderate / Severe (%)	18 / 22 / 41 / 19	23 / 25 / 25 / 27
Comorbidity †† (%)		
0 / 1 / 2,3 / >3	30 / 28 / 31 / 11	N/A
Barthel Index at three days (0-100)		
Mean ± SD	51.1 ± 31.3	N/A
SIS-16 at three days (0-100)		
Mean ± SD	37.6 ± 23.2	N/A
Barthel Index at Discharge (0-100)		
Mean ± SD	71.0 ± 26.4	71.3 ± 25.9

Abbreviations: BI, (Barthel Index of basic activities of daily living); CNS, (Canadian Neurological Stroke scale); LTC, (long term care); N/A, (not available); SD, (standard deviation); SIS, (Stroke Impact Scale, 16 question version).

* Significantly different; P<.01

†CNS Best score: 11.5; with: Very Mild ≥11.0; 9.5 ≤Mild <11; 5< Moderate <9.5; and Severe <5.

†† Comorbidity based on the Charlson Comorbid Index (304).

17 **Table 4.3a Observed Performance Scores of Subjects at Three Months** (n=235)

Construct	Observed	% Ceiling	% Floor
Motor Recovery Mean ± SD			
Total STREAM score (0-100)	83.4 ± 23.0	18	1
Total CMSA score (1-42)	34.3 ± 7.6	12	0
Mobility Mean ± SD			
STREAM Mobility (0-100)	77.7 ± 26.1	25	1
Walking speed (m/s)	0.76 ± 0.5		12
Two Minute Walk Test (meters)*	91.0 ± 8.1		12
Walking aids (%)	28		
Lower Limb Ability Mean ± SD			
STREAM L/E (0-100)	85.1 ± 24.0	45	1
CMSA leg (1-7)	5.8 ± 1.2	28	1
CMSA foot (1-7)	5.4 ± 1.5	27	3
Balance Mean ± SD			
CMSA Posture(1-7)	5.5 ± 1.4	25	2
Balance Scale (0-56)	43.4 ± 16.0	15	7
Upper limb Ability Mean ± SD			
STREAM U/E (0-100)	87.3 ± 25.6	61	2
CMSA Pain (1-7)	6.2 ± 1.4	69	2
CMSA Arm (1-7)	5.7 ± 1.6	49	2
CMSA Hand (1-7)	5.7 ± 1.6	40	3
Grip Strength kg force*			
affected hand	19.9 ± 13.5	8	12
less affected hand	26.6 ± 11.1	12	0
Box & Blocks # moved in 60 sec*			
affected hand	35.6 ± 20.0	14	13
less affected hand	46.4 ± 14.3	25	0
Dominant Hand (%) Right	96		

*N varies between 223 and 234; Force was measured with a Jamar Dynamometer with the handle in the second position, percent ceiling and floor represent the percent of the sample with the highest and lowest scores, respectively.

Abbreviations: #, (number); CMSA; (Chedoke McMaster Stroke Assessment), kg, (kilograms); m, (meters); m/s, (meters per second); sec, (seconds); SD; (standard deviation), STREAM; (Stroke Rehabilitation Assessment).

Table 4.3a Continued. Additional Observed Performance Scores of Subjects at Three Months

Construct	Capacity
Cognition Mean ± SD	
MMSE (0-22)*	19.1 ± 3.3
Neglect (%)	
Albert's test of perceptual neglect	6
Cognitively unable to do the test	1
Sensation of the Affected Side Mean ± SD	
Sensation (0-9)	8.1 ± 1.8
Normal (%)	59
Poor	41
Absent	0

Abbreviations: MMSE, (Mini-Mental State Exam).

18 **Table 4.3b Self-Rating Performance Scores of Subjects (n=235)**

Self-Rating of Performance Index	Mean	SD	% Ceiling	% Floor
Stroke Impact Scale Domains 0-100				
Strength	65.3	25.9	15	2
Memory	87.3	18.1	6	1
Emotion	75.8	17.1	38	1
Communication	91.0	15.3	47	1
ADL	70.8	27.8	16	2
Mobility	70.9	28.8	16	3
Hand functions	63.8	37.3	26	17
Participation	56.0	31.9	10	8
Physical functions	68.6	26.7	4	1
SIS-16	73.1	27.1	12	1
Recovery (VAS)	68.5	21.6	6	1
EQ-5D states* 0-100	62.4	21.6	0	1
EQ thermometer 0-100	70.0	19.8	6	1
PBSI score weights 0-100	67.7	21.0	5	1
MOS SF-36 Domains 0-100				
Physical functioning	48.5	32.5	4	12
Role-physical	29.8	38.6	17	54
Role-emotional	56.0	43.7	45	30
Vitality	53.0	22.9	2	3
Pain index	73.1	28.3	42	3
Health perceptions	61.9	20.0	3	1
Mental health index	69.3	22.0	7	1
Social functioning	62.4	31.2	25	5
Physical composite score^{+}	38.6	10.3	16	1
Mental composite score^{+}	47.5	11.9	38	1

*12person's data imputed

Percent ceiling and floor represent the percent of the sample with the highest and lowest scores respectively

+transformed to a score with a mean of 50 and standard deviation of 10

Abbreviations: ADL, (Activity of Daily Living); EQ-5D, (EuroQol instrument); MOS SF-36, (Medical Outcomes Trust Short Form-36 questionnaire); PBSI, (Preference Based Stroke Index); PCS, (physical composite score of the SF-36); MCS, (mental composite score of the SF-36); SD, (standard deviation); SIS-16, (Stroke Impact Scale-16 question version); VAS, (Visual Analog Scale).

19 **Table 4.4 Global Fit Statistics for the Rasch Models of the Three Months Measure of Functioning**

	*Full 231-item model (n=235)	89-item pool model (n=232)	44-item model (n=231)
ITEM-TRAIT INTERACTION			
Total Item Chi Square	5,123.99	237.89	120.50
Total Deg of Freedom	693	267	132
Total Chi Square Probability	00000.00	0.899	0.75
ITEM-PERSON INTERACTION			
ITEMS			
Difficulty	0.0 ± 1.73	0.0 ± 2.30	0.0 ± 2.40
Fit Residual	-0.48 ± 2.80	-0.30 ± 0.53	-0.32 ± 0.58
PERSONS			
Measure	1.57 ± 1.15	1.95 ± 2.55	1.31 ± 2.50
Fit Residual	-0.03 ± 1.44	-0.28 ± 0.66	-0.26 ± 0.53
RELIABILITY INDICES			
PERSONS			
Reliability Index	0.987	0.978	0.963
Cronbach's Alpha	Not applicable with missing data	Not applicable with missing data	Not applicable with missing data
Separation index	8.7	6.67	5.1
Strata	11.9	9.2	7.1
ITEMS			
Reliability Index	0.988	0.998	0.998
Separation Index	9.1	22.3	22.3
Strata	12.4	30	30
Power of Test- of- Fit	Excellent based on a Person reliability of 0.98	Excellent based on a Person reliability of 0.98	Excellent based on a Person reliability of 0.96

*Two extreme items removed

20 Table 4.5 Characteristics of the Items in the Measure of Functioning at Three Months (F-3m)

Index	44-Items	Difficulty	SE	Fit residuals	†χ^2	†F-statistic
CMSA	Tandem Walking 2m in 10 sec	3.86	0.21	-0.37	0.89	0.51
CMSA	Bounce a ball 4x in succession, then catch	3.76	0.20	-0.39	6.06	3.33
PBSI	*Perform physically demanding activities	3.25	0.14	0.10	2.26	0.75
PBSI	Drive a car	3.21	0.19	-0.30	5.87	2.30
CMSA	Foot off floor: foot circumduction	3.04	0.19	-0.17	4.55	1.28
CMSA	Trace a pattern: forward, side, back, return	2.92	0.18	-0.55	4.55	2.16
SIS	Do heavy household chores	2.66	0.18	-0.22	3.33	1.30
CMSA	Stand on weak leg 5 sec	2.53	0.18	-0.66	2.08	1.22
PF	*Ability to perform work or other activities	2.20	0.13	0.95	3.44	1.22
††Gait Speed	*Walking speed	2.05	0.12	-0.93	0.97	0.16
CMSA	Thumb to fingertips, then reverse 3x in 12 sec	2.01	0.18	-0.48	0.87	0.36
BS	Stand with one foot in front	1.94	0.18	1.14	6.37	1.64
CMSA	Elbow at side 90° flexion: resisted shoulder external rotation	1.56	0.18	-0.27	5.51	1.75
SIS	Clip your toenails	1.43	0.18	-0.73	2.00	0.89
CMSA	Pour water from pitcher to cup, then reverse	1.38	0.18	-0.43	2.91	0.84
CMSA	Heel on floor: tap foot 5x in 5 sec	1.21	0.18	-0.78	3.88	1.78
CMSA	Shoulder flexion to 90°: scissors in front 3 x in 5 sec	1.06	0.18	-1.48	5.21	3.08
PF	Walk several blocks	1.05	0.18	-0.63	2.33	1.19
CMSA	Shoulder flexion to 90°: trace a figure 8	0.70	0.19	-1.21	2.24	1.40
SIS	Tie a shoe lace	0.37	0.19	-0.13	1.37	0.23
CMSA	Arm resting at side of body: raise your arm over head with full supination	0.23	0.19	-0.99	2.60	1.08
CMSA	Pronation: tap index finger 10x in 5 sec	0.13	0.19	-0.50	0.43	0.18
PBSI	*Walk in the community	0.08	0.14	-0.77	2.52	0.93
STREAM	Walk 3 steps sideways	0.07	0.20	-1.17	3.08	1.50
CMSA	Hip extension with knee flexion	-0.13	0.20	-0.33	1.63	0.65
SIS	Turn a doorknob	-0.27	0.20	-0.19	1.29	0.12

Table 4.5 continued Characteristics Items in the F3m

Index	44-Items	Difficulty	SE	Fit residuals	†χ^2	†F-statistic
PF	Climb one flights of stairs	-0.33	0.21	0.63	2.70	0.44
CMSA	Pronation: wrist and finger extension with finger abduction	-0.50	0.21	-0.89	1.76	1.16
CMSA	Shoulder flexion to 90°: supination, then pronation	-0.82	0.22	-0.29	2.50	0.93
SIS	Bathe yourself	-0.90	0.22	-0.96	3.77	1.55
CMSA	Lift foot off floor 5X in 5 sec	-0.91	0.22	0.29	1.48	0.46
CMSA	Hand unsupported: opposition of thumb to little finger	-1.12	0.23	0.06	2.28	0.60
SIS	Dress the top part of your body	-1.32	0.23	-0.36	0.73	0.28
SIS	*Get to the toilet on time	-1.55	0.17	1.25	8.45	1.72
STREAM	Open hand from fully Closed position	-1.88	0.25	-0.24	3.47	1.65
CMSA	Ankle inversion	-2.40	0.27	0.02	0.67	0.34
STREAM	*Knee flexion in sitting	-2.48	0.20	0.58	4.20	0.65
CMSA	Bridging hip with equal weight bearing	-2.86	0.30	-0.58	0.80	0.87
CMSA	Finger/ wrist flexion >½ range	-3.36	0.33	-0.56	0.88	0.55
STREAM	*Facilitate hip flexion in lying	-3.46	0.23	-0.32	0.60	0.19
CMSA	Facilitate log roll to side lying	-3.95	0.37	-0.11	0.76	0.38
CMSA	Facilitate dorsiflexion or toe extension	-4.47	0.42	-0.10	5.08	0.71
BS	Sit unsupported	-4.76	0.46	-0.48	1.17	0.78
CMSA	Facilitate finger flexion	-5.18	0.51	-0.42	0.96	0.48

Items are listed in order of difficulty from hard to easy top to bottom.

Abbreviations: SE, standard error; Fit, (Fit residuals; standardized fit residuals); χ^2 :Chi-Square; DF, degrees of freedom; F, (F-statistic from a one way ANOVA); CMSA (Chedoke McMaster Stroke Assessment); BS (Balance Scale); STREAM (Stroke Rehabilitation Assessment) ; SIS (Stroke Impact scale); SF-36, PF (Medical Outcomes Trust Short Form-36 questionnaire Physical Function index), PBSI (Preference Based Stroke Index)

*Polytomous items. †Bonferroni corrected significance level p <.00011.

††Walking speed in meters per second per category: 0:0-0.5; 1:0.6-0.8; 2:0.9-1.3; 3: >1.3

21 Table 4.6 **Item Difficulty and Person Ability in Logits and Equivalent Expected Scores (0-52) for the Measure of Functioning at Three Months, F3m**

44 Items	Item Thresholds Logit Difficulty	Raw score	Person Scores Equivalent Expected	Logit Ability
		0	#0	-6.89
Facilitate finger flexion	-5.18	1	1	-5.99
Sit unsupported	-4.76	2	2	-5.32
*Partial hip flexion lying	-4.64	3	3	-4.81
Dorsiflexion of foot	-4.47	4	4	-4.38
Log roll	-3.95	5	5	-4.01
Finger/wrist flex >1/2 range	-3.36	6	6	-3.68
*Partial knee flexion	-2.94	7	7	-3.38
Bridge	-2.86	8	8	-3.11
Ankle inversion	-2.40	9	9	-2.86
† Full hip flexion lying	-2.27	10	10	-2.62
*Toilet on time with difficulty	-2.09	11	11	-2.40
† Full knee flexion	-2.04	12	12	-2.19
Open hand from closed	-1.88	13	13	-2.00
Dress top half of body	-1.32	14	14	-1.81
*Walk in the house	-1.27	15	15	-1.62
Oppose little finger and thumb	-1.13	16	16	-1.44
† Get to the toilet on time without difficulty	-1.00	17	17	-1.27
Lift foot off floor quickly sit	-0.91	18	18	-1.10
Bathe without difficulty	-0.90	19	19	-0.94
Flex arm 90 supinate/ pronate	-0.82	20	20	-0.78
Finger extension & abduction	-0.50	21	21	-0.62
Climb one flight of stairs	-0.33	22	22	-0.47
Turn doorknob without difficulty	-0.27	23	23	-0.31
Hip flexion & knee extension	-0.13	24	24	-0.16
Walk sideways	0.08	25	25	-0.01
Tap index finger quickly	0.13	26	26	0.13
Fully abduct arm	0.23	27	27	0.28
*Gait speed >0.5 <0.8 m/s	0.32	28	28	0.43
Lace shoes without difficulty	0.37	29	29	0.57
Draw an 8 with your arm	0.70	30	30	0.72
*Unable to work/ do activities	0.90	31	31	0.87
† Gait speed >0.8 <1.3 m/s	0.99	32	32	1.02
Walk several blocks	1.05	33	33	1.17
Do arms scissors	1.06	34	34	1.32
Tap foot quickly	1.21	35	35	1.47

Table 4.6 continued. Item Difficulty and Person Ability in Logits and Equivalent Expected Scores (0-52) for the F3m

44 Items	Item Thresholds Logit Difficulty	Item Thresholds Raw score	Person Scores Equivalent Expected	Person Scores Logit Ability
Pour water	1.38	36	36	1.63
† Walk in the community	1.42	37	37	1.80
Clip toe nails without difficulty	1.43	38	38	1.97
External rotation of the arm	1.57	39	39	2.14
Stand with one foot in front 30sec	1.94	40	40	2.32
*Unable to do physically demanding activities	2.01	41	41	2.51
Touch fingertips quickly	2.01	42	42	2.71
Stand on 1 leg for 5s	2.53	43	43	2.92
Do heavy housework without difficulty	2.66	44	44	3.14
Trace leg pattern quickly	2.92	45	45	3.37
Quick ankle circumduction	3.04	46	46	3.63
Drive a car as before	3.21	47	47	3.91
† Able to work/do activities	3.50	48	48	4.23
Bounce a ball	3.76	49	49	4.60
Tandem walk for 2 m	3.81	50	50	5.06
† Do physically demanding activities	4.51	51	51	5.70
Gait speed >1.3 m/s	4.86	52	#52	6.59

The items are ordered by difficulty from top to bottom by the threshold values of each response option. Shaded items represent those where persons rate their difficulties in performing physical activities; non-shaded items are those where performance is observed and rated.

* Items with more than one response option, the first response option

† Items with more than one response option, subsequent response options

††Walking speed in meters per second per category: 0=0-0.5; 1=0.6-0.8; 2=0.9-1.3; 3>1.3

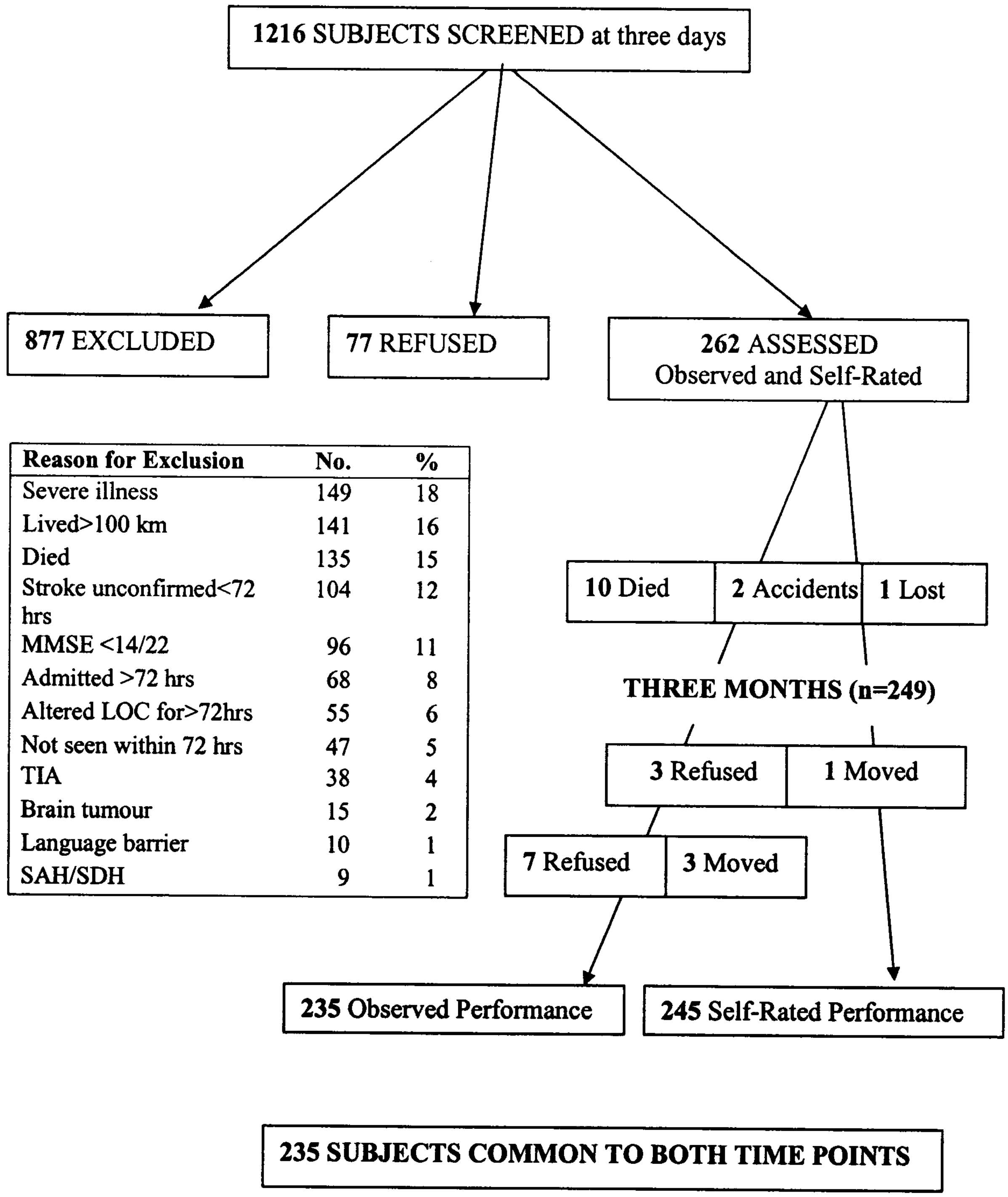
Extreme score: the last score is extreme and was estimated by extrapolation from last three known estimates

22 Table 4.7 Convergent and Divergent Validity Spearman Correlation Coefficients for the Functioning Measure at Three Months, the F3m and Other Indices.

Convergent*		Divergent*		
	F3m	Emotion SIS	Memory SIS	MHI
SIS (0-100)				
ADL/IADL	0.89	0.43	0.46	0.33
Physical composite	0.89	0.46	0.48	0.37
Hand	0.76	0.40	0.38	0.30
Mobility	0.75	0.40	0.37	0.32
Participation	0.70	0.46	0.43	0.43
Strength	0.65	0.40	0.40	0.30
Recovery	0.54	0.37	0.34	0.34
Emotion	0.41	--	0.46	0.62
Communication	0.27	0.35	0.55	0.23
Memory	0.36	0.45	--	0.34
MOS SF-36 (0-100)				
PF	0.82	0.41	0.36	0.35
MH	0.28	0.62	0.34	--
VT	0.33	0.50	0.30	0.58
RP	0.47	0.35	0.32	0.37
SF	0.52	0.43	0.33	0.47
EQ-5D (0-100)	0.71	0.48	0.45	0.40
PBSI (0-100)	0.80	0.57	0.54	0.45
STREAM (0-100)	0.87	0.34	0.33	0.21
CMSA (0-42)	0.93	0.30	0.33	0.24
Balance scale (0-56)	0.85	0.37	0.37	0.22
Grip strength (kg)	0.75	0.22	0.28	0.15
B & B (# blocks)	0.83	0.30	0.30	0.20
Gait speed (m/s)	0.85	0.37	0.34	0.24
Two Minute Walk test (m)	0.87	0.36	0.38	0.25

Abbreviations: CMSA, (Chedoke McMaster Stroke Assessment); STREAM, (Stroke Rehabilitation Assessment) ; ADL, (Activities of Daily Living); IADL, (instrumental activity of daily living) ; MOS SF-36, (Medical Outcomes Trust Short Form-36 questionnaire); SF-36 domains: PF, (physical functioning scale); MH, (mental health); VT, (vitality); RE,(role emotional); RP(role Physical); SF (Social Functioning); B&B (Box and Blocks); SIS; (Stroke Impact Scale); PBSI (Preference Based Stroke Index); EQ-5D, (EuroQoL, 5 dimensions) ; m, (meters); m/sec, (meters /second).

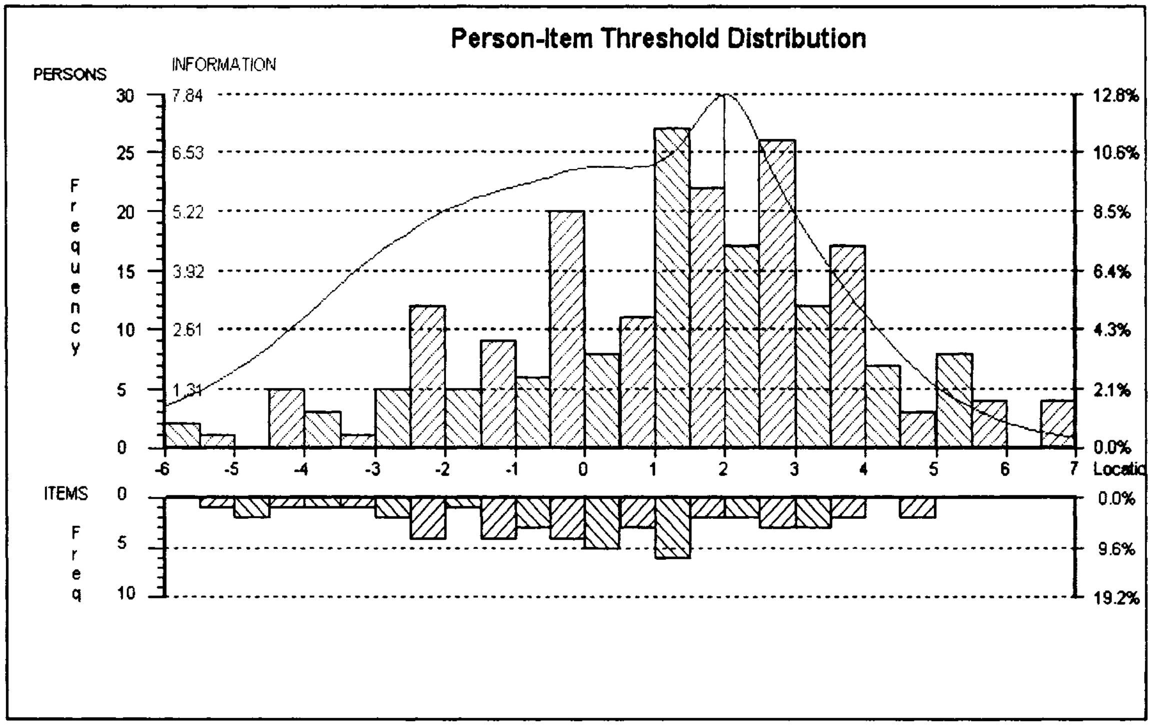
*All correlations are significant at $p<0.001$.



Reason for Exclusion	No.	%
Severe illness	149	18
Lived>100 km	141	16
Died	135	15
Stroke unconfirmed<72 hrs	104	12
MMSE <14/22	96	11
Admitted >72 hrs	68	8
Altered LOC for>72hrs	55	6
Not seen within 72 hrs	47	5
TIA	38	4
Brain tumour	15	2
Language barrier	10	1
SAH/SDH	9	1

5 Figure4.1 The Screening Process, Participants and Reasons for Exclusion.

Figure 4.1 Legend: Exclusion Table abbreviations: hrs, (hours); km, (kilometer); LOC, (level of consciousness); MMSE, (Mini-Mental State Exam); TIA, (Trans-ischemic attack); SAH, (subarachnoid haemorrhage); SDH, (subdural hematoma).



6 Figure 4.2 The Item-Person Threshold Distribution and Test Information Function for the Measure of Functioning at Three Months, the F3m.

Figure 4.2 Legend. The horizontal axis, scaled in logits, denotes functioning from least functioning at the left to most functioning at the right. The vertical axis denotes the frequency. The bars represent the distribution of subjects and items at each location. The line in the top of the figure represents the Test Information Function (TIF). An item's information function is the inverse of the item standard error squared; a TIF is the sum of item information functions

```
               -6        -5        -4        -3        -2        -1         0         1         2         3         4         5
                |---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
Finger flex     ----0---|---------------------------------------------------1--------------------*------------------------------
Sit             ------0-----|-------------------------------------------------1-------------------*-----------------------------
Df/toe          -------0-------|-----------------------------------------------1-------------------*----------------------------
Log roll        ----------0---------|---------------------------------------------1----------------*----------------------------
Hip flex ly     ------0------|-----------1-----------|------------------------------------2--------*----------------------------
Finger flex     -------------0------------|------------------------------------------1-------------*----------------------------
Bridge          ---------------0---------------|---------------------------------------1-----------*----------------------------
Knee flex       ---------------0--------------|----1---|-----------------------------------2-------*---------------------------
Inversion       -----------------0-----------------|-------------------------------------1---------*----------------------------
Open hand       --------------------0--------------------|----------------------------------1-------*---------------------------
Toilet time     -------------------0-------------------|----1----|------------------------------2----*--------------------------
Dress top       -----------------------0----------------------|--------------------------------1----*---------------------------
Oppose little   ------------------------0-----------------------|-------------------------------1----*--------------------------
Foot off floor  -------------------------0-----------------*------|------------------------------1-----------------------------
Bath            -------------------------0-------------------------|-----------------------------1-----*------------------------
Flex arm        -------------------------0-------------------------|-----------------------------1-----*------------------------
Finger ext&abd  ---------------------------0---------------------------|---------------------------1----*-----------------------
Stairs          ----------------------------0---------------------------|---------------------------1-----*---------------------
Door knob       ----------------------------0----------------------------|--------------------------1----*----------------------
Hip & knext     -----------------------------0----------*-----------------|--------------------------1-------------------------
Walk side       ------------------------------0-----------------------------|-------------------------1-----*-------------------
Walk            -----------------------0-----------------------|-------------1---------*---|------------------2-----------------
Tap finger      ------------------------------0------------------------------|------------------------1--------*----------------
Arm abducts     -------------------------------0------------------------------|------------------------1-------*----------------
Lace shoe       -------------------------------0-------------------------------|-----------------------1-------*----------------
Arm figure8     ---------------------------------0---------------------------------|---------------------1-----*----------------
Several blocks  -----------------------------------0-------------*---------------------|--------------------1-------------------
Arm scissors    -----------------------------------0----------------------------------|--------------------1------*-------------
Tap foot        ------------------------------------0----------*-------------------------|-------------------1------------------
Pour water      ------------------------------------0------------------------------------|------------------1-----*-------------
Clip nails      -------------------------------------0------------------------------------|------------------1------*-----------
Arm rotation    -----------------------------*--------0-------------------------------------|-----------------1-----------------
Stand tandem    -----------------------------*----------0---------------------------------------|---------------1---------------
Finger tips     -----------------------------*-----------0---------------------------------------|---------------1--------------
Gait speed      -------------------------------0-------------------------------|--1--|------------------*-2------------------|3-
Work/activities ----------------------------------0----------------------------------|------------1------*-----|--------2-------
oneleg5sec      --------------------------------*----------0------------------------------------------|------------1------------
House work      --------------------------------*-----------0------------------------------------------|------------1-----------
Trace quickly   --------------------------------*------------0--------------------------------------------|----------1----------
Ankle circle    ---------------------------------*------------0--------------------------------------------|----------1---------
Drive           ---------------------------------*-------------0---------------------------------------------|---------1--------
Do activities   ----------------------------------------0---------------------------------------|------*------1-----------|--2--
Bounce ball     ----------------------------------*--------------0------------------------------------------------|------1------
Tandem walk     ----------------------------------*---------------0------------------------------------------------|------1-----
```

7 Figure 4.3 The Item Threshold Map For Each Item in the F3m, with the Responses of One Average Subject.

Figure 4.3 Legend. The horizontal axis scaled in logits, denotes functioning from least functioning at the left to most functioning at the right. The items are ordered from top down by difficulty with the most difficult at the bottom. The location of each response option (0, 1 or 2) increases from left to right as the numbers increase. The short vertical line indicates the expected half-way point between any two response options indicating that the person with an ability at that level has a 50% probability of responding with either 0 or 1; or, 1 or 2. The stars represent an average person's response options on each item. The stars represent the responses on an item by a subject with an average ability of 1.32 (SE: 0.39) logits

Chapter 5 Manuscript 3: *The Impact of Stroke on Early Functioning: The Functioning Measure at three days, The F3d.*

Preface to Manuscript 3

The F3m covers all the components of the ICF and is ready to be used to quantify recovery at three months post-stroke. However, interventions to improve early functioning post-stroke must impact favourably on the factors that affect early recovery. As the most influential factor related to recovery is early functioning and because a measure of such early functioning does not exist a measure of functioning at three days was constructed in a manner similar to the F3m.

The first days after a stroke are crucial to recovery. Evidence from animal and human studies indicates that after a lesion, the brain recovers spontaneously through resolution of the secondary effects of stroke, prevention of further neuronal loss, and neural plasticity (8). Post injury, the brain demonstrates a capacity to reorganize, both structurally and functionally, that depends on usage and the relearning of skills (357) (130). Therefore, it is possible that the use of impaired limbs early post-stroke could enhance neural growth to improve the recovery.

Nudo et al. (357) (7) reinforced the fact that behaviour leads to neural changes. Using a monkey model, they found that the cortical map representation of a specific motor task in the brain was lost unless training took place post infarct. The monkeys, with surgically induced minor cortical lesions, were pre-trained to retrieve food pellets and retrained within 5 days post infarct. Intracortical microstimulation techniques defined the cortical maps of the distal forelimb representation before and after the training. After training, the increase in the map areas of spared wrist (57%) and spared digits (15%) were postulated to be due to repetitive practice. Although the tasks promoted cortical reorganization, reorganization may depend on the kind of practice and learning - its timing, intensity and the training environment. These factors have been explored by others.

Reisdal et al. (4) explored the environmental influences on rats, post Middle Cerebral Artery Occlusion (MCAO), housed either in an enriched environment or in standard laboratory cages and concluded that both an enriched environment and training facilitated better functioning post-stroke. Jones et al. (16) addressed learning as a strategy in their experiments with rats trained for 28 days, starting early at day 2-4 post MCAO, on an acrobat course that required learning or a repetitive task that did not. The acrobatic training that required learning improved the neural structures and performance more than the repetitive training.

From this evidence, the best rehabilitation intervention would seem to incorporate early, graded, and rewarding tasks that require learning and repetition. The training should start within two days post-stroke, be graded in intensity for the first week, and increase after 7-10 days, (4) (16) incorporate the use of both limbs, and be rewarding to increase motivation (357). As activity differs from learning a skill, training should require learning and repetition (16) (357). Lastly, the training environment should allow for social interactions and an opportunity to engage in everyday activities (4)

The most successful early rehabilitation interventions have incorporated these ingredients to some extent (74) (259) (358) (359), but have not always been targeted to those subjects with the capacity for recovery, especially at the level of the brain (156) (150).

To date, researchers studying the links between recovery of functioning (360) (163) (361) and brain activity, in humans post rehabilitation, have used a single outcome; namely, hand strength or dexterity or a set of criteria on a number of hand function indices (162)to characterize changes in activation or the effects of training. The areas activated in the brain through imaging (163) (164) (362), or electro-physiological studies (363) (364), are dependent on the tasks and the functioning level of the subjects. Thus, the measure of functioning would appear to be as important as the measure of brain activation.

To characterize the impact of stroke or the impact of interventions on brain tissue and the person requires adequate quantification of the impact of stroke on functioning. The very purpose of Manuscript 3 was to develop a comprehensive measure of the acute impact of stroke on functioning three days after stroke. An accurate measure to quantify the impact of stroke on early functioning with a strong relationship to later functioning and brain capacity could assist in selecting subjects to evaluate early interventional trials.

Again, the problem of defining a comprehensive baseline measure of early functioning presented itself. We chose to define acute functioning, in the same manner as before, using the ICF as a conceptual framework and Rasch analysis as the method of quantification. The content was chosen from early measures assessing relevant aspects of the impact of stroke on functioning including, impairments such as strength, and activity limitations such as those related to activities of daily living and mobility. Multiple measures are methodologically difficulty to deal with, and as a single index quantifying functioning in the acute phase does not exist, the objective of manuscript 3 is to develop a comprehensive measure of the impact of stroke on early functioning three days after stroke incorporating the framework of functioning within the ICF model.

The following manuscript outlines the development of the F3d, a measure of early functioning and is to be submitted to the journal *Stroke.*

Title Page

The Impact of Stroke on Early Functioning: The Functioning Measure at three days (F3d)

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For Submission to the Journal *Stroke*

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Keywords: Rasch analysis, Early Functioning, ICF

Abstract

The first days after a stroke are crucial to recovery as interventions targeting survival and functioning may have greater impact if offered early. A critical step in evaluating therapeutic interventions for persons with stroke is an accurate quantification of early functioning. Numerous tests and indices assess various relevant aspects of functioning early post-stroke including, impairments such as strength, and activity limitations such as those related to activities of daily living and mobility. Multiple measures are methodologically difficult, but a single index quantifying functioning in acute stroke does not exist.

Objective: To develop a measure of the impact of stroke on early functioning.

Methods: A longitudinal prognostic study of 262 people with stroke was carried out. Assessments were made at three days and three months post-stroke using 15 indices and tests for 260 items. Information on variables with prognostic importance was also collected: age, stroke type and severity, and previous health state. For this study, the measurements on 174 functioning items made at three days post-stroke were used.

Analysis: Factor analysis and Rasch analysis were used to confirm the item factor structure, item hierarchy and unidimensionality of the measure. Items that did not fit the Rasch model were deleted iteratively based on fit and relationship to the construct. The final measure was confirmed via fit statistics; internal reliability was also assessed.

Results: A 38-item unidimensional measure of the impact of stroke on early functioning, the Functioning 3-day measure (F3d) was developed. All items and persons fit the model. The item's difficulty matched the person's ability with a person ability of -0.31 logits. The person and item reliability were both 0.97 indicating a stable person-item hierarchy. Precision of the measure (standard error) was 0.37 and 1.3 logits for items and persons, respectively.

Conclusions: Rasch analysis identified 38 items for a measure of the impact of stroke on early functioning, the F3d with good psychometric properties. The F3d expands the range of assessment in acute stroke, covers a broad spectrum of difficulty and shows promise as a predictive measure.

Introduction

The impact of stroke is highly variable with deficits spanning the range of physical, sensory, cognitive, and emotional functions (1). The vulnerable brain is influenced the most, for good or for harm, in the first days after stroke (2) (3) (4) (5) (6). To date, the interventions with the greatest early benefit for a person with stroke are thrombolysis with tissue plasminogen activator (97) and organized care provided in acute stroke units (101) (100), with the units impacting on greater numbers of persons (99).The benefits of organized care appear to arise from good medical management and early initiation of rehabilitation; however, the definition of early in the provision of rehabilitation varies from within 24 hours (102) (365) (366) (367), to 2 weeks post-stroke (368). The effects of early stroke unit interventions have been shown to reduce the probability of death (odds ratio (OR) 0.66), death or institutionalization (OR 0.70) and death or dependency (OR 0.85) (101). The outcome "dependency" in these analyses was a dichotomous variable derived from the Barthel Index or Modified Rankin Index total scores (12) (68) reflecting only "dependency" in activities of daily living (ADL). In fact, stroke impacts on more than the activities of daily living or the ability to carry out activities as before, it impacts on the totality of what is considered functioning (93) (24).

A vital step in the evaluation of early therapeutic interventions is the accurate and comprehensive quantification and definition of "functioning" in this early period. The World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) (24) defines functioning, and its antithesis disability, as having two components: 1) body functions (the physiological expressions of body systems), and body structures (the anatomical parts of the body, organs limbs), and 2) activities and participation. Functioning is defined in the positive sense, while disability is defined negatively and refers to impairments of body structures and functions, limitations of activities and restrictions to participation. Activities are tasks or actions an individual performs. Involvement in life situations is considered participation. Functioning is further qualified by distinguishing between capacity, what people do in a standard environment (test situation), and performance, what people do in their usual environment (community, home). The ICF identifies the necessary components of functioning, but does not provide a measure to quantify functioning. A measure is essential to understand how stroke impacts on functioning and the subsequent changes in functioning. For such a measure, adequate content is only the first step, an indication of quantity is crucial.

Rasch analysis is a statistical technique that provides a method of quantifying constructs or latent traits such as functioning. The analysis produces a unidimensional measure on which items pertaining to functioning and the people assessed are organized hierarchically, by difficulty and ability respectively, on the same measurement scale in natural logarithm linear units or logits. Items that fit a Rasch model would form a measure of functioning with a total score that would determine that person's ability on the functioning construct (26). An improvement in functioning is inherent in the term recovery. Thus, without a measure of functioning, recovery cannot be quantified. Rasch analysis has been used to develop (235), summarize (300), refine, and combine items from different indices (134) into a single measure evaluating functioning. For example, the Stroke Impact Scale-16 (75), refined using Rasch analysis, provides an assessment of the impact of stroke on functioning, but targets persons with mild to moderate stroke at one month, and focuses on basic activities of daily living. Typically, most stroke indices are aimed at summarizing the functional skills needed later in the course of stroke recovery, for example the ability to carry out complex daily activities and community re-engagement (87) (369). Few stroke indices are used within the first three days, and few comprehensively cover the concept of early functioning (370) (12) (371) (5).

Objective

The object of this study was to develop a comprehensive measure of the impact of stroke on early functioning three days after stroke incorporating the framework of functioning within the ICF model.

Methods

A longitudinal prognostic study was carried out involving 262 people hospitalized following a cerebrovascular accident, using the World Health Organization definition: "rapidly developing clinical signs of focal (or sometimes global) disturbances of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin" (33). Persons were excluded if a diagnosis of stroke was not confirmed by imaging or clinical examination within 24 to 72 hours. Additionally, persons with the following were excluded: transient ischemic attacks, admission to hospital more than 72 hours after stroke, hemiplegia resulting from non-vascular causes, subdural hematoma, or subarachnoid haemorrhage, those with severe illness, such as end-stage cancer, pulmonary, cardiac or renal disease, those with severe cognitive or severe comprehension impairments and those persons in an altered state of consciousness at 72 hours as a result of their stroke.

Subjects were evaluated within three days of their stroke by observing their performance on specific tasks, and by asking them to rate how difficult is was for them to perform certain tasks such as, climb stairs, walk, and take a bath (75). They were reassessed at three months using the same tasks, complemented by additional ratings of their activities and participation which, while relevant at 3 months, were not relevant at three days.

Any subject classified as having a severe stroke, (Canadian Neurological Stroke score <5), (251) was evaluated twice to control for a possible rapid change in ability within the first three days. The subjects were assessed at three days on five of the indices, and at 7-days on 12 indices.

The study had ethical approval from McGill University Institutional Review Board and from the Research Ethics committees of all participating hospitals.

Indices of Early Functioning

The measure of the impact of stroke on early functioning at three days, the F3d, was created from items contained in 11 tests and indices commonly used to assess the impact of stroke, and from interviews pertaining to daily activities. The indices and their characteristics are found in Table 5.1a.

The indices that required the subjects to perform tasks were scored either by the quality of their movement or by the time it took to accomplish the task. Interviews with the subjects reflected the ratings of their own performance on the SIS-16 (75). Of the 11 indices, four were scored continuously (grip strength, Box and Block, walking speed, and the Two Minute Walk test). Their data were categorized, for entry into the Rasch model, based on age and gender norms and the relationship of the specific category to every day tasks as shown in Table 5.1b. Trained healthcare professionals carried out all evaluations three days after stroke. The evaluation procedure lasted on average 1.5 hours.

Additionally, data for 31 items representing the signs and symptoms of stroke, coded as present or absent, (diplopia, blurred vision, ataxia, nausea), and the 7 impairment items from the Canadian Neurological Stroke scale were collected (252) (372) (250). These data were abstracted from the neurological examination and the notes written in the chart by the health care professionals recorded at the time of maximum impairment within the first 72 hours of stroke.

Socioeconomic data and information on potential influencing factors were also collected via interview and included: age, gender, level of education, living arrangements, comorbid conditions (304), type of stroke, and cognition (305) (306). Data on the type of stroke were obtained from the neurological and radiological reports. The previous level of health of individuals was categorized into four groups based on the weights in the Charlton Comorbid index: 0; 1; 2&3; >3. The index weights are determined by the severity and number of comorbid diseases (304). Age was categorized into 4 groups (< 65, between 66 and 75, between 76 and 85, and > 85 years).

Analysis

Responses were available for analysis from 262 subjects on 16 self-report items and 31 symptoms and observations of performance on 165 tasks. The aim was to create a parsimonious list of items to quantify the impact of stroke on early functioning as conceptualized by the ICF. Obtaining observed performance data took precedence over the self-report data. For reasons of fatigue and comprehension, the SIS-16 proxy version was used in 21 subjects (83) representing 8% of the data. The subjects with proxy responses differed by stroke severity and disability from the subjects who responded. Nevertheless, the SIS-16 data from both groups were combined to insure subjects with a severe stroke were included in the analysis. Missing responses represented less than 10% of the data and were not replaced.

Descriptive statistics were used to characterize the sample; analysis of variance, χ^2 and t-tests were used for targeted contrasts. Principal component analysis (PCA), factor analysis (FA) and Rasch analysis were used to develop the measure. PCA and FA are multivariate techniques that summarize data and point out linear relationships between variables to help understand the underlying structure of the data (165) (268). The PCA and FA analyses require the data be normally distributed. The techniques were used to determine which items belonged together and if there was a single strong construct which could be considered "functioning" (268). A PCA was performed through the FACTOR procedure in the statistical analysis software SAS 9.1 (165) (239) (268). As would be expected from indices with items covering the same constructs, there were more than 30 pairs of items with inter-item correlations greater than 0.80. The items assessing the signs and symptoms of stroke and the items from the CNS loaded on conceptually different factors than the rest of the items and were not carried forward to the Rasch analysis; the remaining 174 items were.

Combining items from indices with ordinal response options requires an additional approach, such as, Rasch analysis that develops measures by transforming ordinal observations onto an interval scale. Unlike more traditional analyses where a model is fitted to the data, Rasch analysis requires the data fit the chosen model. The analysis relates a person's response to a specific item to the interaction between the amount of ability the person has and the level of difficulty that item represents (25) (207). Each person's ability and each item's difficulty are estimated precisely, with their own standard error, and are organized hierarchically by difficulty and ability respectively, on the same measurement scale in logits, the log of the odds of successfully completing to failing the task (207) (odds ratio). (For items the ratio is the probability of failure to the probability of success, difficulty; for persons the ratio is the probability of success to the probability of failure, ability). The impact of stroke can then be gauged by the person's total score. The total score would quantify the person's functioning defined by the items within the measure itself and impacted on by a stroke. The less importance the impact of a stroke on a person's ability relative to the difficulty of an item the greater the probability that person will succeed on that item. When a person's ability and an item's difficulty are equal the probability of performing that item is 50%. By convention, the average difficulty of the items is "zero" and only the relative position of the items can be estimated (207). This zero average item helps to determine the match between item difficulty and person ability. To adequately measure "functioning" the items' difficulty should match or target the ability of the subjects in the sample.

When the data fit the Rasch model, a unidimensional and invariant measure results; the measure describes only one attribute of the object being measured- here it is "the impact of stroke on early functioning". The item difficulty and person ability estimates remain invariant across the scale of measurement as the level of item difficulty does not depend on the particular characteristics of the people responding to the items, and the ability of the people does not depend on the characteristics of the items. These properties are assessed by fit statistics, item characteristic curves (ICCs) and category characteristic curves (217) (218) (219) (220).

A number of Rasch models can be employed to develop a measure; the one chosen depends on the data and the objectives of the measure (207). A conditional pair-wise estimation method for ordered response categories within an extended logistic Rasch model (26) (241), using the Rasch Unidimensional Measurement Model program (RUMM 2020) (215) (231) (228) was used here. This method was judged the most appropriate for fitting the data, as the number of item responses and their meanings differed across and within the various indices (228) (231). The mathematical model for ordered response options from "m" to "m + 1" exists in different forms, but as stated by Andrich et al. (228) are equivalent to:

$$P\{X_{vi} = x\} = \frac{1}{\gamma_{vi}} \exp\left[-\sum_{s=1}^{x} \tau_{is} + s(\theta_v - \delta_i)\right] \qquad (1)$$

"Where X_{vi}, $x_{vi} \in (0, 1, 2\ldots m)$ is a random variable taking the values of successive integers for successive categories, θ_v and δ_i are the locations of person v, and item i, and $\tau_{is,}$ where s=1,...m are the thresholds of the item response options and

$$\gamma_{vi} = \sum_{x=0}^{m} \exp\left[-\sum_{s=1}^{x} \tau_{is} + s(\theta_v - \delta_i)\right] \qquad (2)$$

is the normalizing factor to insure the probability ranges between 0 and 1" (228) (Andrich) p 1. In addition, as the mean of all the thresholds are bound by δ_i the item location, all thresholds add to "zero" for each item.

For proper structuring of the measure, the method requires the item response options be ordered such that the probability of responding to any item response option is possible. A disordered category results when people with more ability do not have a greater probability of successfully responding to a more difficult level of a question than those with less ability. This is judged by an item's threshold or the pivotal point in an item's response options, the point at which the likelihood of failure equals the likelihood of success at a specific option; for example, between 0 and 1, or between 1 and 2 (25) (215). The threshold or the difference in difficulty between response categories should indicate a distinct functioning level per response category. For adequate distinction of difficulty levels within an item, the difference in threshold values should be evenly spaced. If they are too far apart (represented by large differences), the impact of stroke that falls between the two response categories is unknown, while response option difficulty levels that are too close together are indistinguishable (373). Items with disordered response options are rescored, usually by collapsing categories.

The quality of the fit of the data to the model, after rescoring of items (as necessary), was examined iteratively and the poorest fitting items removed until the best fit of the data to the model was obtained. The data qualities were judged by the criteria in Table 5.2a-c. There are no absolute criteria on which to base judgments of quality, rather they depend on the estimation method, the statistic and type of program used. The guidelines, as developed and set out in Table 5.2a-c, provide an indication of quality. All indicators should be considered in any discussion of fit to the model and the quality of the resultant measure.

Redundant items in the model were removed, based on their association with the construct and their precision, the most precise item was retained (26) (226). In addition, a Test Information Function, summed from each item's Information Function was derived. An item Information Function, or the inverse of the standard error squared, is an indication of the precision of the estimation method (310) (374) (311).

A Rasch analysis does not include any item to which all subjects either chose the maximal or minimal response option, or any person that achieves the top or bottom score on all the items, as neither of these (items or persons), provides information about difficulty or ability (207). Two CMSA items and two SIS-16 items were deleted for this reason.

As all the items were administered at the same time, they were co-calibrated using the concurrent calibration method (195). This method determines the difficulty level of a set of items concurrently and allows items from various indices to be measured in the same units, despite the differences in numbers and types of response options, as long as the items measure the same construct.

Differential Item Functioning

Once the data from items, response categories, and persons were judged to fit the model, the stability of the item location or differential item functioning (DIF) across the different influencing variables (gender, age, stroke severity, and previous health) (258) (260) was tested with a two-way ANOVA. To quantify an underlying construct such as functioning, the measure must be invariant, that is unaffected by the characteristics of the people it measures (258). For example, a difficult item in the measure should be equally difficult for men or women, young or old, and at different times of assessment. The absence of DIF improves the ability of a measure to detect change as the item calibrations are stable. For the DIF analysis the participants were divided into four groups of roughly equal ability and then by the influencing variable within that group. The difference in the level of difficulty per item was assessed across the groups by a two-way analysis of variance of the person-item residuals (215) (261). The significance level was adjusted for multiple comparisons by a Bonferroni correction (262).

The sample size needed for stable person and item estimates (within ± 0.5 logits at the 99% confidence level), based on an expected standard error of ± 0.19 in the measure was 200, (263) taking into consideration fair targeting of items to persons (309).

Content and Construct validity

Content validity subsumes the idea of differing levels of impact on functioning. Thus, the extent or spread of the items and participants along the measure confirms the breadth of the concept of the impact of stroke on early functioning and allows the identification of individual differences.

Validity of measures developed with Rasch methodology is assured if the data fit the model (214), and is reinforced if the hierarchy of items and persons is reliable and consistent with the theory of the underlying construct. The impact of stroke on early functioning is a result of a complex interaction between the consequences of stroke on brain tissue and the person, together with their personal and environmental factors as set out by the ICF (24). The theory is that the impact of stroke on early functioning must include various items indicative of functioning at various levels of difficulty (24), from being barely able to move an arm or a leg, to the control of complex rapid dexterous movements, to basic ADL tasks, such as eating and bathing, to more complex tasks such as climbing stairs.

As no gold standard exists against which to compare this measure of functioning, three types of construct validity, convergent, divergent and discriminative, were evaluated with correlational and known groups approaches (266).

For convergent and divergent validity, it was hypothesised that the correlations between the raw F3d score and the total scores from the 10 physical indices measuring the more physical aspects of functioning, set out in Table 5.1a and 5.1b, would be higher (0.7 or greater) than the correlations between the sensory aspects of functioning measured by Albert's test or the Fugl-Meyer sensory test (0.4 or less).

The impact of stoke can vary across levels of stroke severity (251) and global disability (72). Thus, a general linear model with post-hoc t-tests estimated whether the F3d could discriminate between subjects across four levels of stroke severity measured by the CNS (250) (252) and six levels of global disability at discharge measured by the Modified Rankin Scale (337). As a comprehensive measure of functioning the F3d should be able to predict a person's ADL functioning level post-stroke as well as other measures of physical ability, such as the CMSA or the SIS-16. The ability of the F3d to predict ADL on the BI at discharge after adjusting for length of stay, age and stroke severity was determined via multiple linear regressions.

Results

A total of 1216 patients were screened at three days post-stroke for entry into the study, 262 accepted to participate, 77 refused and 877 were excluded. The average time to interview was 2.98 days (SD: 1.7). Of the 262 subjects evaluated later than five days post-stroke, all 49 (19%) had sustained a severe stroke (CNS: mean: 3.7; SD: 1.1). The two sets of data for these subjects evaluated at 3- and 7-days, in Table 5.4, did not differ; the 7-day data were included.

Figure 5.1 illustrates the screening process, participants and reasons for exclusion. Table 5.3 lists the baseline characteristics of the participants and those who refused. Despite the four year age difference between the two groups, in Table 5.3, the non participants had a milder stroke (CNS: mean: 7.7; SD: 3.5), with a higher discharge ADL score (BI: mean: 71.3; SD: 25.9), and shorter length of stay (mean: 13.5; SD: 9.7) than the participants.

The average age of the cohort of 262 persons assessed at three days post-stroke was 71.4 (SD: 12.9) years; 63% were men, 86% had an ischemic stroke and their median length of stay in hospital was 11 days (mean: 16.6; SD: 21.0). More than 2/3 of the sample had one or more concomitant medical conditions, primarily hypertension, cancer, prior stroke, and previous myocardial infarction. The majority of the subjects had a moderate stroke (42 %); 19% had a severe stroke and most were discharged to a rehabilitation facility (52%) or home (40%).

Table 5.5a demonstrates the impact of acute stroke on the observed performance of the subjects at three days. The large standard deviations in each of the indices points out the variability of the impact on functioning. Mobility, balance and hand ability (strength and dexterity) seem to be affected more than the movements of the arms or legs. Indications of impaired mobility are reflected in the number of subjects unable to walk (48%), the mean distance walked for two minutes, 46.7 meters (SD: 61.7) (312), the average walking speed of 0.38 m/s (SD: 0.5) (313) (314), the STREAM mobility score (mean: 57.4 out of 100; SD: 31.5) and the very low balance scores (mean: 28.3 out of 56; SD: 20.4).

The impairments in overall movement of the limbs are seen in the total STREAM (mean: 68.4 out of 100; SD: 30.9) and CMSA scores (mean: 30.1 out of 42; SD: 8.4) with the specific impairments illustrated in the STREAM and CMSA upper and lower extremity scores. Although the impact of stroke on the extremities varied greatly, 10% of the subjects showed no leg impairment on the CSMA, 26% achieved the top STREAM leg score, and only 13% had no foot impairment. As for the upper extremity, 20% had "normal" arm ability (CSMA arm stage of recovery 7), and 17% had no hand disability (CSMA hand stage of recovery 7). Greater impairment in upper extremity ability is seen in hand strength, which was only 44% of the norm for 70-year old persons (317) (mean affected hand strength: 16.9; SD: 14.2 kg), and dexterity, which was 34% of the expected normal function (mean affected hand B&B: 23; SD: 20.7 blocks) (315) (316).

Activity limitations are generally related to the level of impairment (375). This is reflected in the subjects' rating of their performance on the SIS-16 (mean: 38.2; SD: 23.5) and their actual observed ability in performing the ADL tasks on the BI (mean: 51.4; SD: 31.2) in Table 5.5b. The SIS-16 and the BI contain identical items on bathing, and climbing stairs. Interestingly, the subjects rated their own performance lower on the SIS-16 item for bathing than the evaluator who rated their actual observed performance on the bathing item in the BI. Table 5.5a also indicates other impairments, for example 19% of the sample had perceptual neglect. As one of the study's inclusion criteria was mental competency, the mean score on the MMSE was 18.0 out of 22 (SD: 3.3). Only average ability is discernable from the scores in Tables 5.5a and 5.5b as the ceiling and floor effects of the indices make it impossible to discern the ability of individuals at the top or bottom of the scale in any index.

Data Structure

The first principal component of the PCA was responsible for 43% of the variance indicating that this component formed a unidimensional structure (276) (165) (268). However, as the data are ordinal and not normally distributed, the component does not form a linear combination of items (268) (276).

Before a full Rasch analysis was carried out, the disordered response thresholds in the polytomous items revealed by the analysis were rescored. The SIS had too many response options for subjects this early post-stroke. This was reflected by the inability of the subjects to use the middle response options. Three BI items, and all the continuously scored tasks that were rescored categorically, had disordered response thresholds with infrequent use of the middle categories. The rest of the items, the Balance Scale items, and the STREAM hand and foot items, had adequate response frequencies in each category, but the raters observing the performance on the tasks were unable to rate consistently those with poor ability in the easier categories or those with good ability in the harder categories. In all, 26% (I=44) of the polytomous items were rescored considering the criteria for optimizing category effectiveness, inspection of category characteristic curves, item fit and standard errors (228) (227).

Item Reduction

After rescoring the disordered items, the fit statistics were re-examined and the poorest fitting items were removed iteratively until the best fit of the data to the model was obtained. After each deletion, the match between item difficulty and person ability, the fit statistics and response options were reassessed. A fit of the data to the model was achieved with the removal of 78 items; 92 items remained. Items deleted based on standardized fit residuals represented constructs divergent from physical abilities, namely the continence (3, SIS-16 items; 2, BI items) and Albert's neglect items. Also deleted were items assessing physical abilities that were not part of the same concept or irrelevant to the construct: seven sensation items, and two STREAM low level mobility items. The SIS-16 bathing item was deleted as confusing; few subjects considered a sponge bath by a patient attendant as a true bath. The SIS items that assessed strength were deleted for misfit, as were the CNS strength items that misfit in an earlier analysis (data not presented). Strength may represent a different concept of functioning from the one here. Subsequent items were deleted for fit or relevance to the population (SIS-16: 'carry groceries or heavy items', 'get into a car'), or were measured at too low a level even for this acute group of subjects (CMSA items, 'arm and foot not in stage 1') or were redundant (CMSA and STREAM items of hand and arm function 'pronation and supination', B&B; Balance Scale, CMSA, SIS, and STREAM 'stand' items); 92 items remained

Structure of the Item Pool

The 92 items formed a pool of observed performance items (capacity) and self-rating of performance items to indicate the impact of stroke on early functioning. (These items and their characteristics are found in the Appendix.) The model global fit statistics and quality indicators of person and item reliability, separation and fit residuals in Table 5.6 indicate the quality of the item pool was adequate (item–trait interaction χ^2 of 314: person and item fit residuals; -0.18 ± 0.41 and -0.13 ± 0.24). The spread of functioning measured by person ability and item difficulty was 15 and 18 logits respectively, with the sample mean logit ability of 0.87 (SD: 3.15) slightly above the average item difficulty of 0.0 logits.

Unidimensionality of the item pool was confirmed by the overall model fit and the low Rasch residual variance from a PCA. However, 100 pairs of residual inter-item correlations were greater than 0.4 indicating item redundancies (26) (226). The redundancies were found in the CMSA hand and arm movement items; foot and leg movement items; between the STREAM and CMSA items, and between the CMSA posture and Balance Scale items. The items for the F3d measure were chosen from the item pool based on their relationship to the ICF constructs of functioning, targeting to the subjects, content coverage, and precision of measurement. The reduction in items from 92 to 38 resulted in a slight decrease in person reliability, but did not compromise the item reliability.

Structure and Properties of the Measure of Functioning

The global fit statistics in Table 5.6 confirm that the 38 items chosen from the item pool operate well together to define the impact of stroke on early functioning. That is, all item (mean standardized residuals:-0.24; SD: 0.37) and person (mean standardized residuals:-0.23; SD: 0.41 logits) fit statistics meet the requirements of the Rasch model. The reliability of the hierarchy of person ability and item difficulty was excellent at 0.97 and 0.98, respectively. The person separation index of 5.6 indicates the subjects separated into 6 distinct strata, while the items separated into 9 statistically distinct groups

The distribution of the 262 persons and 38 items across the F3d is depicted in Figures 5.2 and Table 5.3. The horizontal axes in both figures, scaled in logits, symbolize the impact of stroke on early functioning from most impact at the left to least impact at the right. In Figure 5.2, the vertical axis denotes the proportions; with the bars represent the frequency distribution of subjects and items at each location. The item thresholds and average item difficulty range across 12 logits from -6.87 logits (SE: 0.38) for the item 'facilitate finger flexion' to 5.00 logits (SE: 0.33) for the item 'bounce and catch a ball'. Person ability spans approximately 15 logits from -8.24 (SE: 0.95) to 6.82 (SE: 1.3) logits with the majority of the subjects located between -2 and + 2.5 logits. The difference between the item difficulty and the average person ability is -0.31 (average SE: 0.23) logits below the item mean of "0" indicating the items are a bit too difficult for the subjects, although still matching the person ability. A difference greater than 0.5 logits or 1 SE of the measure is considered a mismatch (209). The level of item precision varies from 0.11 logit to 0.37

logit standard error. Precision was slightly compromised for the subjects above 3 logits. As depicted in Figure 5.2, the Test Information Function (TIF), (235) drops off sharply to the right of 2 logits indicating a decrease in precision. Additionally, information is decreased below -3.9 logits, secondary to a lack of items between -5.6 and -3.9 logits. A floor effect is not present, but a minor ceiling effect of 1% is seen; three subjects are above 5.00 logits.

Figure 5.3 displays the threshold item map with the location of each response option (0, 1 or 2). The distance between the numbers indicates the spread of the impact of stroke represented by each response option. The impact decreases from left to right as the numbers increase. The short vertical lines indicate the expected half-way point between any two response options, the place where the person has a 50% probability of responding with either 0 or 1; or 1 or 2. The responses of a specific subject with the average ability score of -0.31 logits (SE: 0.42) are depicted in Figure 5.3. The 95% confidence interval around his ability is -1.13 to 0.51 logits; that is, 95 % of the time his average logit ability will be between -1.13 and 0.51 logits. The equivalent raw score for the subject is 22 (out of a maximum of 51) which can be calculated by summing this person's actual responses that are shown by the stars on the horizontal lines in Figure 5.3.

The usefulness of this map is illustrated with an example. A 82 year old man with a mild, left hemisphere, ischemic stroke has a probability of 100% for successfully completing the tasks below his ability. The probability of success decreases as the item difficulty approaches his ability; for example, the probability of success for the item, 'get on and off the toilet' is 75%. He is less likely to successfully complete the tasks above his ability level (-0.31 logits; SE: 0.42); for example, his probability of success on the item 'walk independently on a level surface' (difficulty: 1.12 logits; SE: 0.14) is 43%, and is only 0.6% for the item 'tandem walk 2 meters' (difficulty: 4.89 logits; SE: 0.26). At the group level, all the subjects in Figure 5.2, at 6.82 logits of ability, can tandem walk 2 meters in less than 10 seconds and report that they can climb stairs independently; the subjects at the lower end of ability, at -8.24 logits, are totally dependent and unable to move.

Table 5.8 arranges the items and persons by ability and difficulty with their logits and equivalent expected scores from 0 to 51. The smallest measurable difference, the difference in the measure that corresponds to a one unit increase in the score from 0 to 51, (see Figure 5.3 and Tables 5.7 & 5.8) forms an approximately uniform distribution varying between 0.6 and 0.1 logits (253). The difference in a score of 1, or -6.87 logits, on the F3d, and a score of 2, or -6.68 logits, is 0.19 logits, while the difference between a person score of 22 and 23 is 0.26 logits (Table 5.8). The increase in ability required to improve functioning at the lower end of the measure is similar to that in the middle. As the total raw score and logit score correlate at 1.00, the raw score responses can replace the logit scores in the F3d.

The unidimensionality of the measure was confirmed, first, by a PCA analysis of the Rasch F3d item raw scores with a first principal component explaining 65% of the variance and, second, by the fact that the first principal component from the analysis of the Rasch item residuals explained 11% of the remaining variance (276) (268). The internal consistency, measured by a standardized Cronbach's alpha, of the Rasch items was 0.96. The standardized item to total correlations were all between 0.30 and 0.81 (mean: 0.63; SD: 0.13) (267).

Differential Item Functioning

The difficulty level of the F3d measure was uniform across stroke type, gender, age, previous health, and stroke severity. However, one STREAM item, requiring observation of stair climbing ability, was thought to demonstrate non-uniform DIF, a difference due to stroke severity and person ability. For this analysis, the subjects were divided into 4 groups by ability; low, moderate, high, and very high, and within each of the 4 ability groups by stroke severity; severe, moderate, mild and very mild. The evaluators rated the high ability group within the severe stroke group with a stair climbing ability greater than expected, a score of 3, instead of an expected 1 out of 3. This high ability class interval of subjects with a severe stroke contained one subject. She was misclassified as a severe stroke due to the scoring requirements of the CNS used to define stroke severity. As she was dysphasic during the neurological examination in the first few hours of her stroke, the CNS items coding strength were all rated "zero". Although she had some strength, it was un-testable, and thus a "zero" score resulted. Based on a single subject, it is unlikely this item functions differently across ability levels in the severe stroke group.

Validity

The content of the F3d, seen in Tables 5.7 and 5.8, includes all the necessary functioning components of importance to a person after stroke; 22 body function items related to movement in the upper (11 items) and lower extremity (11 items); 8 activity items related to basic self-care (3 items), and mobility (5 items,) and 8 balance items. The items cover a broad spectrum of difficulty across 14 logits (see Figure 5.2 and Table 5.7) and are part of the comprehensive ICF core set for stroke (197). Although almost all the items in the F3d are those rated by a health professionals (I=36), it does include two items where the person rates his or her own mobility and balance performance (Table 5.8).

As hypothesised, the correlations, in Table 5.9, between the total scores of the F3d and the indices assessing the physical aspects of functioning were stronger (>0.70) than those between sensation and the physical indices, confirming convergent and divergent validity.

Discriminative validity

The distribution of F3d scores across the levels of stroke severity in Table 5.10 indicates the discriminative ability of the F3d. All but the very mildest stroke group was differentiated. A comparison of the SIS-16 and F3d scores across stroke severity at three days, and the modified Rankin Scale categories at discharge, in Table 5.10, demonstrates the increased sensitivity of the F3d over the SIS-16. The SIS-16 discriminates the lower categories (moderate and severe) of stroke severity, but is insensitive to higher levels. In contrast, the F3d discriminates between all but the very mildest strokes and is slightly better than the SIS-16 in discriminating between the levels of disability in the modified Rankin Scale.

In a multivariate linear regression model, the F3d explained more of the activities of daily living ability on the BI, at discharge, than either the 3-day SIS-16, CMSA or BI; the F3d explained 66% of the variance compared to 62% by the CMSA, 59% by the SIS-16; and 60% by the BI, adjusted for length of stay, age and stroke severity. Although the responsiveness of this measure needs to be tested, the reliability of the hierarchy, content of the measure and the distance between the items indicates that the measure would be responsive, except at the very lowest end of the measure.

Discussion

Rasch analysis was used to identify 38 items for a measure of the impact of stroke on early functioning. The resultant F3d measure demonstrates construct validity and good internal reliability. It expands the range of assessment in acute stroke beyond observational tasks and self-rating of performance by including items from both perspectives. It covers a broad spectrum of difficulty from more complex activities such as 'tandem walking' to 'bathing' to the rating of one's performance on the SIS-16 of 'standing without losing balance'. The F3d does not have floor or ceiling effects, discriminates across three levels of stroke severity and shows promise as a predictive measure.

The F3d presents the optimal set of items in the early phase of stroke to quantify the impact of stroke on functioning; it covers a multitude of abilities concentrating on the physical components of functioning and includes items that form a relationship to physical functioning as set out by the ICF. Not included in the F3d are the signs and symptoms at the onset of stroke that are related more to the pathophysiological consequences of stroke and that differ from this body functioning- and activity-based measure. The CNS items were not retained in the F3d. The CNS was developed to cover 3 concepts, alertness, orientation and language, and strength and has two scoring algorithms (250) (251), one for those able to cooperate and one for those unable to cooperate with the examination due to receptive aphasia. In aphasic subjects, the CNS may measure a multidimensional construct, the interaction between ability to perform a task and language. Dysphasic subjects may be misclassified with a more severe stroke. This was seen in one subject whose excellent stair climbing ability would not have been predicted based on her CNS score.

The correlations between the F3d and 11 indices measuring the physical impact of stroke on functioning (Table 5.9), illustrates the validity of the measure. The high correlations suggest that there is a redundancy at the item and the index level of measurement between the numerous indices used to evaluate functioning (266). This fact was reinforced by the high number of residual inter-item correlations in the Rasch pool of items (195). The F3d could replace these indices.

In Table 5.8, a few of the items in the F3d may appear redundant, for example, 'get on and off toilet independently' (0.67 logit) and 'hand to forehead quickly' (0.68 logits); these items differ by ICF component and body part measured. This redundancy is reinforced by the high Cronbach's alpha, items were retained at the expense of redundancy to maintain face validity. While a lack of items occurs at the extremes of indices preventing an accurate assessment of functioning (195), redundant items are usually found in the central portion of a measure. The F3d defines higher levels of functioning fairly well, from 2.79 to 5.0 logits, but lacks some definition and precision at the lowest levels, from -3.9 to -5.6 (236). Additional items at the lower end could improve the measure.

The construct validity of the measure was further assured by the fit of the data to the model and the hierarchy of items and persons. As theorized, the items are organized from body functions ('facilitate hip movement': -6.87 logits), to activity ('stand without losing balance': -0.28 logits) items, and from simple tasks, such as 'wrist extension >1/2 range' at -3.52 logits, to more complex tasks of 'walk down 3 stairs with alternate feet', 1.18 logits, or 'bathe oneself independently' 3.81 logits (Table 5.6). The ordering of the balance items are as suggested by Berg et al., (334) (340) from 'standing to sitting' to 'reaching forward with outstretched arm' to 'standing on one foot' (from the CMSA). Although the scoring options (original 0-4, rescored 0, 1, 2) and populations differ (elderly versus stroke survivors) the hierarchy is similar. Many of the basic self-care and mobility tasks in the BI and the SIS ('climbing stairs', 'walking', 'bathing and dressing') were similar, yet they were rated differently, the BI was rated by actual performance and the SIS-16 is a self-rated questionnaire. Despite this, the two SIS-16 items and four BI items, retained in the model, are ordered as perceived by Duncan et al. (209) and others for ADL functions (242) (264). Interestingly, the ordering of the stair items, one based on self-rating of ability (SIS-16) and one on actual performance (STREAM), are similar, suggesting congruence in actual and perceived performance. The hierarchy of SIS-16 bath self-rated item and the BI observed performance bath item were divergent; the SIS-16 item was deleted. Unlike a number of measures (264) (336) (337), the F3d is not restricted to ADL or impairment items, but incorporates both.

The ceiling effects frequently seen in other global measures of functioning (BI, MRS and FIM) make it difficult to discriminate between levels of ability and limits the potential to observe shifts and changes in functioning (376) (72) (377). In contrast to these measures, the F3d encompasses a broad range of impairments and activity limitations and its psychometric properties support its use to measure change. The separation index for both items and person is excellent; an indicator of the ability to distinguish between groups of people by ability, a clue that the sensitivity of the F3d might be adequate when tested. Additionally, the ability of the items to separate persons into distinct groups makes the F3d an excellent measure capable of stratifying people for efficacy or effectiveness trials evaluating interventions.

The diverse set of items in the F3d, could characterize early functioning as a result of stroke, assist in devising treatment plans, or the progress of care decisions. For example, using the item map in Figure 5.3, or the total score (22 out of 51), can assist in defining a rehabilitation program for our average subject, who lacks balance (standing on one foot, score"0"), perceives his lower extremity strength as poor (get up off the toilet score,"0") and is deficient in fine foot and hand control. His program could consist of tasks that would strengthen his lower extremities eccentrically, balance activities progressing from a wide base of support, to a smaller one, and exercises that would challenge his ability to control his hands and feet movements. His goal was to bathe independently, one of the most demanding self-care tasks (1) (242) that stroke survivors find difficult to regain. The F3d change score should be capable of judging more than a specific outcome, such as the ability to take a bath. What is needed is a measure to judge the comprehensive outcome of existing rehabilitation programs and newer ones in development (22) (378).

Few clinical trials have studied the effects of early initiation of rehabilitation (379) (148) (380) (365) (381) (382) (155) (156). Recently trials evaluating the early initiation of rehabilitation have combined early therapy with increased intensity of therapy. In a meta-analysis of efficacy studies, summarizing rehabilitation interventions, only six studies out of 20 could be classified as starting early; the earliest started at 7-days post-stroke (129) (181) (15). The effects on ADL were not all positive, the effect sizes ranged from -0.38 to 0.75 standard deviation units (129). The effect sizes varied with the methodical quality of the studies: the more rigorous the methodology, the smaller the effect.[4] These conflicting results are partly due to combining studies that varied by type, timing, and intensity of the intervention, inadequate operationalization and quantification of functioning, and

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[*] Effect sizes are calculated as the ratio of change to variability. By convention, effect sizes >0.8 are considered large, those around 0.5 are considered moderate and those less than 0.2 small (143)

insufficient categorization of the sample to reflect the individual's capacity for post-stroke recovery of functioning (129) (142).

The majority of studies measured outcome by the level of independence in activities of daily living (12). Yet (65) (77) (61) (383), ADL as a construct is too narrowly focused to adequate quantify functioning post-stroke and indicates the compensatory elements a person uses to perform ADL tasks rather than the true ADL capacity. To date, the adequate understanding of the impact of stroke on functioning and the evaluation of rehabilitation programs has required the use of multiple indices and tests measuring impairments and activity limitations. Concerns remain over which indices to use. For example, the Functional Independence Measure (FIM) (200) does not include items on impairment, the SIS-16 (75) only covers activity limitations, and the BI and modified Rankin have significant floor and ceiling effects (375) (72). In addition, these indices were not developed on acute stroke populations, unlike the F3d measure.

It is difficult to characterize the impacts of stroke on the person's functioning based on a multitude of indices, rather an understanding of interrelationships is required if our present interventions are to be effectively applied (212) (129). To characterize this impact requires adequate quantification of the impact of stroke on early functioning as accomplished by the F3d. New rehabilitation interventions, based on animal models of intense early therapy (6) (5), are being developed and refined (384). A comprehensive measure of functioning, such as the F3d, that reflects the whole spectrum of early functioning and that is able to adequately capture change could assist in the planning of early interventions and be used to stratify subjects in trials of early therapy.

Limitations

The F3d was developed on a single sample of acute subjects, thus, it is difficult to compare this sample with others beyond demographics and a general description of impairments, as few other studies have measured the impact of stroke on functioning as early (13) (1) (55). However, the impact of stroke on functioning, as measured by the F3d, appears similar to that of a previous cohort of stroke subjects that characterized stroke recovery at 10 days (1).The subjects in this three day cohort, compared to those at 10 days, functioned at a lower level, emphasising that the return of functioning is rapid in this early period (1). The two groups compare well as to the proportion unable to walk, 48% versus 28%, mean hand strength 16.9 versus 17.6 kg, average dexterity 23 blocks in 60 seconds versus 25.3, and average ADL scores, measured with the BI of 51.4 versus 58.1 out of 100. However, our sample does not represent the majority of stroke subjects, especially those with a very mild stroke not admitted to hospital, or those with dysphasia or inadequate cognition to consent to participate. Additionally, although the internal consistency and separation indices are excellent, the test-retest reliability and a confirmation of the change in rating scale efficiency should be verified. Longitudinal validity or responsiveness to change (203) also needs to be assessed

Conclusions

Rasch analysis was used to identify 38 items for a measure of the impact of stroke on early functioning, the F3d. This measure demonstrates good psychometric properties, expands the range of assessment in acute stroke by including observational tasks and self-rating of performance items and covers a broad spectrum of difficulty. The F3d does not demonstrate floor or ceiling effects, discriminates across three levels of stroke severity and shows promise as a predictive measure. The hierarchy of the items in the F3d could aid to understand the early process of recovery of functioning, what is needed to successfully complete each successive stage and assist in the development of treatment plans.

23 Table 5.1a Index Characteristics in the Measure of Functioning at Three Days (F3d)

Construct	Index	Validity	Reliability	Responsiveness	Units, items /Scaling
Body Function	Activity Movement mobility STREAM (53) (54) (332).	Content Convergent Discriminate	Inter-rater: r : 0.99 Cronbach's α : 0.98 κ : 0.8 – 1.0	SRM: 0.89	Scale: 0 – 100; 30 items: 10 upper, 10 lower, responses: 0,1,2, 10 mobility; responses: 0,1,2,3.
Body Function	Movement balance pain CMSA (50) (51) (52)	Construct Concurrent Predictive	Varies by domain Intra-rater: ICC :0.94-0.96 Inter-rater-: ICC:0.88-97; Test retest: ICC:0.75-94	Not deter-mined	Scale: 1-7; 19 items each in 5 domains: posture, arm, hand, leg, and foot; shoulder pain 7 items responses; 0,1
Body Function	Balance scale (340) (334) (335)	Content Construct Discriminate	Intra-rater: ICC: 0 .99 Inter-rater: 0.99	Yes	Scale: 0-56; 14 items; responses; 0-4
Body Function	Sensation: Sensation portion of the Fugl-Meyer (46) measure of sensori-motor recovery after stroke	Content criterion	Sensation inter-rater: 0.85	SEM: 2.9	Scale: 0-24 12 Items: Light touch on arm and leg and position sense 8 joints. Only the 4 light touch and 1 joint items used scale 0-9 responses 0-2

Table 5.1a cont Index Characteristics in the F3d

Construct	Index	Validity	Reliability	Respons-iveness	Units, items /Scaling
Body Function	Cognition: MMSE telephone version (305) (306)	Content Construct	Not reported	Not reported	Scale: 0-22 6 items responses vary by item
Body Function	Perceptual neglect: Albert's test (341) (342)	Content Construct	Test-retest r:0.79	Not reported	Lateralized neglect is present when > 70 % of the lines are uncrossed on the same side as the motor deficit.
Activity	Basic ADL: BI (264) self-care continence mobility	Concurrent Construct Content Predictive	Inter-rater Reliability: r : 0.88 – 0.99 α : 0.96 SRM : 0.99	SRM: 0.99	10 items: 2 items; 2-point scale 0-1 6 items; 3 point scale 0-2 2 items; 4-point scale; 0-3;
Activity	SIS-16 (75) Proxy version (83)	Construct Convergent Known groups	Test-retest: ICC : 0.70-Reliability Index: 0.94, Person separation Index:3.82 Item separation 19.5	Estimated Clinically important change 10-15 points	Scale: 0-100; 16 items; physical domain Responses: 1-5.

Abbreviations: ADL, (Activities of daily living); BI, (Barthel Index); CMSA, (Chedoke-McMaster Stroke Assessment Impairment Inventory); α, (Cronbach's alpha reliability coefficient); ICC (inter-correlation coefficient), κ, (Kappa reliability coefficient); MMSE, (Mini-Mental State Examination); SEM, (standard error of the measure); STREAM, (Stroke Rehabilitation Assessment of Movement); SIS-16, (Stroke Impact scale-16 items); SRM, (Standardized response mean).

Table 5.1b Continuous Measure Characteristics and Categorization for Items in the F3d

Construct	Measure	**Validity**	**Reliability**	**Respons-iveness**	**Units, items /Scaling**
Body Function	†Strength: Grip Strength (350) (318) (351) (352)	Not Applicable	Test retest ICC: Right:0.93 Left:0.90	Not reported	kg of force Norms available
Body Function	Walking Speed: 5 Meter walk (332) (313) (314)	Not Applicable	Test-rest: r : 0.89 – 1.0	SRM : 1.19 m/s	Meters per second Norms available
Activity	†Dexterity: Box and Block test (356) (315) (316) (352)	Construct	Inter-Rater r: 1.0 both hands Test-Retest: ICC:97-89 depends on the sample	Estimated as 7 blocks	Norms available Number of Blocks per 60 sec
Activity	Endurance : Two Minute Walk test (353) (354) (355)	Construct	95% CI for repeatability : -27% to 38% Inter-rater ICC: 0.92	Minimal detectible change in stroke (90% CI) 19.8 meters (52)	Distance in meters walked in two minutes Norms available

Table5. 1b Continued. Categorization of Continuous Measures for Items in the F3d

Categories	0	1	2	3	4	5	6
Measure							
Walking speed category: meters per second (332) (313) (314)	0	0.12	0.25	0.5	0.8	1.3	>1.3
Two Minute Walk Test: category, distances (353) (354) (355)	<7	15	30	60	110	199	>199
Grip strength category: kg of force (317)	0	8	15	28	40	>40	-
Box and Blocks category: number of blocks (315) (316) (352)	0	10	25	40	66	>66	-

†As the effects of gender and handedness on grip strength and dexterity as measured by the Jamar dynamometer and B&B test are minimal, the data for males and females, and for the left hand dominant (n=4), and right hand dominant subjects were combined (316) (352). Grip strength and hand dexterity were classified by whether the hand was the affected or less affected hand.

Abbreviations: CI, (confidence interval); ICC, (inter correlation coefficient); SEM, (standard error of the measure); r, (correlation coefficient); SRM, (Standardized response mean).

24 Table 5.2a Model Quality Criteria for a Rasch Measure [*]

Quality Indicators		
Fit to the model	**Criteria**	1.Derivation / 2.Interpretation
Item trait interaction	Non significant model summary χ^2	1. The residuals derived from the difference between the observed and expected score with the expected determined by the model and the hypothesis that the data fit the model. The expected value and variance per item person interaction are calculated, summed across all items and squared to form a χ^2 per item $Z_{ni} = \frac{x_{ni} - E[X_{ni}]}{\sqrt{V[x_{ni}]}}$ summed across all items for a component χ^2 z =standardized residuals of the observed score from that predicted by the model. 2. Indicates that the level of item difficulty of the measure is consistent across subjects. It suggests the items form a linear and unidimensional measure. The difference between the observed and expected means along the continuum of the trait is smaller than expected by chance alone and the data fit the model (238) (215)
Unidimensionality		
The data fit the model	Non significant χ^2	1. See above fit section
Principal Component Analysis (PCA) of person item residuals	Variance explained by 1st component <10% (268)	2. If a measure is unidimensional there should be no meaningful correlations between item residuals. This is tested through a PCA of the residuals after the variance accounted for by the model has been removed. The amount of acceptable variance in the residual PCA analysis indicative of unidimensionality ranges from less than 10 to less than 20% (268). The ratio of the first to the second Eigen values can be used with a larger ratio indicative of unidimensionality(276)
Principal Component Analysis of the Rasch raw items scores	Variance explained by 1st component >40% (268)	Reflects the degree of invariance across the trait (165)
ICCs A graphical representation of the items' fit to the model	Non crossing	The graphs of ICCs do not cross, but are parallel if the items (with the same number of response options) belong to a single construct (228) (198)

[*] The Quality criteria for a Rasch model are dependent on the program used for analysis. The criteria here are based on the Rasch Unidimensional Measurement Model program (RUMM2020) (215). Additional criteria considered for analysis techniques and models are not included.

Table 5.2a continued. Model Quality Criteria for a Rasch Measure *

Quality Indicators: Fit to the model	Criteria	1.Derivation / 2.Interpretation
Invariance	The data fit the model	2. A Person's True ability does NOT depend on items administered. An Item's difficulty does NOT depend on the characteristics of the people taking it
Precision		
Information function	The larger the more precise $I_i(\beta)=\frac{[P_i'(\beta)]^2}{P_i(\beta)(1-P_i(\beta))}$	I=information, P= probability correct, Beta =ability. (135;235;310) 1. It is the inverse of the standard error squared per item 2. indicates a) the precision of the estimation procedure per item, 2b) The amount of information provided by an item at an ability level i.e. it delineates the range over which an item is most useful for defining person ability
Test information function (TIF)	The larger the more precise $TIF(\beta)=\sum_{i=1}^{k} I_i(\beta)$	1. Provides an indication of the precision of the measure or the Standard Error of the measure. SEM= (TIF) $^{1/2}$. 2a)The amount of information provided by a test about ability level at each maximum likelihood estimate(310) 2b) Can be used to compare the amount of information in different measures or subsets of items within a measure

* The Quality criteria for a Rasch model are dependent on the program used for analysis. The criteria here are based on the Rasch Unidimensional Measurement Model program (RUMM2020) (215). Additional criteria considered for analysis techniques and models are not included.

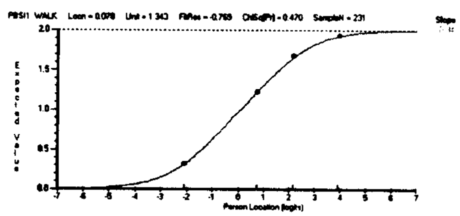
[25] **Table 5.2b Item Quality Criteria for a Rasch Measure***

Quality Indicators			
Item Fit		**Criteria**	1.Derivation / 2.Interpretation
	Standardized residuals	Per item -2 < residuals< + 2 Mean residuals close to '0' and SD of residuals close to '1' Power to detect fit is affected by number of items and sample size	1. Residuals from χ^2, squared and summed over all groups of subjects, transformed to approximate a normal distribution z =standardized residuals of the observed score from that predicted by the model then log transformed (215;219) $Z_{ni} = \frac{x_{ni} - E[X_{ni}]}{\sqrt{V[x_{ni}]}}$ 2. Items are considered to fit the model if residuals are not greater/less than ± 2 the 95% confidence interval of the normal distribution. >+ 2 can indicate irregular response patterns, noise, & multidimensionality (321) >- 2 indicates irregular response patterns, statistical dependency, and redundancy. (215)
Statistic	Chi-square	Non significant	1. The residuals derived from the observed-expected score with the expected determined by the model with the hypothesis that the data fit the model 2. The difference between the observed and expected is smaller than expected by chance alone and the item fits the model. Provides a general idea of fit. It tests the data against a perfect fit to the model not against a better fit (26)
	F-statistic	Non significant	1. A one way analysis of variance on the standardized residuals 2. A comparison between the F and χ^2 assists in determining item fit (215)

* **The Quality criteria for a Rasch model are dependent on the program used for analysis. The criteria here are based on the Rasch Unidimensional Measurement Model program (215) Additional criteria considered for analysis techniques and models are not included.**

Table 5.2b continued. Item Quality Criteria for a Rasch Measure *

Quality Indicators

Item Fit	**Criteria**	**1.Derivation / 2.Interpretation**
Graph: Item characteristic curves (ICCs),	The sample is divided into groups by ability, 4 in the example below, with observed responses plotted against the predicted and represented by dots on the predicted model curve or ICC 	1. ICCs are graphical indicators of item fit. On an ICC graph the x-axis is logit ability, the y-axis the expected logit value. The observed ability is plotted against that predicted by the model. 2. ICCs indicate the location of the item and the probability of success on that item for each person's level of ability along the item's continuum. The slope of the ICC indicates the rate of change in the probability of success on that item as a function of ability. (215)

* The Quality criteria for a Rasch model are dependent on the program used for analysis.The criteria here are based on the Rasch Unidimensional Measurement Model program (215) Additional criteria considered for analysis techniques and models are not included.

Table 5.2b continued. Item Quality Criteria for a Rasch Measure

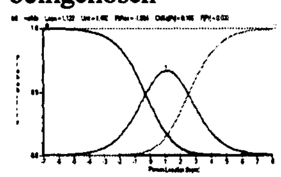
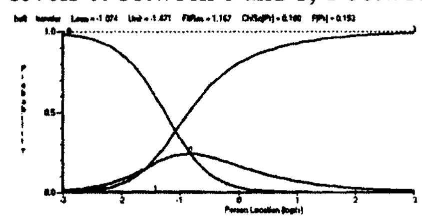
	Quality Indicators	Criteria	
Ordered Response Options			**1.Derivation / 2.Interpretation**
Statistic	Threshold values	Thresholds ordered from low to high based on numeric response options	2. A disordered response option results when more able people do not have a greater probability of successfully responding to a more difficult level of an item than the less able. (229) (226) (217)
Graph	Category Characteristic Curves (CCCs)	Ordered response options are seen as a series of hills Each option has a probability of beingchosen 	1. The horizontal axis represents ability the vertical axis represents the probability of endorsing a response option. Each curve represents the threshold between response levels 0: between 0 and 1; 1 between 1 and 2.(215) 
Reliability			
	Reliability index	Ranges from 0-1 with 1 representing perfect reliability and 0 no reliability	1. An indication of the consistency of the item responses in the sample r=1-(MSEi)/ (Mean Variance of Items); MSEi = $\Sigma(SE^2)/N$ where σ is the estimated variance of the item. A ratio of the adjust item variance to the observed item variance in logits 2. Reliability of the item hierarchy; if the items were given to a different population of person with same attributes (321) (214) the hierarchy would remain the same
	Separation index(219) (214) (255)	Ranges from 0 to ∞ and is interpreted as a Cronbach's alpha: Acceptable: 1.5 or α=0.7; good: 2.0 or α =0.8; and excellent: 3.0 or α= 0.9	1. Separation Index or G = $\sqrt{\frac{\textit{reliability}\text{ coefficient}}{(1-\textit{reliabiltycoefficient})}}$ 2. Indicates the spread of person ability or item difficulty in standard error units. The larger the index the better the differentiation is between subjects and item difficulty. It aids in quantifying the construct and facilitates the measurement of change
	Strata		1 Derived from the separation index: Strata = (4G+1)/3 2 Number of statistically different levels, separated by 3 standard errors, of item difficulty that can be identified (214) (321)

Table 5.2b continued. Item Quality Criteria for a Rasch Measure

Quality Indicators		
Precision	**Criteria**	**1.Derivation / 2.Interpretation**
Information function	The larger the more precise $I_i(\beta)=\frac{[P_i'(\beta)]^2}{P_i(\beta)(1-P_i)(\beta)}$	I=information P= probability correct Theta =ability 1. It is the inverse of the standard error squared per item 2. Indicates a) the precision of the estimation procedure, b) The amount of information provided by an item at an ability level (135;235;275;310) The information statistic indicates where the item contributes the most information along the continuum.
Statistical independence of the items	Standardized Fit statistics >-2.0, residual inter-item correlations>0.3	1. See above for determination of standardized residuals 2. Ability is based only on ability and not influenced by other factors. The answer to one items is not influenced by the answers to any other item (135;235;310)
Differential Item Function (DIF) or Item bias.	1. Separate calibration t-test non-significant (253) 2. Between group item fit statistic (385) likelihood ratio chi-square in RUMM non-significant (216) two-way ANOVA of residuals with people divided by ability and divided within that group by the factor	Differential Item Functioning or item bias (DIF) indicates that each item works in the same way for different subpopulations of the sample that are compared. (215) 1. t-test based on 2 separate calibrations of the same item on 2 subpopulations of interest e.g. male, female. $t = \frac{d_{i1} - d_{i2}}{(s_{i1} + s_{i2})^{1/2}}$ d_{i1} = difficulty of item I in subpopulation 1ie male d_{i2} = difficulty of item I in subpopulation 2 ie female s_{i1} = standard error for d_{i1} s_{i2} = standard error for d_{i2} * Multiple comparisons for a single item raise questions about the appropriateness of the Type I error rates. 2. This statistic is based on subpopulation residuals after the variance for the items have been calibrated (Between group item fit statistic criteria based on the WINSTEPS programme (253) Per item -2 < residuals< + 2)

[26] **Table 5.2c Person Quality Criteria for a Rasch Measure***

Quality Indicators Fit	Person Criteria	1.Derivation / 2.Interpretation
Standardized residuals	Per person - 2 < residuals<+ 2 Mean residuals close to '0' and SD close to '1'. Affected by sample size and spread of ability	1. Residuals from χ^2, squared and summed over all groups of subjects, transformed to approximate a normal distribution z =standardized residuals of the observed score from that predicted by the model then log transformed(215) (219) $Z_{ni} = \frac{x_{ni} - E[X_{ni}]}{\sqrt{V[x_{ni}]}}$ 2. Persons are considered to fit the model if residuals are not greater/less than ± 2 the 95% confidence interval of the normal distribution. >+ 2 indicates irregular response patterns, or noise, data entry errors (321) >- 2 indicates irregular response patterns, statistical dependency of responses. (215)
Chi-square	Non significant	1. The residuals derived from observed-expected score with the expected determined by the model with the hypothesis that the data fit the model 2. The difference between the observed and expected is smaller than expected by chance alone and the person fits the model

* The Quality criteria for a Rasch model are dependent on the program used for analysis. The criteria here are based on the Rasch Unidimensional Measurement Model program (215). Additional criteria considered for analysis techniques and models are not included.

Table 5.2c continued. Person Quality Criteria for a Rasch Measure *

Quality Indicators	Person	1.Derivation / 2.Interpretation
Fit	**Criteria**	
Reliability index	Ranges from 0-1 with 1 representing a perfect reliability and 0 no reliability	1. An indication of the consistency of the responses in the sample r = 1- (MSE_p)/ (Mean Variance of persons), $MSE_p = \Sigma(SE^2)/N$ where σ is the estimated variance 2. Reliability of the of person hierarchy if the same people were given a different test of the same construct (214;321)
Separation index	Similar to Cronbach's alpha Acceptable 1.5 good 2.0, and excellent 3.0	1. Separation Index or G= $\sqrt{\frac{\textit{reliability}\ \text{coefficient}}{(1-\textit{reliabiltycoefficient})}}$ (219) (214) (255) 2. Indicates the spread of person ability in standard error units. The larger the index the better the differentiation is between subjects and item difficulty, aids in quantifying the construct and facilitates the measurement of change (269) (214)
Strata		1 derived from the separation index: STRATA=(4G+1)/3 2 Number of statistically different levels, separated by 3 standard errors, of person ability that can be identified (214) (321)
Invariance		2. A Person's True ability does NOT depend on items administered An Item's difficulty does NOT depend on the people taking it

* The Quality criteria for a Rasch model are dependent on the program used for analysis. The criteria here are based on the Rasch Unidimensional Measurement Model program (215). Additional criteria considered for analysis techniques and models are not included.

27 **Table 5.3 Baseline Characteristics of the Subjects**

Characteristic	Participants (n=262)	Refusals (n=77)
Age at stroke onset (years)		
Mean ± SD	71.4 ± 12.9	75.2 ± 10.5*
64>/ 65-74/ 75-84/ ≥85 (%)	29 / 25 / 35 / 11	13 / 36 / 33 / 18
Men/Women (%)	63 / 37	51 / 49
Level of Education Finished (%)		
None/ Grade school / High school/College	18 / 39 / 14 / 29	N/A
Living where before stroke (%)		
Home/Residence/Other	94 / 5 /1	90 / 9 / 1
Living with whom before stroke (%)		
Family/Alone /Other	50 / 34 / 6	66 / 31 / 3
Discharge Destination (%)		
Rehab / Home / Transferred / LTC / Died	52 / 40 /2 / 5 / 1	53 / 35 / 3 / 5 / 3
Ischemic/Hemorrhagic/Other (%)	86 / 14 /<.1	87 / 13 / 0
First stroke (%)	78	78
Side of hemiplegia %		
Right / Left /Bilateral / None	36 / 53 / 0 / 11	36 / 40 / 1 / 23
Length of stay in acute care (days)		
Mean ± SD	16.4 ± 21.0	13.5 ± 9.7
Comorbidity † (%)		
0 / 1 / 2, 3 / >3	30 / 28 / 31 /11	N/A
Stroke severity CNS score at admission††		
Mean ± SD	8.2 ± 2.6	7.7 ± 3 .5
Very Mild / Mild /Moderate / Severe (%)	17 / 22 / 42 / 19	23 / 25 / 25 / 27

Abbreviations: LTC, (Long term care); rehab, (rehabilitation); SD, (Standard Deviation); *Significantly different; P<.01 [†]Comorbid conditions based on the Charlton weighted index (304) [††] CNS (Canadian Neurological Scale) best score;= 11.5; severity; very mild>=11.0; 9.5<=mild <11; 5<moderate <9.5; and severe <5(386)

28 **Table 5.4 Scores For Subjects with a Severe Stroke at Three and Seven Days.**

Variable (N=49)	Day Three	Day Seven
CNS (1.5-11.5)	3.7	-
CMSA (1-7)		
Arm	2	2.3
Leg	2	3
STREAM (0-70)		
Arm score (0-20)	4	5.7
Leg score (0-20)	4	5.9
BS (0-56)	3	9.0
Proprioception	1	1.1
Walking ability m/s	0	0.2

Abbreviations: BS, (Balance Scale); CNS, (Canadian Neurological Stroke scale); CMSA, (Chedoke McMaster Stroke Assessment Scale); STREAM, (Stroke Rehabilitation Assessment Measure).

29 **Table 5.5a Observed Performance Scores of Subjects at Three Days (n=262)**

Construct	Capacity		Ceiling %	Floor %
F-3d (0-51) Mean ± SD	29.9 ±	14.2	1	
Motor Recovery Mean ± SD				
Total STREAM score (0-100)	68.4 ±	30.3	12	1
Total CMSA score (1-42)	30.1 ±	8.4	5	1
Mobility Mean ± SD				
STREAM Mobility (0-100)	57.4 ±	31.5	2	15
Walking speed (m/s)	0.38 ±	0.47		49
Two Minute Walk test (meters)*	46.7 ±	61.7		51
Walking aids %	24			
Lower Limb Ability Mean ± SD				
STREAM L/E (0-100)	71.6 ±	33.3	26	6
CMSA leg (1-7)	5.0 ±	1.6	10	3
CMSA foot (1-7)	5.6 ±	1.7	13	8
Balance Mean ± SD				
CMSA Posture (1-7)	4.4 ±	1.6	10	3
Balance Scale (0-56)	28.3 ±	20.4	8	3
Upper limb Ability Mean ± SD				
STREAM U/E (0-100)	76.1 ±	34.1	46	5
CMSA Pain (1-7)	6.5 ±	0.8	60	
CMSA Arm (1-7)	4.7 ±	1.9	20	8
CMSA Hand (1-7)	4.8 ±	1.7	17	13
Grip Strength kg force*				
affected hand	16.9 ±	14.2		24
less affected hand	27.9 ±	11.7		
Box & Blocks # moved in 60 sec*				
affected hand	23.0 ±	20.7		29
less affected hand	40.2 ±	14.7		
Dominant Hand: Right %	96			

Table 5.5a Continued. Additional Observed Performance Scores of Subjects at Three Days

Construct	Capacity
Cognition Mean ± SD	
MMSE (0-22)*	18.0 ± 3.3
Neglect %	
Albert's test of perceptual neglect	19
Sensation of the Affected Side Mean ± SD	
Light touch & position sense (0-9.1)	
Normal %	46
Poor	50
Absent	4

*N varies between 255 and 262

Abbreviations: CMSA, (Chedoke McMaster Stroke Assessment); F-3d, (Functioning measure at three days); kg, (kilograms); L/E, (lower extremity); MMSE, (Mini-Mental State Exam); SD, (standard deviation); STREAM, (Stroke Rehabilitation Assessment); #; (number); U/E, (upper extremity);.

30 **Table 5.5b Baseline Self-Rating Scores of the Subjects**

Characteristic	**Participants (n=262)**		**Refusals (n=77)**
Barthel Index at three days (0-100)		Ceiling %	
Mean ± SD	51.4 ± 31.2	11	N/A
Stroke Impact Scale 16 at three days (0-100) All respondents			
Mean ± SD	38.2 ± 23.5	0	N/A
Stroke Impact Scale 16 at three days (0-100) Non proxy respondents (n=241)			
Mean ± SD	40.3 ± 22.5		
Stroke Impact Scale 16 at three days (0-100)* proxy respondents (n=21)			
Mean ± SD	13.8 ± 21.1		
Barthel Index at Discharge (0-100)			
Mean ± SD	71.2 ± 26.7	24	71.3 ± 25.9
Modified Rankin Score at Discharge (0-5) %			
0-1 No symptoms or significant disability	19		
2 Slight disability	23		
3 Moderate disability; able to walk unaided	21		
4 Moderate severe; disability unable to walk	30		
5 Severe disability; bed ridden/ Dead	7		

* Stroke Impact Scale 16 proxy responses differ significantly from the person's self rating $p<0.0001$

Abbreviations: SD; (standard deviation), N/A; (not available)

31 Table 5.6 Summary of the Global Fit Statistics for the Functioning Measure at Three Days (F3d)

	Full-170 item model (n=262)	92-item pool model (n=262)	38-item model (n=258)
ITEM-TRAIT INTERACTION			
Total Item Chi Square	3702.57	314	121
Total Deg of Freedom	510	276	114
Total Chi Square Probability	00000.00	0.06	0.29
ITEM-PERSON INTERACTION			
ITEMS			
Difficulty	0.0 ± 2.49	0.0 ± 3.22	0.0 ± 3.311
Fit Residual	-0.36 ± 1.86	-0.18 ± 0.41	-0.24 ± 0.37
PERSONS			
Measure	0.86 ± 2.22	0.87 ± 3.15	-0.31 ± 3.13
Fit Residual	-0.22 ± 0.68	-0.13 ± 0.24	-0.23 ± 0.41
RELIABILITY INDICES			
PERSONS			
Reliability Index	0.992	0.985	0.970
Cronbach's Alpha	Not applicable with missing data		
Separation index	9.96	7.02	5.69
Strata	13.61	9.7	7.96
ITEMS			
Reliability Index	0.97	0.98	0.98
Separation Index	5.69	6.8	6.7
Strata	7.9	9.4	9.3
Power of Test- of- Fit	Excellent based on a Person reliability of 0.98	Excellent based on a Person reliability of 0.99	Excellent based on a Person reliability of 0.97

32 Table 5.7 Characteristics of the Items in the Functioning Measure at Three Days (F3d)

Index	Item	Difficulty	+SE	Fit residuals	++ χ^2	F-statistic
CMSA	Facilitate hip Flexion	-6.87	0.38	-0.05	4.64	1.53
CMSA	Resistance to trunk rotation	-6.68	0.36	0.00	3.20	1.24
CMSA	Facilitate finger flexion	-5.67	0.31	-0.40	2.22	2.42
CMSA	Touch opposite knee	-3.95	0.26	-0.42	2.63	1.48
CMSA	Wrist extension >1/2	-3.52	0.25	0.22	1.49	0.81
STREAM*	Knee extension in sitting	-3.51	0.18	0.13	2.17	0.38
CMSA	Bridge hips with equal weight on feet	-3.38	0.25	-0.39	1.59	0.68
CMSA	Ankle inversion	-2.89	0.23	-0.12	5.18	1.65
STREAM*	Place hand on sacrum	-2.43	0.16	-0.14	3.31	1.54
CMSA	Finger flxion/extension	-2.41	0.22	0.03	4.10	1.67
CMSA	Dynamic righting with feet on floor	-2.40	0.22	-0.82	8.07	3.01
CMSA	Toe extension with ankle	-1.70	0.20	-0.05	3.45	0.50
BS*	Standing to sitting	-1.23	0.11	0.20	4.15	2.01
STREAM	Opposition of thumb to little finger	-1.13	0.19	-0.16	5.99	2.07
SIS*	Stand without losing balance	-0.28	0.13	0.62	0.67	0.26
BS*	Turning to look behind	0.06	0.13	-1.20	4.49	2.12
BS*	Reaching forward with o arm	0.21	0.13	-1.15	2.62	1.17
CMSA	Raise arm overhead sideways	0.24	0.18	-0.32	5.85	2.13
CMSA	Heel on floor ankle eversion	0.59	0.18	-0.31	4.23	1.42
BI*	Get on and off the toilet independently	0.67	0.13	-0.62	0.84	0.22

Table 5.7 continued Characteristics of the Items in the F-3d

Index	Item	Difficulty	+SE	Fit residuals	++ χ^2	F-statistic
CMSA	Hand to forehead quickly 5x 5sec	0.68	0.18	-0.20	1.46	0.32
CMSA	Trace a Figure 8 with your arm	0.90	0.18	-0.07	2.77	0.75
BI*	Walk independently on a level surface	1.12	0.14	-1.06	6.12	2.95
CMSA	Pour water from pitcher to cup/reverse	1.43	0.19	-0.24	1.56	0.43
CMSA	Tap foot 5x in 5 sec	1.57	0.19	-0.46	1.13	0.66
BI	Do personal hygiene independently	1.70	0.19	0.02	2.84	0.51
STREAM*	Walk down 3 stairs with alternate feet	1.81	0.11	-0.51	3.57	1.13
CMSA	Trace a pattern with your leg	2.01	0.20	-0.41	5.63	2.48
SIS*	Climb stairs independently	2.11	0.14	0.15	4.20	1.62
CMSA	Circumduction of foot	2.43	0.21	-0.30	1.12	0.34
BS*	Standing on one foot	2.59	0.15	-0.03	1.64	0.21
CMSA	Thumb to fingertips x 3 in 12 sec	2.79	0.21	-0.01	4.89	1.76
CMSA	Touch toe backward heel forward	3.08	0.22	-0.38	2.10	2.01
BI	Bathe self independently	3.81	0.25	-0.05	1.33	0.81
CMSA	Walk on toes 2m in 5 sec	4.04	0.26	-0.27	3.10	2.37
CMSA	Trace a pattern quickly with your leg	4.30	0.28	-0.22	0.76	0.45
CMSA	Tandem Walking 2m in 10 sec	4.89	0.32	-0.22	2.99	2.48
CMSA	Bounce and catch a ball x 4	5.00	0.33	0.04	3.73	0.69

Items are listed in order of difficulty from hard to easy, from top to bottom.

*Items not scored dichotomously 0, 1.

Abbreviations: BI, (Barthel Index of Activities of Daily living); BS, (Balance Scale); CMSA, (Chedoke McMaster Stroke Assessment); DF, (degrees of freedom); F-3d, (Functioning measure at three days); Fit residuals, (standardized fit residuals); F-statistic, (statistic from a one way ANOVA); SE, (standard error); STREAM, (Stroke Rehabilitation Assessment); SIS, (Stroke Impact Scale).; χ^2 ,(Chi-Square);

Degrees of freedom for: Fit residuals: 249.89; χ^2: 3; F-statistic: 254.

++Bonferroni corrected significance level $p < 0.0013$

33 **Table 5.8 Item Difficulty and Person Ability in Logits and the Equivalent Expected Scores (0-52) in the Functioning Measure at Three days (F-3d)**

38 Items	Item Thresholds		Person	
	Difficulty in logits	Raw score	Ability logits	Equivalent Expected scores
		0[#]	-8.24	0[#]
Facilitate hip flexion	-6.87	1	-7.12	1
Resist Trunk rotation	-6.68	2	-6.19	2
Facilitate finger flexion	-5.67	3	-5.42	3
Partial knee extension*	-4.07	4	-4.82	4
Touch opposite knee	-3.95	5	-4.34	5
Wrist extension ½ range	-3.52	6	-3.96	6
Bridge	-3.38	7	-3.62	7
Full knee extension[†]	-2.94	8	-3.33	8
Ankle inversion	-2.89	9	-3.06	9
Partially put hand on sacrum *	-2.70	10	-2.80	10
Finger flexion & extension	-2.41	11	-2.56	11
Dynamic righting feet on floor	-2.40	12	-2.32	12
Stand to sit uncontrolled*	-2.27	13	-2.10	13
Fully put hand on sacrum[†]	-2.16	14	-1.88	14
Stand to sit with hands[†]	-1.72	15	-1.67	15
Toe ext & ankle plantarflexion	-1.70	16	-1.46	16
Oppose little finger and thumb	-1.13	17	-1.25	17
Some difficulty standing without losing balance*	-0.77	18	-1.04	18
Get on & off toilet with help*	-0.66	19	-0.84	19
Walk 50 feet with assistance*	-0.28	20	-0.65	20
Turn to look behind turn only*	-0.26	21	-0.46	21
Reach forward =12 cm*	-0.24	22	-0.28	22
No difficulty standing without losing balance[†]	0.21	23	-0.11	23
Fully abduct arm	0.24	24	0.06	24
Stand to sit without hands[††]	0.30	25	0.23	25
Turn look behind & shift weight[†]	0.38	26	0.40	26
Ankle eversion	0.59	27	0.56	27
Reach forward >25 cm[†]	0.66	28	0.72	28

Table 5.8 continued Item Difficulty and Person Ability in Logits and Equivalent Expected Scores (0-52) in Functioning Measure at Three days

38 Items	Item Thresholds		Person	
	Difficulty in logits	Raw score	Ability logits	Equivalent Expected scores
Hand to forehead	0.68	29	0.88	29
Draw an 8 with your arm	0.90	30	1.04	30
Walk down 3 stairs with deviation*	1.21	31	1.20	31
Pour water into a glass	1.43	32	1.36	32
Tap foot quickly	1.57	33	1.51	33
Personal hygiene independently	1.70	34	1.67	34
Climb one flight of stairs with difficulty*	1.86	35	1.82	35
Walk down 3 stairs with assist†	1.93	36	1.98	36
Stand on one foot >5 s*	1.97	37	2.1	37
Get on & off toilet independently†	2.00	38	2.30	38
Trace pattern with leg	2.01	39	2.47	39
Walk down 3 stairs normally††	2.30	40	2.65	40
Climb one flight of stairs without difficulty†	2.36	41	2.82	41
Quick ankle circumduction	2.43	42	3.02	42
Walk 50 feet independently†	2.53	43	3.26	43
Touch fingertips quickly	2.79	44	3.49	44
Heel forward & toe back quick	3.08	45	3.75	45
Stand on one foot> 10 s†	3.21	46	4.05	46
Bath independently	3.81	47	4.38	47
Walk on toes 2 m	4.04	48	4.78	48
Trace leg pattern quickly	4.30	49	5.26	49
Walk tandem for 2 m	4.89	50	5.92	50
Bounce a ball	# 5.00	51	6.82	# 51

The items are ordered by difficulty from top to bottom by the threshold values of each response option. Shaded items represent those where persons rate their difficulties in performing physical activities; non-shaded items are those where performance is observed and rated.

* Items with more than one response option, the first response option

† Items with more than one response option, subsequent response options

Extreme score: the last score is extreme and was estimated by extrapolation from last three known estimates

34 Table 5.9 Convergent and Divergent Validity Spearman Correlation Coefficients for the F3d and Other Indices.

Index	Convergent*	Divergent*	
	F3d	Sensation	Neglect
SIS-16 (0-100)	0.88	0.33	-0.34
BI three days (0-100)	0.91	0.35	-0.40
STREAM (0-30)			
Mobility	0.94	0.32	-0.35
Lower	0.88	0.32	-0.33
Upper	0.79	0.34	-0.34
Total score	0.96	0.35	-0.35
CMSA (0-42)			
Posture	0.91	0.34	-0.33
Arm	0.85	0.29	-0.40
Hand	0.78	0.32	-0.34
Leg	0.88	0.29	-0.29
Foot	0.86	0.32	-0.24
Shoulder pain	0.67	0.26	-0.33
Total score	0.94	0.34	-0.36
Balance scale (0-56)			
Total score	0.94	0.31	-0.36
Continuous variables			
Grip strength km	0.69	0.32	-0.34
B & B (blocks/sec)	0.83	0.35	-0.38
Gait speed (m/sec)	0.86	0.28	-0.30
Two minute walk test (m)	0.84	0.29	-0.26
Neglect (Albert's test)	-0.34	-0.24	
Sensation	0.36		-0.24

Abbreviations: F3d, (Functioning measure at three days);SIS; (Stroke Impact scale), BI; (Barthel Index of activities of Daily Living), CMSA; (Chedoke McMaster Stroke Assessment), B&B; (Box and Blocks)

m; (meters), m/sec; (meters /second).

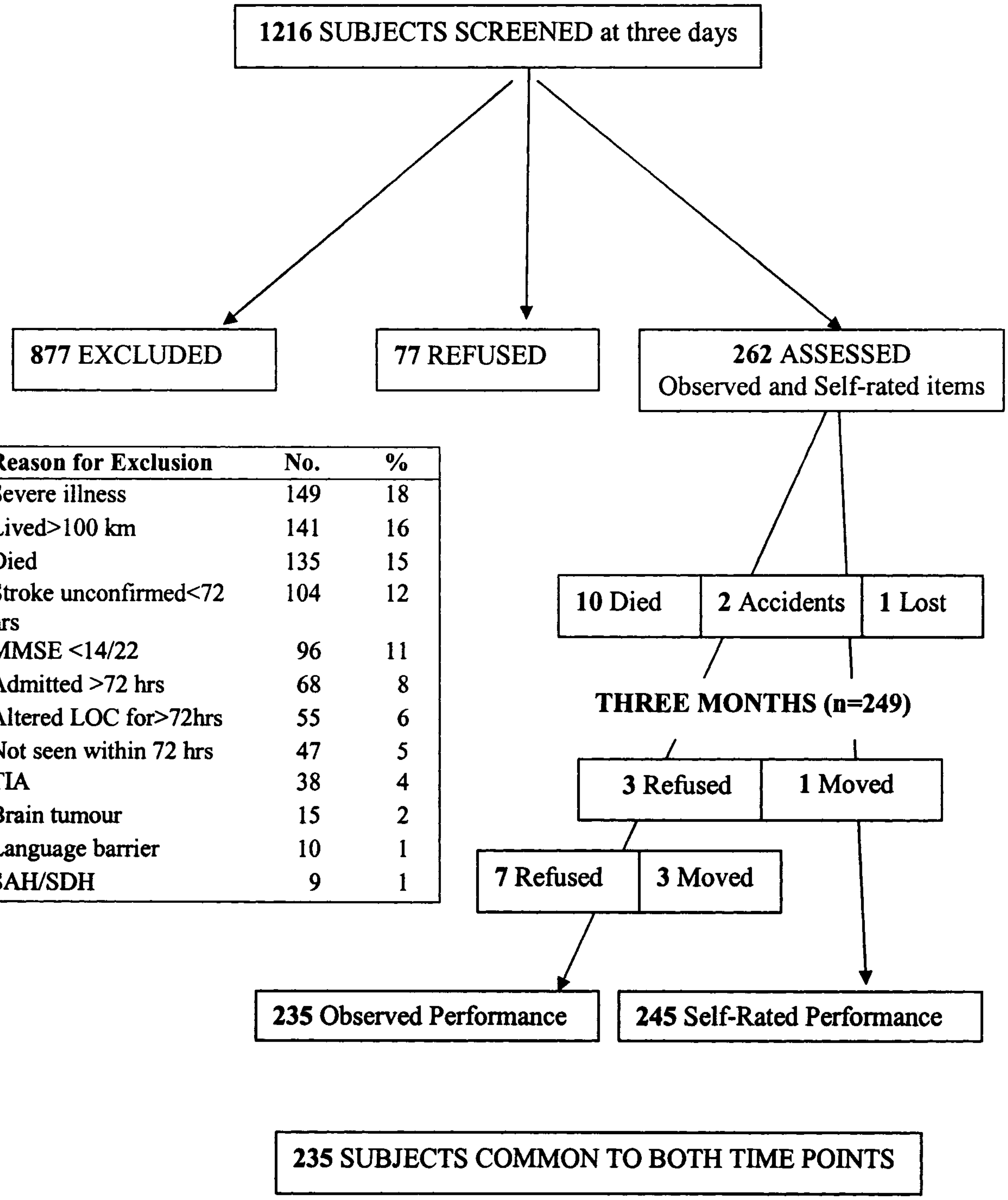
*All correlations are significant at $p<0.03$ or less.

35 Table 5.10 Comparison of the Stroke Impact Scale-16 and The Functioning Measure at Three days (F3d) Across The Canadian Neurological Stroke Scale Determined Stroke Severity Categories and Discharge Modified Rankin Disability Categories.

		SIS-16 (0-100)		F3d (0-51)	
Modified Rankin Category	N	Mean	95% CI	Mean	95% CI
0. No symptoms at all	9	65.3	55.7-74.8	45.7	43.1-48.7
1. No significant disability despite symptoms	42	57.7	52.7-63.0	37.8	35.0-40.6
2. Slight disability	59	56.0	52.3-59.7	33.8	31.5-36.0
3. Moderate disability; able to walk unaided	56	36.1	31.7-40.4	25.5	20.5-24.5
4. Moderate severe; disability unable to walk	78	18.9	15.6-22.3	11.4	9.7-13.1
5. Severe disability; bed ridden	18	10.3	1.9-18.7	7.1	2.3-11.8
* Stroke severity Levels					
1.Very mild	45	51.7	46.2-57.1	33.2	29.9-36.5
2. Mild	57	48.1	43.2-52.9	30.4	27.4-33.5
3. Moderate	111	38.2	34.1-42.4	23.7	21.3-26.0
4.Severe	49	14.3	8.9-19.6	8.35	5.5-11.2

Abbreviations: SIS-16, (Stroke Impact Scale); F3d, (Functioning measure at three days).

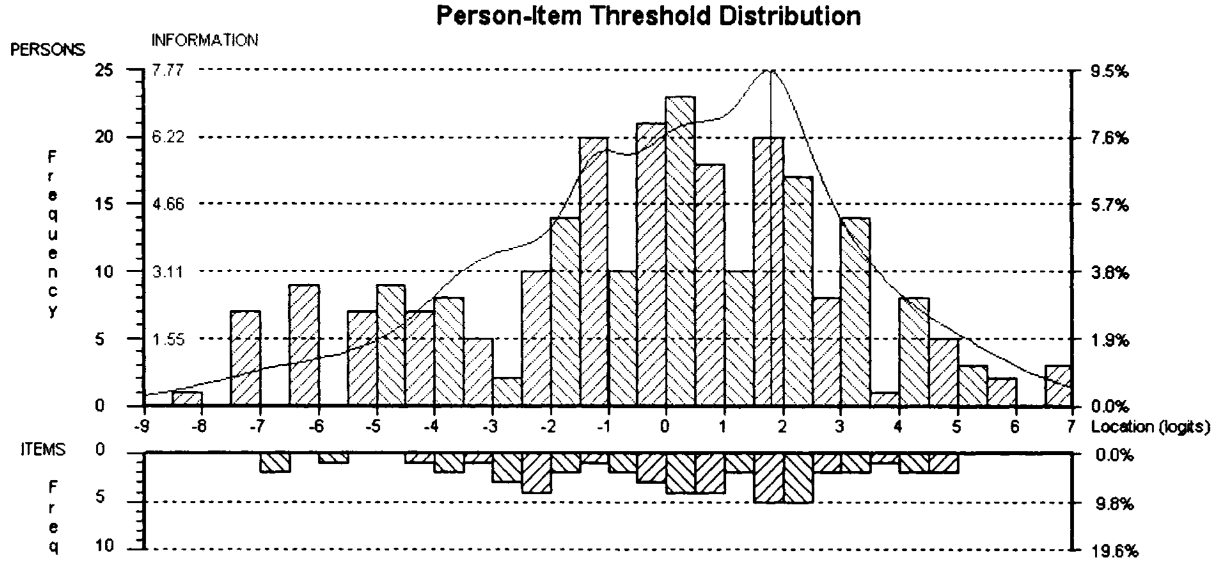
* Stroke severity determined by Canadian Neurological Scale (Best score: 11.5) with: Very Mild: ≥11.0; 9.5 ≤Mild <11; 5 <Moderate <9.5; and Severe <5.



Reason for Exclusion	No.	%
Severe illness	149	18
Lived>100 km	141	16
Died	135	15
Stroke unconfirmed<72 hrs	104	12
MMSE <14/22	96	11
Admitted >72 hrs	68	8
Altered LOC for>72hrs	55	6
Not seen within 72 hrs	47	5
TIA	38	4
Brain tumour	15	2
Language barrier	10	1
SAH/SDH	9	1

8 Figure 5.1 The Screening Process, Participants and Reasons for Exclusion

Figure 5.1 Legend: Exclusion table abbreviations: hrs, (hours); km, (kilo meter); LOC, (level of consciousness); MMSE, (Mini-Mental State Exam); TIA, (Transient Ischemic attack); SAH, (subarachnoid haemorrhage); SDH,(subdural hematoma).



9 Figure 5.2 The Item-Person Threshold Distributions and Test Information Function for the Functioning measure at Three Days, the F3d.

Figure 5.2 Legend The horizontal axis, scaled in logits, denotes functioning from least functioning at the left to most functioning at the right. The vertical axis denotes the frequency. The bars represent the distribution of subjects and items at each location. The line in the top of the figure represents the Test Information Function (TIF). An item's information function is the inverse of the item standard error squared; a TIF is the sum of item information functions

```
                  -7   -6   -5   -4   -3   -2   -1    0    1    2    3    4    5    6    7    8
                   |----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
Facilitate hip   0|-------------------------------------1----------*---------------------------
Trunk rotate     0-|-------------------------------------1---------*---------------------------
Facil flex finger ---0--|----------------------------------1--------*--------------------------
Touch knee        -------0-------|------------------------------1---*--------------------------
Wrist ext 1/2     --------0--------|-----------------------------1--*--------------------------
Knee ext          -------0------|--1--|---------------------------2-*--------------------------
Bridge            ---------0--------|----------------------------1----*------------------------
Ankle inversion   ----------0---------|---------------------------1---*------------------------
Touch sacrum      ----------0----------|1-|-------------------------2-*------------------------
Finger flex/ext   -----------0----------|--------------------------1---*-----------------------
Righting w feet   -----------0----------|--------------------------1-----*---------------------
Toe ext/plant     -------------0------------|------------------------1---*---------------------
Stand to sit      -----------0-----------|1-|----2--*--|-------------------3-------------------
Oppose finger     --------------0--------------|-----------------------1---*-------------------
Stand             ---------------0---------------|--*1-|-------------------2-------------------
Look behind       ----------------0-*---------------|1-|-------------------2-------------------
Reach forward     ----------------0-*---------------|--1-|------------------2------------------
Arm abduction     ------------------0-----------------|-----*--------------1-------------------
Foot eversion     ------------------0------------------|----*---------------1------------------
Get on/off toilet ---------------0--------------*-|------1------|---------------2--------------
Hand to forehead  -------------------0------------------|---*---------------1------------------
Figure 8 with arm -------------------0-------------------|---*---------------1-----------------
Walk 50 feet      ----------------0----------------|------1------|--------------2-------------
Pour water        ---------------------0--------------------|---*-------------1----------------
Tap foot          ---------------------0--------------------|----*------------1----------------
Personal hygiene  ---------------------0---------------------|---*-------------1---------------
Go down stairs    --------------------0------------------*--|1-|2|--------------3--------------
Pattern with leg  ----------------------0-----------------*-----|---------------1--------------
Climb stairs      ----------------------0---------------------|1|--------*------2--------------
Circumduction ankle-----------------------0---------------*--------|--------------1-------------
Stand on 1 foot   ----------------------0-----------------*----|---1--|------------2-----------
Touch fingertips  ------------------------0---------------*--------|-------------1-------------
Toe fwd/bwd       -------------------------0--------------*----------|------------1------------
Bath              ---------------------------0------------*--------------|----------1----------
Walk on toes      ---------------------------0------------*---------------|----------1---------
Trace quickly     ----------------------------0-----------*----------------|---------1---------
Tandem walk 2m    -----------------------------0----------*-------------------|--------1-------
Bounce a ball     -----------------------------0----------*-------------------|--------1-------
                 |----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
                 -7   -6   -5   -4   -3   -2   -1    0    1    2    3    4    5    6    7    8
```

10 Figure 5.3 Item Threshold Map for each Item in the Functioning Measure at Three Days the F3d with the Responses of One Average Subject.

Legend Figure 5.3 The horizontal axis scaled in logits denotes functioning from least functioning at the left to most functioning at the right. The items are ordered from top down by difficulty with the most difficult at the bottom. The location of each response option (0, 1 or 2) increases from left to right as the numbers increase. The short vertical line indicates the expected half-way point between any two response options indicating that the person with an ability at that level has a 50% probability of responding with either 0 or 1; or, 1 or 2. The stars represent the responses on an item by a subject with an average ability of -0.31 (SE; 42) logits and fit residuals of 0.18.

Chapter 6 Manuscript 4 *A Profile of Functioning at Three Days and Three Months Post-Stroke and Associated Factors*

Preface to Manuscript 4

The first three manuscripts provided measures of functioning early in the course of stroke and at three months that can be used to gauge recovery. Stroke is not a stable entity and the effects of stroke evolve continuously over its course. As physical recovery varies across individuals, patient characteristics are influential in interpreting the effects of any intervention. Etiological factors (haemorrhage or ischemia), lesion characteristics (site, size and side), severity of deficits (mild, moderate and severe), and socio-demographic factors (age, gender, social support) are some of the elements that play a role.

Data from stroke cohorts such as the one here have allowed the identification and differentiation of factors associated with a number of outcomes (survival, improved function, and institutionalization). The identification of favourable and unfavourable factors may permit the optimization of interventions and their appropriate timing during the course of recovery of functioning. Which factors dominate may fluctuate in influence depending on the time at which or how they are evaluated.

The two global measures of functioning developed in Manuscripts 2 and 3, the F3m and the F3d that incorporate the components of the ICF, provide an excellent opportunity to uncover important factors related to global functioning at two different points in time.

Over 50 predictive models for various stroke outcomes exist in the literature with numerous factors related to each outcome (30). Rather than a chapter reviewing the literature on the factors predictive of functioning in stroke, this fourth manuscript, entitled *A Profile of Functioning at Three Days and Three Months Post-Stroke and Associated Factors,* was written. The objective of this manuscript is to identify correlates of functioning at three days and three months post-stroke.

To enhance the chance of defining the various relationships between factors and functioning, a wide range of variables collected within 72 hours post-stroke were examined related to: the person, stroke event, process of care and baseline ability. The analysis to determine the univariate relationship of these variables with two reliable, valid and comprehensive measures of functioning progressed sequentially. Variables consistently associated with these two measures could identify the favourable and unfavourable factors that could then be individually optimized to improve functioning. The details on the associations between the various factors and measures of functioning are found in the following manuscript which is to be submitted to the Journal *Neurology*.

Title Page

Title: *A Profile of Functioning at Three Days and Three Months Post-Stroke and Associated Factors*

For Submission to the Journal *Neurology*

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Keywords: Functioning, Relationships, Process of Care

Abstract

Decreasing the impact of stroke requires interventions focused on the modifiable determinants within the course of recovery that improve functioning. Identifying those factors that impact on the full spectrum of a person's life post-stroke requires a measure of functioning that goes beyond activities of daily living. Two new measures, the Functioning measure at three days, F3d, and the Functioning measure at three months, F3m, quantify functioning across the components of the International Classification of Functioning, Disability and Health. These measures combined items from observed performance on tasks and items from self-report questionnaires through Rasch analysis. A profile of variables consistently associated with these two measures allows for the identification of favourable or unfavourable factors that could then be individually optimized to improve functioning.

Objective To identify correlates of Functioning at three days and three months post-stroke.

Methods: A longitudinal prognostic study involving 235 people with stroke was performed. The F3d and the F3m measured functioning. Information on variables with potential prognostic importance related to the person, the stroke event, the process of care and ability, was also collected 24-72 hours post-stroke. The association between the variables and functioning was estimated univariately through correlations or general linear models depending on the scale of the variable.

Results: Eighteen early factors were associated with functioning at three days and three months post-stroke, and 10 others were related to functioning at one point in time. All the modifiable factors significantly related to functioning, except pre-stroke functioning, were related to the process of care: control of glucose, temperature and oxygen saturation, the amount of therapy given, and the need for interventions.

Conclusions: Multiple factors were associated with functioning at two times post-stroke. Most were related to the process of care, indicating that the optimization of post-stroke care is essential to improve functioning in the life of a stroke survivor. Defining the factors related to functioning is the first step in understanding the impact of stroke on an individual.

Introduction

Stroke is one of the most disabling of chronic diseases (387). Of those who experience stroke and survive, 87% report restrictions in activities of daily living, 42% have mobility problems, 21% cognitive problems and 69% of post-stroke seniors report their health status as poor (36). Decreasing the impact of stroke requires interventions designed to promote or improve functioning, interventions that are focused on the modifiable determinants within the course of the recovery of functioning (66).

Identifying the determinants or factors related to functioning depends on how functioning is defined and quantified, as well as, when post stroke, the factors are evaluated. To date, the majority of the studies reviewing the predictive factors related to functioning have defined this as independence in activities of daily living (ADL), (28) (30) (31) or motor ability and (14) (81) have quantified these using a total score on a single index (68) (129) (140) (126). ADL and motor ability only cover a narrow range of activities that a person performs (65) (77) (388) (59) and are considered inadequate to fully encompass functioning.

Two recently developed measures of functioning, the Functioning Measure at three days (F3d) and the Functioning Measure at three months (F3m), that quantify functioning across the components of body functions, activity and participation as defined by the World Health Organization International Classification of Functioning, Disability and Health (24) might reveal key relationships between factors and functioning not previously recognized. The two measures defining functioning at three days and three months were formed using Rasch analysis by combining items from indices where a person's performance is observed on tasks and items from self-report questionnaires where a person rates their difficulties in performing physical activities. Rasch analysis transforms ordinal observations in indices into an interval scale where the items and people are organized hierarchically, by difficulty and ability respectively, on the same measurement scale in natural logarithm linear units or logits (25) (230).

A profile of variables consistently associated with these two measures could allow the identification of a spectrum of favourable or unfavourable factors that could then be individually optimized for improved individual functioning.

Objective

The purpose of this study is to identify correlates of functioning at three days and three months post-stroke.

Method

Details of the methodology and outcomes for the stroke survivors have been reported elsewhere (Chapters 4-5). In brief, a longitudinal prognostic study involving 235 people with acute stroke was carried out. Subjects were evaluated within three days of their stroke by observing their performance on tasks and, by asking the subjects how difficulty it was for them to perform certain activities, such as walking, climbing stairs and bathing (75). The subjects were reassessed at three months using the same tasks complemented by self-reports of performance on daily living and community activities. The tasks and self-report items were combined using Rasch analysis to form the F3m (25) (26) and the F3d. Information on variables with potential prognostic importance was also collected. The study had ethical approval from McGill University Institutional Review Board and from the Research Ethics committees of all participating hospitals and all participations provided informed consent.

Subjects

The study subjects were hospitalized from June 2002 to March 2005 following a cerebrovascular accident (33). Persons were excluded if a stroke diagnosis was not confirmed within 24–72 hours; also excluded were those diagnosed with a transient ischemic attack, admitted to hospital more than 72 hours after stroke, those with a hemiplegia from non-vascular causes, a subdural hematoma, or subarachnoid hemorrhage, or those with a severe illness, such as end-stage cancer, pulmonary, cardiac or renal disease and those with severe cognitive or comprehension impairments. For these analyses, only subjects with data from both time points (at three days and at three months) were included.

Measurement of Functioning

Functioning was defined at two time points, at three days by the F3d and at three months by the F3m. These measures represent functioning as conceptualized by the International Classification of Functioning, Disability and Health (24).

The F3m includes 44 items (see Manuscript 2): 15 items evaluate movements of the affected arm, and nine the affected leg, four items evaluate balance, four self-care activities, 10 items evaluate mobility, and three items are related to participation in life roles. It is scored from 0 to 51. The internal reliability of the F3m is 0.99 and validity was judged as excellent based on the fit to the Rasch model and high correlations between the F3m and other indices. The acute F3d measure, a 38 item measure of the physical impact of acute stroke on functioning at three days, was developed in a similar manner to the F3m and also has excellent internal reliability (0.98) and validity. The F3d is scored from 0 to 52 (see Manuscript 3).

These measures were developed from similar sets of items, and their logits scores were linearly transformed to scores ranging from a low of 0 to a high of 100. A higher score indicates better functioning for both measures.

Influencing Factors

Table 6.1 lists the influencing variables chosen based on the literature and on their accessibility within 24-72 hours post-stroke (31) (30) (29) (28) (77) (14). The variables were classified into four groups as related to: the person, the stroke event, the process of care, and the person's ability on certain tasks after an acute stroke. (The literature supporting the variable choice is summarized in the Appendix.) The information about the factors was collected from the patient's chart, through interviews, and by assessing the subject's performance and capacity within 24-72 hours post-stroke.

Factors Related To the Person

Pre-stroke Activity

The Physical Functioning scale of the SF-36 (PF) (346) (347) was used to identify pre-existing activity limitations one month prior to stroke. For this analysis a subject's prior physical functioning was defined as the mean score on the PF.

An additional estimate of the pre-stroke activity levels of the subjects was made from the energy expended on activities related to hobbies, sports, household chores, volunteer activities or work. The energy cost in metabolic equivalent units (Met) was estimated from the updated version of the Compendium of Physical Activities classification (389) (390). When an activity was unlisted the Mets were determined from the units of similar activities. The Mets were assigned by two research assistants based on consensus; disagreements were settled by a third party.

The average energy cost for each of the five activity groups was determined by multiplying the average Mets by the number of hours spent per week on an activity. Two time periods were considered: the month prior to stroke and the period between the ages of 20 and 30. (Examples of the activities and the assigned metabolic units are in the Appendix.)

For the analysis, a lifestyle activity level was defined by the quartiles of the average metabolic units in the past and present across all five groups of activities a subject had participated in, and the metabolic units required to confer a health benefit (>7.5 Mets per week) (391). Thus, an active present lifestyle was defined by a Mets level > 15, and an active past lifestyle by a Mets level > 25. These Met levels are higher than required for a health effect, but were chosen to compensate for the potential bias people might have in overestimating their activity levels (392) (393) (391) (394). A subject's activity level was then classified as: active, indicating the person was active in the past and present; inactive, indicating the person was inactive at both time; and irregularly active, where a person was active at only one point in time, the present or the past.

Personal factors

Living arrangements were defined according to where, and with whom the person lived. For the analysis, a residence was considered as an independent domicile that had 12 or 24 hour nursing services, could provide assistance with bathing and household chores and some meals. Long term care was defined as a residence that provided total assisted living and nursing care.

Six questions from the Older Americans Resource Scale (277) (278) (OARS) were used to indicate social support. The questions (279)covered marital status, the number of people known well enough to visit, the number of people talked to on the telephone, the presence of a trusted confidant, and the presence and quality of a potential caregiver. For this analysis, a total score from 0-6 was used, with "0" indicating a lack of social network.

Education was defined as the highest level of education completed, categorized as: none, elementary, high school, college, and more than college; for the analysis only two categories were used: more than and less than finishing college. A variable for financial security was created based on the amount of money left over at the end of the month to make ends meet: more than enough (ample), enough (sufficient), or not enough (insufficient).

The previous level of health was based on the weights of the Charlson Comorbidity index that are determined by the severity and number of comorbid diseases. For the analysis, the weights were categorized into four groups: 0; 1; 2 and 3; and >3. (304).

Any accident or fall sustained by a subject that resulted in an injury was recorded as present or absent and for the analysis was combined into an accident/fall variable. Age was categorized into 4 groups (<65, between 65 and 74, between 75 and 84, and >85 years).

Stroke Related Factors

Information from the radiological reports, the Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans, taken within the first 24 to 72 hours, was coded on a standardized image data collection form used in a previous study (395) and pre-tested for this study on a separate sample of stroke survivors (242) (unpublished data).

One researcher coded all the data which was checked for accuracy by a neuroradiologist. Coding discrepancies were verified against the actual scans as appropriate. The type of lesion was classified as ischemic or hemorrhagic and the lesion variables were categorized as general lesion or infarct lesion characteristics. The general characteristics included the presence or absence of: a mass effect, atrophy, white matter disease, a visible lesion on first scan, and any another abnormality on the scan. The infarct lesion characteristics were: size of lesion (small: <0.5 to 1.5 cm; medium: 1.6 to 3 cm; and large: >3 cm), side of lesion, (right, left, posterior or bilateral hemispheres), anatomical location (cortical, subcortical, posterior or multiple), and lesion pathology (superficial, deep, or both deep and superficial). The number of lesions, per scan, was recorded. For this analysis, the lesion characteristics were grouped based on the frequency of each trait. (Distribution of the imaging variables is listed in the Appendix.)

The data for the signs and symptoms associated with stroke, such as diplopia, blurred vision, ataxia, nausea, were abstracted from notes on the neurological examination and those written in the chart by the health care professionals. The data were recorded at the time of maximum impairment within the first 72 hours of stroke. (The distribution for the signs and symptoms is given in the Appendix.) For the analysis, the signs and symptoms were coded as present or absent, but only those significantly related to functioning were reported.

The Canadian Neurological Stroke scale (CNS) (250) was used to classify stroke severity. The CNS is scored from 1.5 (most severe) to 11.5 (least severe) and is an accurate and valid measure for middle cerebral artery or anterior circulatory strokes (63), but only evaluates three set of signs and symptoms: level of consciousness, orientation and language, and muscle strength. The CNS correlates with the neurological exam ($r=0.77$) and has accurately predicted the outcome on the Katz ADL index at 6 months (251). For the analysis, stroke severity was classified, into four groups: very mild with a score > 11; mild a score between 9.5 and 11; moderate a score between 9.5 and 5; and severe < 5 (251) (252) Categorization was necessary due to the non-normal distribution of the CNS data.

Process-of-Care Factors

Information on process of care was abstracted from the chart using the Veterans Affairs Structure, Process and Outcomes of Post-Acute Stroke Rehabilitation Abstraction Instrument Acute episode version (396) (397), supplemented with a physiological variable collection form.

The Veterans Affairs' acute care chart audit abstraction instrument covers 9 domains with 109 questions. Both the inter-rater and intra-rater reliability of the instrument are good (inter-rater ICC=0.69-0.76; intra-rater $\kappa=0.75$-0.93) (397) (398) (397) (399). For this analysis, the item scores were aggregated over the dimensions into a single compliance score from 0-100% per person, and summed to a total institution compliance score. (The nine acute care domains with their criteria, scoring and compliance achieved are depicted in a Figure in the Appendix.)

Complications during hospitalization were defined as: a fall, urinary tract infection, pressure ulcer, aspiration pneumonia, an embolism, recurrent stroke, shoulder injury or depression (using DSCM criteria). Some of the information was collected for the time period beyond three days, as it was considered relevant to functioning at three months.

Usual practice is to measure and record the following three times daily: body temperature, hydration, oxygen saturation, blood pressure and glucose level. For these analyses, data from the first 72 hours were retained. The first four variables were dichotomized as normal or abnormal based on the following criteria for normality: temperature, < 38 degrees Celsius; hydration, the presence of an intravenous line; oxygen saturation, >95% blood oxygen saturation (400) (401) (402). Blood pressure was recorded with two variables and two criteria: (1) a mean arterial blood pressure (MAP), lower limit of >100 millimetres of mercury (mm Hg); and an MAP, upper limit <140 mm Hg; (403) (404) or (2) as a systolic pressure, < 220; and a diastolic pressure, less than 140 mm Hg (405) (406) (407) (404).

To define the relationship between glucose and the F3m and F3d measures, four variables were defined: (1) the average level of glucose over 72 hours; (2) a count of the number of times that glucose levels were above 7 millimoles per liter; or (3) above 10 mmol/l; and (4) presence or absence of pre-stroke diabetes(402) (408) (409) (410).

As information on the components of optimal therapy, the timing, intensity or the ingredients of the interventions (140) (126) (159) is limited, therapy was defined as the combined direct hands-on amount of therapy given by the Physical (PT) and Occupational therapist (OT). This was determined from the discipline specific departmental reporting statistics of the hospital. For this analysis, the amount of therapy given in the first three days was calculated per subject as:

Therapy given over three days = (Sum (PT&OT workload in hours)/Sum (PT&OT attendances in days)/ length of stay in days)*3.

The number of medical and surgical interventions for the first three days was also recorded. (A list of interventions is in the Appendix.) Location of treatment and whether the patient received thrombolysis was noted as part of the Veterans Affairs Structure, Process and Outcomes of Post-Acute Stroke Rehabilitation Abstraction Instrument Acute episode version (396) (397).

Ability Factors

The tasks defining post-stroke ability within the first three days not included in the F3d physical measure include: sensation, visual perceptual neglect and cognition. Perceptual neglect was evaluated by Albert's test (341) (342), cognitive level by the Telephone Version of the Mini-Mental State Examination (MMSE) (305) (306), and the level of sensory impairment by combining the sensory part of the Fugl-Meyer (46) measure of sensorimotor recovery after stroke with the score on the Orpington test of thumb proprioception (48). For the analysis, sensation was categorized as normal, diminished or absent based on the combined total sensory scores.

Analysis

The level of functioning for the subjects was estimated at three months and three days as the mean F3m or F3d score with their 95% confidence intervals (CI). Missing values in less than 5% of the data were not replaced; missing values (9% of the data) for the amount of therapy received in the first three days were imputed by predictive mean matching using the monotone mean matching method (308) (307). The mean of the five imputed values for the therapy variable were used throughout the analysis

Descriptive statistics were used to characterize the sample and analysis of variance, $\chi 2$ and t-tests were to contrast participants and non participants. The strength of the association between each variable and the F3d and F3m, was estimated using Spearman's correlation and associated 95% confidence intervals for variables measured on an ordinal or continuous scale. General linear models with the Tukey post-hoc test were used to compare functioning across level of the selected factors. Significance was set at $p<0.05$ and the analyses were performed using SAS version 9.1 (SAS institute, 100 SAS Campus Dr, Cary NC 27513).

Results

A total of 1216 patients were screened at three days post-stroke (mean; 69.6: SD; 40.8 hours) for entry into the study of these 262 accepted to participate, 77 refused and 877 were excluded; 89% of the participants were assessed at three months, (10 died, 10 refused, 4 moved, 1 was lost to follow up and 2 had an accident). Figure 6.1 illustrates the screening process, participants and reasons for exclusion. Table 6.2 lists the baseline characteristics at three days of the 235 participants common to both time points, the non-participants and those lost to follow up.

Although the non-participants were on average four years older than the participants (Table 6.2), they had a milder stroke (CNS mean: 7.7; SD: 3.5), a higher discharge ADL score (mean BI difference: -8.4; 95% CI:-19.5 to -2.6), and shorter length of stay (mean: 13.5; SD: 9.7) compared to the participants. There were no significant differences between those lost to follow up and the participants at three months.

The 235 persons in the cohort assessed at three days post-stroke were predominately men aged 71.6 (SD: 12.5) years, who had an ischemic stroke and a median length of stay of 11 days (mean: 15.9; SD: 20.9). The majority lived at home prior to hospital admission (94%), and 5% lived in a nursing home. The major comorbid conditions present in the subjects were: hypertension, cancer, a prior stroke, and myocardial infarction. At three days, the average neurological impact of stroke was 8.2 out of 11.5 on the CNS (SD: 2.6), and 19% had a severe stroke. Their average level of functioning prior to having a stroke measured on the Physical Functioning scale of the SF-36 (PF, mean: 74.6; SD: 29.4) is comparable to Canadian norms for men aged 65 to 74 (mean: 78.6; SD: 20.5) (265). The average F3d score was 52.5 (SD: 20.5; maximum: 100), while the average functioning level at three months on the F3m, 60.8 (SD: 18.4; maximum: 99.8), was only 8 points above the average three day score.

The majority of the cohort was discharged to rehabilitation (53%) and at the time of the three month interview, 75% were at home. Eleven percent of the subjects had an assessment after three months, but as the data did not differ from those assessed on time, they were merged.

Table 6.3 outlines the univariate relationship between the person factors and functioning at three days and at three months. The three variables significantly related to functioning at both time points were age, prior functioning level, and prior health state; these had a stronger relationship with the F3m than the F3d. Four additional variables were significantly related to the F3m only: income, education, active lifestyle, and gender. Social network and previous falls/accidents were not associated with functioning at either time point.

Age was linearly related to both the F3d and F3m. Those older than 85 had an average functioning score 5.6 points less (95% CI: 13.8 to 22.1) at three days and 17.3 points (95% CI: 10.1 to 24.5) less at 3 months than those in the younger age groups.

The F3d did not differ between men and women, but men had 5 more functioning points (95% CI: 0.4 to 10.1) than the women at three months.

The two indicators of pre-stroke activity levels, the PF and active lifestyle, correlated at 0.34 (95% CI: 0.2 to 0.46) indicating a minor congruence between the two indices. Those subjects who stated they were active now had a significantly higher PF score (mean: 89.9; SD: 22), than the irregularly active (mean: 70.0; SD: 30.0), and non active group (mean: 69.0; SD: 29.9). Although the two indices are indicative of a prior active life style, only the PF was linearly related to the F3d and the F3m. Interestingly, the prior activities on the PF that people were most limited in were the most difficult: 41% were very limited in performing vigorous activities, 25% were very limited in climbing several flights of stairs and 25% were very limited in walking more than a kilometre. Only 3% of the subjects had prior limitations in the basic ADL activities of dressing and bathing.

The 25% of subjects considered to have an active lifestyle were responsible for the significance of the relationship with the F3m (Spearman's rho: 0.43; 95% CI: 0.36 to 0.58). Although this active group functioned with approximately 10 more points at three months than the other groups (95% CI: 3.5 to 16.8), their level of functioning was similar to the inactive group at three days.

The Charlson Index was linearly related to functioning at both time points, three months (Spearmen's rho: -0.21; 95% CI:-0.35 to -0.08) and three days, (Spearmen's rho: -0.13; 95% CI: -0. 26 to -0.002). At three months, a person with a Charlson Index of >3 had an

F3m score 24 to 17 points lower than those with an index <3. At three days, a Charlson Index of "zero" provided a functional advantage over those with an Index >3 (mean difference: 17.6; 95% CI: 0.5 to 34.8).

Monthly income and education were linearly related to functioning at three months. Those with ample finances had an F3m score on average 6 to 13 points higher (95% CI: 0.6-0.26) than those with inadequate to adequate finances.

Table 6.4 lists the stroke factors related to functioning. While no difference existed in the impact of a very mild, compared to a mild stroke, the F3d and the F3m scores were systematically lower, by 5 to 37 functioning points, with increasing stroke severity. On average, all subjects had at least 6 points more on the F3m than on the F3d, but the subjects with the severest strokes had 12 (95% CI: 7.3 to 16.7) more points than the rest.

Of the signs and symptoms of early stroke, only the presence of blurred vision, neglect, a fall at the time of stroke, and ataxic symptoms were related to functioning at both time points.

The only imaging variables related to functioning at three months were the presence of atrophy and white matter disease. They were both associated with a decrease in functioning by an average of 6 points (95% CI for both: 1.3 to 10.8). The correlation coefficient between these two variables was 0.37 (95% CI: 0.25 to 0.49). There was a negative association between lesions larger than 3 cm and the F3d. The F3d was 11 points higher (95% CI: 21.6 to 0.7) in those subjects with a smaller lesion.

Although imaging evidence of a prior stroke was not related to functioning at three days or three months, the variable "admitted to hospital for a first stroke" was negatively related to functioning at three months. Those with a first stroke had 7 (95% CI: 1.2 to 12.8) more functioning points compared to those admitted for more than a first stroke.

Table 6.5 lists the factors related to the process of care and ability. The process-of-care variables consistently related to functioning were: the number of interventions, amount of therapy received within the first three days, oxygen saturation level, and the number of complications over the length of stay. Those subjects requiring fewer interventions, (surgical or medical) had 11-20 points more on the F3d; this relationship was maintained at three months where the F3ms score was 13 points higher in those without an intervention compared to those with an intervention.

Although significantly related to the F3d and the F3m, only the levels of blood oxygen less than 95% of the normal level at day two reached significance and were negatively related to functioning at three months. Those with poor oxygen saturation had 14 fewer points (95% CI: 1.2 to 27.0) than those with adequate oxygen saturation. Those subjects with an elevated temperature at three days had 11 fewer F3d points (95% CI: 1.9 to 21.0) than those without a fever. The subjects at three days with a glucose level > 10 mmol/l compared to normal (6 mmol/l) had 6 fewer F3m points (95% CI: 0.9 to 10.9).

The amount of therapy received and the ability variables, cognition, sensation and perceptual neglect, were linearly related to functioning across time. Over the length of stay of a subject, s/he was seen by a PT on average 11.5 (SD: 13.8) times and 9.0 (SD: 9.6) times by an OT. The average time spent with each subject over the length of stay was 7.6 (SD; 8.6) for PT and 7.3 (SD; 7.7) hours for OT.

Discussion

Of the multiple factors known to be associated with functioning after stroke and evaluated here, 18 were associated with functioning at three days and three months post-stroke. Ten other factors were related to functioning at a unique time point after stroke. All the early factors significantly related to functioning that could be considered modifiable, except pre-stroke functioning level, were related to the process of care: control of glucose, temperature and oxygen saturation, the amount of therapy given, and the need for interventions.

In the literature, the strength of the relationship between the plethora of factors and functioning varies due to issues of methodological quality. The existing criteria (14) (28) (30) used to appraise the validity of the predictive studies relate the differences in the relationships to various issues: the population studied, the timing of the evaluations, quality and length of follow up, and whether the models had been validated on another sample. Additional issues related to the quality of the relationship concerned the definitions and quality of the outcomes and the factors used, as well as the sample to variable ratio, statistical methods and the information provided in the papers to judge their quality. With these details in mind, the relationship between the factors related to the F3d and F3m were compared to those factors found relevant in the literature.

Age was an important factor related to functioning at three days and three months. The literature provides little consensus on the effects of age due to the differences in the categorization of age. Being older, compared to younger in age, has a consistent independent association with a number of outcomes: survival (411) (412), neurological and functional status at discharge from acute or rehabilitation hospital (14), improved neurological and functional recovery, and time to best neurological status or ADL score (31) (77) (286). The definition of older in stroke studies varied from >75 (413), to >80 (414), to >85 (415) in relation to functional outcome. The elderly subjects in this study aged >85 (11%) functioned with 17 fewer points at three months than the younger subjects. This is similar to the 7% decrease in the BI score three months post-stroke attributed to subjects older than 75 in a previous study (286). Although the recovery of ADL (BI) in that study declined with age, the 3-4 point decrease could not be considered clinically significant (286) (416). Nakayama et al. (286) suggested that this negative effect on ADL was due to the poorer compensatory abilities of elderly stroke patients. The authors implied that a compensatory therapeutic approach was needed for the elderly as they tend to have a slower neurological recovery rate. The elderly may need a different approach to therapy, not a compensatory one, an approach that permits them enough time to improve.

A hospital-based stoke study, (417) (n=1358) of patients older than 80 contradicted the evidence of Nakayama et al. (286) by stating that age was not independently associated with the use of rehabilitation services, mortality rates at 28 days or three months, length of stay, or disability rate. The authors explained that the higher rates seen in the older subjects, compared to the younger ones, were due the increased comorbidity, risk factors and prior rates of poor health in the elderly. The failure to adequately adjust for multiple factors by Nakayama et al. may explain the difference between the two studies. The definition of older age may be a more important indicator in the functioning relationship than age itself; being older may be a surrogate indicator of increased comorbidity or the numerous risk factors that comes with increasing age.

Gender did not appear to impact differentially on functioning at the onset of stroke, but by three months women had a lower level of functioning than men. The reason for the gender difference in functioning later after stroke has been linked to the multifactorial effects of age (418), lack of social support for women (29), the gender bias in ADL questions (29) (419), poorer levels of prior functioning and greater levels of depression in women (418). Pre-stroke functioning is the most plausible cause here. The F3d demonstrates the differential patterns that stroke has on the F3m measure of functioning without the bias associated with the effect of sample characteristics, such as gender, as the items in both measures were invariant across gender. (See Chapters 4 & 5, Manuscripts 3 & 4) The possibility of an interactive effect between gender and age, or age and prior functioning, however, needs to be tested.

Evidence for social support as a factor is meagre in the literature probably due to the multiple definitions of social support among them: marital status, living arrangements, or scores on social indices. Social relationships have been found to predict survival, and help in adjusting to and recovering from chronic diseases (420) (421). In previous works, the number of social ties predicted a significantly lower 17-year mortality risk for those older than 70 (relative hazard: 1.49; 95% CI: 1.09 to 2.05) (422). When the structure of social networks was investigated the important factors related to the adequacy and availability of support were the presence of a confidant and the number of direct contacts (422) (423) and not the network characteristics themselves. The support network an individual has can be influential in maintaining psychological well being; a factor that can promote successful recovery of functioning (420). Although 34% of our subjects lived alone, the person's social network at three days was not related to functioning on the F3d or the F3m measure. Support was only judged as poor in 7% of subjects. Social support as a factor may fluctuate in influence depending on the time at which or how it is evaluated (422) (424). Additionally, the support system of the subjects here may have changed over the period of three months. The support at three months may be more important for functioning than the support at three days.

In Table 6.2, the prior functioning level of subjects on the PF was comparable to Canadian norms for men aged 65 to 74 (PF, mean: 74.6; SD: 29.4) (265). This score indicates that the subjects had difficulty with the top three items: vigorous activities, walking more than a kilometre, and climbing several flights of stairs. The tasks most of the subjects found difficult immediately after stroke represented approximately 50% of the items on the F3d and can be estimated by the score on the F3d (mean: 52.5; SD: 20.5) as the items are ordered hierarchically by difficulty. The difficult tasks at three months (mean: 60.8; SD: 18.4) represent the top 40% of items on the F3m and include: heavy housework, performing physically demanding activities and walking several blocks. Three months post-stroke subjects have difficulty performing more tasks than before their stroke, but the difficult tasks are similar to those prior to stroke.

Prior life style and habits influence the risk of having a stroke (425) and the ability to regain functioning levels post-stroke (412) (426). In a previous case control study, a dose response relationship existed between the probabilities of not having a stroke and increased activity levels (odds ratio (OR) from 0.39 to 0.23) (427). The strength of the relationship depended on how prior activity was defined and assessed. In this study, activity levels measured by the average metabolic units spent were only related to the F3m, while the degree of pre-stroke functioning on the PF was related to both the F3d and the F3m measures. Of these two indicators of activity, the PF and metabolic units, the PF is easier to assess and should probably be used. The PF may also be less prone to recall bias. In retrospect, the collection of the number of hours and types of activity on a standardized questionnaire such as the CHAMPS (428) or the Physical Activity Scale for the Elderly (429) could have produced a more accurate assessment of activity level. This remains to be tested.

The indices most often used to outline levels of ability prior to stroke are the BI, (430) (413) MRS, (412) and the PF (175). Using the PF, Duncan et al. (175) found 25% of their cohort of 426 stroke survivors achieved their pre-stroke performance by 6-months post-stroke. Using the BI, Pohjasvaara et al. (413) demonstrated an average improvement of 11 points compared to prior levels (413) in a cohort of 267 elderly stroke survivors three months post-stroke. The ceiling effects of the BI in determining prior activity levels make it difficult to compare pre-post results, and define an accurate relationship. The time difference in the outcome assessments between the studies also makes comparisons difficult.

The time spent on activities and the type of activity varied a great deal across our subjects. The subjects engaged in a wide range of activities that were based on the complex interaction of their gender, age, and prior levels of health. The effect of prior lifestyle on functioning, no matter how it is gauged, necessitates the promotion of physical activity as an integral part of every rehabilitation program post-stroke. An increase in activity could make up for the differences in the ability to regain functioning. The Centers for Disease Control and Prevention and the American College of Sports Medicine indicate that >7.5 MET hours weekly is the amount of activity needed to obtain a heath benefit and is equivalent to 30 minutes of activity 5 days a week (391). This is the level that is being studied as feasible for early incorporation into rehabilitation programs (431).

The stroke factors related to functioning in Table 6.1 were the initial severity of stroke measured either by a collection of individual neurological signs and symptoms or by a single stroke scale score that summarizes the neurological variables. The Canadian Neurological Stroke scale (CNS) correlated at -0.56 with the F3d and -0.54 with the F3m and defined the relationship between stroke severity and functioning. The initial severity of stroke is a major factor related to functioning in the literature; as a result, the least amount of improvement and longest time to regain function has been seen in the severest group (56) (60) (41) (55) (34) (13). Interpreting that an individual with a severe stroke does not do as well as others based on a group analysis requires caution, as these subjects can regain functioning as well as those with a less severe stroke (286) (432). The interpretations of the relationship between stroke severity based on the F3d and F3m measures requires less caution at the individual level, as the scores on these measures can be related to specific tasks. For example, the decrease in functioning across the CNS levels of severity did not limit the ability of the subjects to improve, although the score of the group with the severest stroke was 28 /100 on the F3d, they scored 40 /100 on the F3m (see Table 6.4). The average ability of an individual at three days with a score of 28 was limited to the bottom six items of the 38-item F3d measure. At three months a score of 40 in the 44- item F3m is represented by the bottom 15 items that include: the ability to walk in a limited environment, partially dress, and have some difficulty getting to the toilet. Each individual can be described succinctly by his or her score.

Stroke scales, such as the CNS, overemphasise basic motor abilities and relate more to basic impairments ($R^2$of 0.475 between the NIHSS stroke scale and the BI) than to higher level activities or participation in life roles (R^2 of 0.33 between the NIHSS stroke scale and the MRS) (173). The relationship between stroke severity and functioning, on the F3d and the F3m, in this study, was as strong as in the literature, and changed little across time or the two measures that reflect impairments, activity limitations and participation restrictions.

As the acute signs and symptoms of stroke and stroke severity are highly correlated, both may not be retained in a multivariate model. The eye signs in Table 6.4, significantly related to the F3d measure, have usually resolved by three months, a fact that may account for the lack of their relationship to functioning at three months (433).

The relationship between functioning and the imaging variables is complex (Table 6.4). CT and MRI results do not always provide adequate visualization of infarcts early post-stroke (434) (435) and the reliability of the analytical methods determining the lesion characteristics are often challenged (436) (437). The goal here was to determine if any early clinically definable imaging variable was related to functioning at three days or three months. The imaging characteristics outside of the routine CT and MRI radiological clinical reports would be unavailable at three days, thus the data from the reports, confirmed in consultation with a neuroradiologist, were used to characterize the structural and pathophysiological changes of the lesion post-stroke (174).Other methods of classifying lesion characteristics, for instance diffusion tensor imaging (438) (439), or perfusion weighted imaging, lesion volume changes, (81) or functional magnetic resonance imaging (360) (81), may be more useful. Additionally, techniques beyond imaging such as evoked potentials (32), or Transcranial Magnetic Stimulation (440), and others (441) may better delineate the structures and brain functions affected by stroke. Although these techniques are not universally available, precise and specific operational definitions of potential brain reorganization ability and the degree of improvement expected is required to estimate the structural changes underlying the functional brain changes that occur after stroke (442). The two sets of variables, lesion characteristics and person/stroke characteristics related to functioning, are linked, but better early characterization of the lesion structure and residual available functioning brain tissue is needed.

Only the variables representing white matter disease and atrophy seen on the scans were related to functioning. White matter disease may represent an accumulation of old subcortical or lacunar strokes of insignificant import, but in combination with a new stroke may tip the scales to decline functioning, especially in an older person. It could be hypothesized that if brain reorganization is required for recovery, these subjects may take longer to recover. Their remaining healthy brain tissue is less compared to those without white matter disease. Persons with lacunar strokes and those with subcortical strokes have been found to have more disability than other types of stroke (14). The people with more subcortical strokes may require different types of therapy (166).

It is possible that the categorization of CT variables used was inadequate and prevented the establishment of a relationship with functioning, or the sample size was inadequate to estimate the effects of lesion variables, or these scans are too early for the definition of the necessary lesion characteristics to link to functioning(8).

Table 6.5 includes four process variables related consistently to functioning; therapy, interventions, oxygen saturation, complications, and two inconsistently related ones, control of glucose and temperature. The factors related to functioning in the literature (31) (443) (29) (28) (77) (80) (14), include few processes-of-care factors as relevant to functioning. The mounting evidence that routine stroke care should be delivered in an acute Stroke Unit (SU) may be one reason the location of care is no longer considered a factor. The literature asserts that patients cared for on a SU compared to those in a general ward have a 40% reduction in the relative risks of death, poor outcome (death during hospital stay, discharge to nursing home), and 1-year mortality rate. Additionally, the length of stay was reduced by 2 to 3 weeks, in all but the most severe stroke treated in a SU (101).

A relationship between locus of care and functioning was not found here, possibly because only 10% of the sample was treated outside a SU, where their care was supervised by the stroke unit nurse coordinator. Thus, these subjects may have partially benefited from stroke unit care and any relationship due to location of care was eliminated. The process-of-care factors, in this study, related to functioning reinforces the importance of the delivery of care to persons with an acute stroke, and emphases the fact that good clinical care is essential.

Other process factors believed to influence functioning besides the locus of treatment, and stroke care delivery are the timing of rehabilitation interventions and control of physiological variables. The most influential early factors in a SU seemed to be early rehabilitation and better control of physiological parameters such as hydration (102). These factors have been consistently associated with reduced probability of death (Odds Ratio (OR): 0.66), death or institutionalization (OR: 0.70) and death or dependency (OR: 0.85) (101)

Mounting evidence on the benefits of stroke care delivery, especially SU care, has led to the development of stroke practice guidelines that have impacted on the delivery of early care (403) (136) (444) (133) (445), and instruments to assess compliance to these guidelines. Although the compliance instrument used here, the Structure, Process and Outcomes of Post-Acute Stroke Rehabilitation Abstraction Instrument (446) (447) (397) (399) did not measure actual care, but the documentation of care, the developers suggested that compliance with guidelines could be considered a "quality of care indicator" (398). The degree of compliance indicative of quality care was not stated. Unfortunately, compliance can only be assessed at the end of care; consequently, it was treated as a descriptive variable. No relationship was founded between compliance and functioning, which is consistent with the finding in the literature for early functioning (403) (136) (444) (133) (445).

Functioning has been related to the control of physiological homeostasis: control of hydration, glucose, calcium and oxygen saturation and prevention of pyrexia and hypotension (100) (448) (101) (105) (449) (106) (102). This is supported by data from a case control study reporting a poorer outcome from inadequate physiological homeostasis (449) (450). Both the risk of a poor outcome (relative risk: 2.2; 95% CI: 1.4-3.5) and death increased (OR: 2.1; 95% CI: 1.04 to 4.4) (400) with every degree increased in body temperature. The level of glucose, degree of pyrexia and unstable blood pressure have been shown to be independently related to the early progression of stroke, i.e. within the first 24 hours of hospital admission (407) (400) (102). The criterion defining control of each of these physiological factors is controversial (403) (136) (405). For example, if hypertension is left untreated, the initial damage may worsen through increased edema or hemorrhagic formation, while a reduction in blood pressure may increase the ischemia (451) by reducing the cerebral perfusion pressure. The best course of action may be to control the variation in both the systolic and diastolic blood pressure through monitoring of mean arterial pressure (405) (404) (102). Measures of blood pressure control (BP) were unrelated to functioning; however, only 4% of the subjects were outside the systolic and diastolic criteria (The distribution of the physiological variables is included in the Appendix.). Even when BP control was measured using MAP criteria, only 13% of subjects had a high MAP, compared to 84% with a MAP lower than 100 mmHg over 72 hours. Neither variable was related to functioning.

The association between elevated temperature and functioning at three days is similar to that reported in the literature for subjects treated in a SU (406). A temperature greater than 38° Celsius was associated with an increase in the F3d of 5 points. A relationship between fever and functioning later post-stroke was not noted here or in the literature, but a fever later may be confounded by subsequent secondary complications (452).

The relationship between glucose control and functioning is complex and maybe influenced by stroke severity and diabetes, both of which are related to functioning and glucose control (453). Additionally, the stress of having a stroke can raise glucose readings (454) (455). What defines uncontrolled glucose depends on how it is measured and how often: is it impaired glucose control, glucose intolerance, raised blood glucose, or diabetes that is important (456) (443) (453) (457) (410)? In the quest to define the relationship between glucose and functioning, a relationship with functioning was only found in one of the four indicators used, namely, glucose levels >10mmol/l. As ongoing studies are evaluating this problem (406) (410), it is enough to say that the number of times glucose is above 10 mmol/l is associated with a decrease in functioning at three months. Whether the relationship will persist in the face of stroke severity and diabetes remains to be tested.

Nevertheless, the concept of glucose control is an important one. Elevated glucose is considered a neurotoxin (410) (449). It has been linked to early infarct volume increases in a very select sample of 20 diabetic subjects with a first stroke (410). Uncontrolled glucose, >7.2 mmol/l, on admission to hospital increased mortality three fold (OR: 3.15; 95% CI: 1.4 to 6.85) within the first 48 hours after stroke (409), despite adjustment for stroke severity, age, risk factors and comorbidity. Glucose must be controlled more diligently. The levels of control may be controversial, especially when the patient is diabetic; regardless, the guidelines set out in most hospitals for the control of glucose need to be followed closely (404) (133).

Stroke is not a static event and the factors that are related early on to functioning may differ from those later. Knowing which early factors could influence functioning could lead to earlier treatments that are aimed at and are relevant to a large proportion of stroke survivors. The process-of-care factors here were by far the largest set of modifiable factors related to functioning at three days and three months. Recent stroke literature indicates that the control of the process-of-care variables is an essential factor in achieving better brain protection (406) essential for recovery.

Therapy given within the first few days post-stroke has been linked to improved outcomes (102) (365) (366) (367) (379) (382) (148). Few studies of acute therapy, within the first 24 hours to 15 days, have determined the ingredients related to the improvement in functioning as their focus was on the timing of therapy as a factor. In fact, studies have only recently begun to unpack the "black box" of post acute care rehabilitation later in the course of recovery (458) (160). In this study, the amount of therapy given within the first three days, not the components of therapy, was linked to functioning at three days and three months. Even the limited amount of therapy given here was related to functioning.

Baselines levels of functioning (142) (158) (28) (30) (31), no matter how they are measured, or when they are measured, are strongly related to later functioning. While sensation, neglect and cognition were related to the F3m and F3d, the acute impact of stroke on functioning, the F3d had the strongest association with the F3m (r: 0.79; 95% CI: 0.72-0.85).

Eighteen factors were related to functioning at both three days and three months. The strength of the relationships changed based on the time of assessment and the measure of functioning. This allows for the planning of interventions based on a number of factors at two time points that can optimize treatment through various therapies or strategies linked to the relevant variables. An idea of the multitude of variables related to functioning provides the opportunity to change therapeutic strategies. If one approach is ineffective, another one aimed at modifying a different variable may achieve the desired results.

Limitations

The F3d and the F3m are adequate measures of functioning, but, have not been tested for item stability, test retest reliability or sensitivity to change. The sample here, although similar in many ways to those in the literature (242) (13) (1), does not represent stroke subjects with a very mild stroke not admitted to hospital, or those with dysphasia or lower levels of cognition.

The relationships defined are merely associations and do not reflect causality between factors and functioning. A study of relationships (either associative or predictive) between variables must not only consider the strength of the relationship and its significance, but also the modifying or confounding variables affecting the association. A relationship can have more than one influencing factor; consideration must be given to their interactions and interrelationships when determining the unique contribution of each. In consequence, a multivariate model is needed to define the unique contribution of each variable, adjusted for other related factors.

Conclusion

Of the multiple factors associated with functioning evaluated here, 18 were associated with functioning at three days and three months post-stroke. Ten other factors were related to functioning at a unique time point after stroke. All the modifiable factors significantly related to functioning, except pre-stroke functioning, were associated with the process of care. Stroke is not a stable entity and the effects of stroke will continuously evolve over its course, from onset to the full restitution of functioning. Understanding the factors that could modify functioning at two important time points in the life of a stroke survivor, the first three days and at three months, may allow us to develop and optimize specific interventions at each time point targeted to the specific characteristics of an individual. Defining the individual variables or factors is the first step in understanding the impact of stroke on an individual's functioning.

36 Table 6.1 Potential influencing factors collected within 24-72 hours

	CONSTRUCT	VARIABLE	INDEX USED	ADJUST-MENT VARIABLES
Personal factors	Health Status	Accident, level of health	Questionnaire, Sf-36 Q2 (292) Co-morbidity index*	Risk factors (smoking, drinking)
	Social Support	Social network	OARS-Social Q3,6,9 (277) (278) (279)	Gender, Finance
	Prior Function		SF-36 PF (292)	
	Participation experience and skills	Type and level of work, sports, hobbies	Questionnaire	Education
Stroke factors	Symptoms, Neuro signs,	Symptoms of stroke, orientation, consciousness, weakness	CNS(250), standardized data collection form with variables marked as present or absent	
	Lesion description	Size, Site, Side, Atrophy, # of lesions, Swelling, first stroke	Standardized form for CT/MRI Imaging (395)	Stroke type ischemic or hemorrhagic
Provision of care factors	Stroke intervention	Medical, Surgical	Standardized form: #,	
	PT; OT	Number of days and hours of therapy	Departmental Statistics	
	Expertise of care	Location, Approach, Complications	Standardized chart audit abstraction instrument (396) (397)	
	Physiological factors	Hydration	# with IV	
		Glucose level	# with glucose >10 mmol/l	
		Temperature	# with >38 ° C	
		Oxygen saturation	# with saturation <95%	
		Mean arterial blood pressure (MAP)	# with MAP <100; or MAP>220	
Ability	Clinical abilities	Self-care, mobility, neglect, sensation, impact of stroke, motor control, balance, cognition	F3d (Manuscript 4), MMSE, (305) (306) Fugl-Meyer sensation (46)	Memory, orientation, language Compre-hension

Abbreviations: CNS, (Canadian Neurological Stroke scale); OARS, (Older Americans Resources and Services Questionnaire); F3d (measure of functioning at three days); MMSE, (Mini Mental State Exam); OT, (occupational therapy); PF, (physical function scale of the SF-36); PT, (physical therapy); SF-36, (Medical Outcomes Trust Short Form-36 questionnaire); #, (number).

*Charlson Comorbid Index

37 **Table 6.2 Baseline Characteristics of the Subjects at Three Days**

Characteristic	Participants (n=235)	Lost to follow up (n=27)	Refusals (n=77)
Age at stroke onset (years)			
Mean ± SD	71.6 ± 12.5	69.5 ± 16.5	75.2 ± 10.5*
65> / 65-74 / 75-84 / ≥85 (%)	29 / 25 / 35 / 11	26/ 30 /33 /11	13 / 36 / 33 / 18
Men/Women (%)	62 / 38	67 / 33	51 / 49
Level of Education Finished (%)			
None/Grade /High /College	18 / 39 /14 / 29	15 / 41 / 7 / 37	N/A
Living where pre-stroke† (%)			
Home / Residence / LTC	94 / 5 /1	93 / 7 / 0	90 / 9 /1
Living with pre-stroke (%)			
Family / Alone / Other	59 / 34 /6	52 / 41/ 7	66 / 31 / 3
Discharge Destination (%)			
Rehab /Home /Trans /LTC/Died	53 / 39 /2 / 6 / 0	41 / 44 / 4 /0/11	53 / 35 / 3 / 5 / 3
Ischemic / Haemorrhage / Other (%)	86 / 14 /<0.1	89 / 11 / 0	87 / 13 / 0
First stroke (%)	79	78	78
Side of hemiplegia (%)			
Right / Left / Bilateral / None	36 / 53 / 0 / 11	44 / 48 / 0 / 7	36 / 40 / 1 / 23
Length of stay in acute care (days)			
Mean ± SD	15.9 ± 20.9	14.6 ± 10.9	13.5 ± 9.7
Stroke severity at admission ††			
Mean ± SD	8.2 ± 2.6	8.1 ± 2.5	7.7 ± 3.5
Very Mild / Mild/Moderate/Severe (%)	18 / 22 / 41 / 19	15 / 15 / 55 / 15	23 / 25 / 25 / 27

Table 6.2 continued Baseline Characteristics of the Subjects at Three Days

Characteristic	Participants (n=235)	Lost to follow up (n=27)	Refusals (n=77)
Charlson Comorbidity Index (%)			
0 / 1 / 2, 3 / >3	30 / 28 / 31 /11	41 / 30 / 19 / 11	N/A
F3d (0-100)			
Mean ± SD	52.5 ± 20.5	51.3 ± 21.4	N/A
F3m (0-100			
Mean ± SD	60.8 ± 18.4	N/A	N/A
Pre-stroke SF-36, PF † (0-100)			
Mean ± SD	74.6 ± 29.4	76.1 ± 24.8	N/A

Abbreviations: F3d, (the measure of functioning at three days); F3m, (the measure of functioning at three months); N/A, (not available); SD, (standard deviation); BI, (Barthel Index, basic activities of daily living); LTC, (Long term care); Sf-36 PF, (Medical Outcome Study (MOS) 36-Item Short Form Health Survey (SF-36), the physical functioning scale (PF) (292));CNS, (Canadian Neurological Stroke scale); ††Best score: 11.5; with: Very Mild: ≥11.0; 9.5 ≥Mild <11; 5 ≤Moderate <9.5; Severe: <5,

* Significantly different; p<.01

†Pre-stroke for all variables prior to stroke is based on information one month prior to stoke

38 Table 6.3 Relationship Between The Factors Related to The Person and The Functioning Measure at three days (F3d) and The Functioning Measure at three Months (F3m).

Variable		*Spearman's rho (95% CI)* or Mean ± SD	
	%	F3d	F3m
Sociodemographic variables			
* Age (y)		*-0.18 (-0.32 to -0.05)*	*-0.32 (-0.45 to -0.19)*
<65	29	56.5 ± 23.7	67.4 ± 20.3
65-74	25	53.4 ± 22.2	62.4 ± 17.7
75-84	35	52.5 ± 15.6	59.1 ± 13.3
>85	11	40.2 ± 17.4	45.4 ± 19.9
* All <85	89	54.1 ± 20.4	62.7 ± 17.3
Gender			
Male	62	52.3 ± 21.6	62.8 ± 19.0 †
Female	38	52.9 ± 18.6	57.5 ± 16.9
Place of residence pre-stroke§			
at home	94	52.8 ± 18.6	61.4 ± 18.6
in residence	6	49.0 ± 11.5	52.4 ± 11.5
Dwelling with pre-stroke§			
spouse	54	52.7 ± 22.1	62.7 ± 19.9
family/ friends	11	51.3 ± 24.0	56.1 ± 15.3
alone	35	53.2 ± 18.0	59.3 ± 16.6
Education highest level		*0.11 (-0.01 to 2.4)*	*0.17 (0.05 to 0.29)* †
Secondary or more	29	55.6 ± 19.6	64.5 ± 17.0
Secondary or less	71	51.3 ± 20.8	59.3 ± 18.7
Social Network (OARS 0-6)		*-0.03 (-0.16 to 0.1)*	*-0.13 (-0.26 to 0.007)*
Finances		*-013 (-0.25 to -0.001)*	*-0.20 (-0.32 to -0.08)* †
Insufficient	5	41.4 ± 17.2	51.0 ± 14.8
Adequate	42	51.4 ± 19.7	57.8 ± 18.6
Ample	52	54.4 ± 21.2	64.1 ± 17.9†

Table 6.3 continued. Relationship Between The Factors Related to The Person and The F3d and The F3m.

Variable		*Spearman's rho (95% CI)* or Mean ± SD	
	%	F3d	F3m
Pre-stroke activity [§]			
* Sf-36 PF pre-stroke (0-100)		*0.22 (0.1 to 0.34)*	*0.44 (0.33 to 0.55)*
Active lifestyle			
Active	25	58.5 ± 25.2	66.8 ± 20.4
In the past or present only	56	50.2 ± 18.8	58.6 ± 17.5
Inactive	19	51.7 ± 17.3	56.8 ± 15.3
Prior Health			
* Charlson comorbidity index		*-0.13 (-0.26 to -0.002)*	*-0.21 (-0.35 to -0.08)*
0	30	54.7 ± 23.7	64.8 ± 21.3
1	28	53.5 ± 19.3	61.4 ± 15.2
2, 3	31	52.7 ± 18.6	61.5 ± 15.9
>3.	11	43.6 ± 18.1	46.7 ± 18.2
Accidents/falls pre-stroke			
None	14	50.9 ± 22.7	55.4 ± 21.3
Any	86	52.8 ± 20.2	61.7 ± 17.8

Abbreviations: F3d, (the measure of functioning at three days); F3m, (the measure of functioning at three months); OARS, (Older American resources Scale); SF-36 PF, (Medical Outcome Study (MOS) 36-Item Short Form Health Survey (SF-36) the physical functioning scale (PF))

*Significant correlations and mean differences at p<0.03 or less for the two time points, three months and three days. [†] Significant correlations and mean differences at p<0.03 or less for one of the two time points, three months or three days [§]Pre stroke for all variables prior to stroke is based on information one month prior to stoke

39 Table 6.4 Relationships Between The Stroke Factors and The F3d and The F3m.

Variable		*Spearman's rho (95% CI)* or Mean ± SD	
	%	F3d	F3m
Stroke severity			
Admission for first stroke	80	52.8 ± 21.0	62.3 ± 18.3 †
Not a first stroke	20	51.3 ± 18.6	55.2 ± 17.8
* Stroke severity (CNS)		*-0.56 (-0.66 to - 0.47)*	*-0.54 (-0.44 to - 0.64)*
# Very mild	18	66.1 ± 13.7	75.0 ± 13.8
Mild	22	61.7 ± 15.6	67.2 ± 12.7
Moderate	41	52.9 ± 16.6	60.6 ± 14.7
Severe	19	28.5 ± 17.7	40.5 ± 17.4
Imaging variables§			
Stroke type			
Ischemic	86	53.7 ± 20.2	61.0 ± 18.4
Hemorrhage	14	45.6 ± 21.4	59.8 ± 18.7
No previous lesion	51	51.8 ± 22.8	61.6 ± 20.1
Previous lesion on scan	49	53.3 ± 18.0	59.9 ± 16.5
Mass effect present	85	53.3 ± 20.1	63.1 ± 18.3
No mass effect	15	47.8 ± 22.8	60.3 ± 18.8
* No Evidence of atrophy	66	53.0 ± 21.7	62.8 ± 18.3
Atrophy	34	51.7 ± 18.1	56.8 ± 18.2
* White matter disease	44	50.9 ± 18.2	57.3 ± 17.0
No white matter disease	56	53.8 ± 22.2	63.4 ± 19.1
No visible lesion <24-72 hrs	90	52.4 ± 19.1	60.5 ± 18.7
Visible lesion	10	53.9 ± 16.9	62.6 ± 15.2

Table 6.4 Continued. Relationship between the Stroke Factors and the F3d and the F3m

Variable		Spearman's rho (95% CI) or Mean ± SD	
Imaging variables[§]	%	**F3d**	**F3m**
No abnormalities in scan	66	53.3 ± 20.3	61.6 ± 18.1
Other scan abnormality	34	51.1 ± 18.3	59.0 ± 19.0
Size of lesion		*-0.14 (-0.26 to -0.01)* †	*-0.03 (-0.16 to 0.10)*
Anatomical Site of lesion		*-0.11 (-0.24 to 0.02)*	*-0.04 (-0.20 to 0.09)*
Pathology of lesion		*0.01 (-0.12 to 0.14)*	*0.03 (-0.10 to 0.16)*
Side of lesion		*-0.07 (-0.19 to 0.05)*	*-0.04 (-0.17 to 0.08)*
Signs and Symptoms of stroke			
Deviation of eyes	11	39.8 ± 23.5 †	
No Deviation of eyes	89	54.0 ± 19.6	
Diplopia	2	72.2 ± 28.4 †	
No Diplopia	98	52.1 ± 20.2	
* Blurred vision	3	72.3 ± 13.7	60.3 ± 18.0
No Blurred vision	97	51.8 ± 20.4	74.7 ± 14.6
Hemianopia	14	39.2 ± 18.4 †	
No Hemianopia	86	54.8 ± 20.0	
* Neglect	14	36.8 ± 22.0	49.1 ± 21.1
No Neglect	86	55.0 ± 19.2	62.6 ± 17.3
Hypoactive reflexes	13	43.4 ± 22.8 †	
Non Hypoactive reflexes	87	53.9 ± 19.9	
* Loss of balance fall	20	45.3 ± 19.3	55.0 ± 20.6
No Loss of balance	80	54.4 ± 20.5	62.3 ± 17.5
* Ataxia	24	61.9 ± 13.4	69.5 ± 14.8
No Ataxia	76	49.6 ± 21.5	58.1 ± 18.6

Abbreviations: CNS, (Canadian Neurological Scale); best score: 11.5; with: very mild: ≥11.0; 9.5 ≥mild <11; 5< moderate <9.5; and severe <5; F3d, (the measure of functioning at three days); F3m, (the measure of functioning at three months); hrs (hours).

not significant.

*Significant correlations and mean differences at $p<0.03$ or less for the two time points, three months and three days.

† Significant correlations and mean differences at $p<0.03$ or less for one of the two time points, three months or three days

§N=233 One subject without a CT scan with a functioning score of 72, and one subject with a scan after 72 hours with a functioning score 59.

40 **Table 6.5 Relationships Between The Process-Of-Care Factors, Ability and The F3d and The F3m.**

Variable	%	*Spearman rho (95% CI)* Mean ± SD F3d	F3m
Process variables (Counts)			
* Surgical interventions		*-0.15 (-0.28 to -0.03)*	*-0.21 (-0.32 to -0.10)*
None	90	53.6 ± 20.2	62.1 ± 18.2
Any	10	42.9 ± 16.0	49.7 ± 16.0
* Medical interventions		*-0.40 (-0.50 to -0.27)*	*-0.32 (-0.43 to -0.20)*
0	53	59.7 ± 17.5	66.3 ± 17.0
1	17	48.6 ± 21.1	58.6 ± 18.0
2 or more	14	39.5 ± 20.8	50.8 ± 17.3
Intervention after three days	16	44.1 ± 19.9	53.3 ± 18.1
Compliance to care guidelines		*-0.05 (-0.18 to 0.08)*	*-0.02 (-0.14 to 0.10)*
* Therapy Intensity (hrs/day)		*0.62 (0.58 to 0.66)*	*0.59 (0.55 to 0.63)*
Stroke Unit	90	53.6 ± 20.2	61.2 ± 18.4
No Stroke unit	10	42.9 ± 21.3	56.6 ± 18.2
* Complications over LOS		*-0.37 (-0.48 -0.27)*	*-0.38 (-0.49 to -0.27)*
0	77	56.3 ± 19.7	64.5 ± 16.5
1 to 2	16	42.7 ± 17.4	52.8 ± 18.0
More than 2	7	39.5 ± 20.8	39.0 ± 18.5
Thrombolysis	7	60.1 ± 25.0	65.1 ± 19.2
No Thrombolysis	93	52.0 ± 20.1	60.5 ± 18.3
Physiological variables (Counts)			
Glucose < 10 mmol/l		*-0.10 (-0.22 to 0.03)*	*-0.15 (-0.28 to -0.03)*†
Controlled non DM	61	54.2 ± 21.6	63.2 ± 18.6
Controlled DM	6	52.0 ± 17.7	58.3 ± 12.7
Non Controlled non DM	14	48.0 ± 15.7	57.2 ± 16.0
Non Controlled DM	19	50.4 ± 20.6	56.6 ± 19.9
Not Controlled vs controlled	33	49.4 ±18.6	56.8 ± 18.3†

Table 6.5 continued Relationship between the Process-of-Care Factors, Ability and the F3d and The F3m.

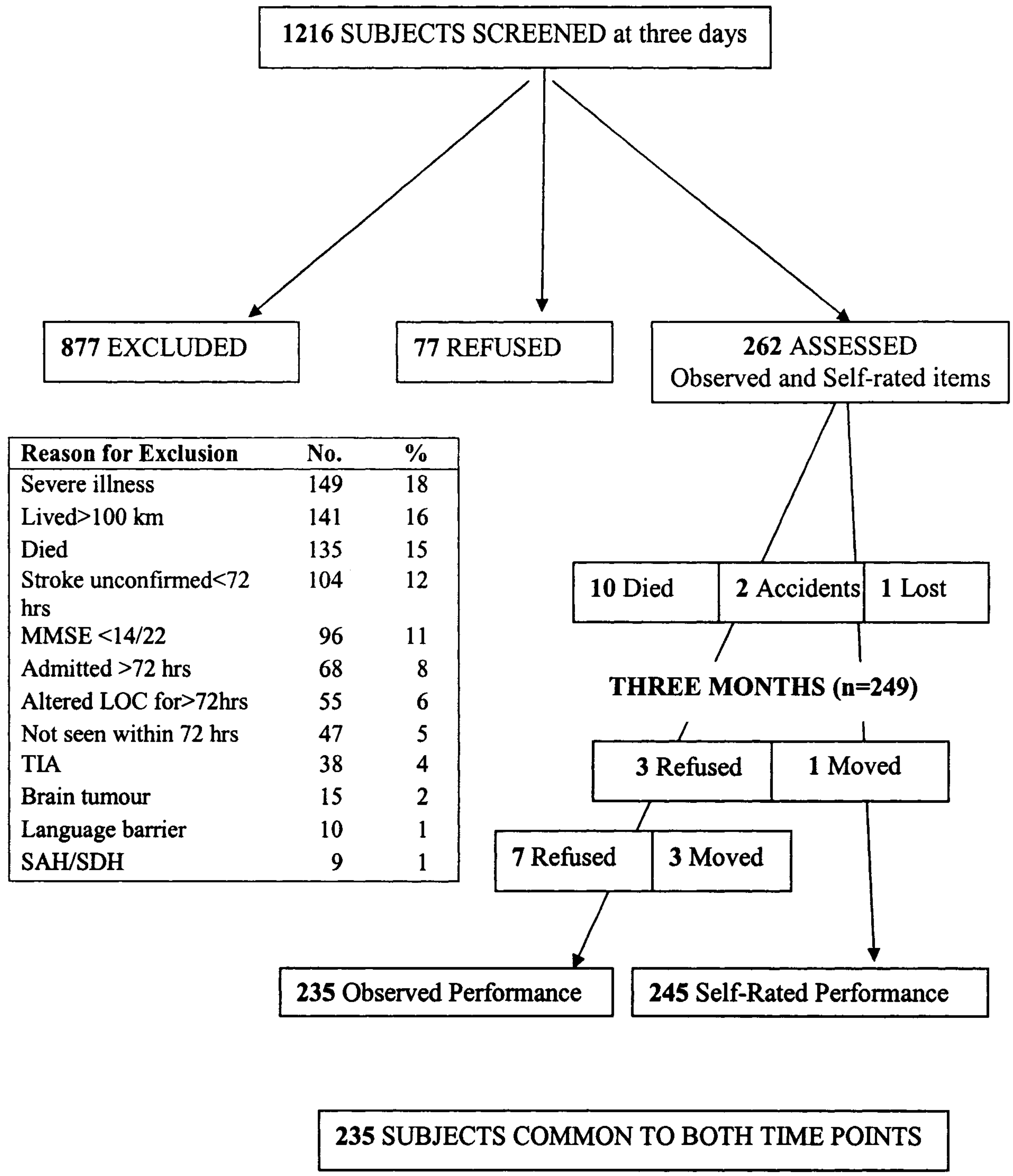
Variable		*Spearman rho (95% CI) or* **Mean ± SD**	
	%	**F3d**	**F3m**
Physiological variables (Counts)			
Low MAP		*-0.09 (-0.22 to 0.03)*	*-0.10 (-0.23 to 0.02)*
MAP <100 mm Hg	84	52.0 ± 20.3	60.0 ± 18.4
High MAP		*-0.08 (-0.21 to 0.04)*	*-0.01 (-0.12 to 0.10)*
MAP >140 mm Hg	13	46.8 ± 22.0	58.1 ± 19.9
Temperature >38° Celsius	8	42.0 ± 22.5 †	54.0 ± 21.1
Temperature <38° Celsius	92	53.5 ± 20.1	61.4 ± 18.1
* Oxygen saturation		*-0.13 (-0.26 to -0.01)*	*-0.20 (-0.32 to -0.08)*
Oxygen saturation> 95%	52	54.5 ± 21.9	62.9 ± 18.3
Oxygen saturation<95% day1	43	50.9 ± 19.0	58.3 ± 18.2
* Oxygen saturation<95% day 2	5	45.8 ± 16.9	49.8 ± 14.5
Hydration	78	52.2 ± 20.3	60.3 ± 18.2
Not hydrated	22	53.7 ± 21.1	62.4 ± 18.4
Ability variables			
* Neglect (Albert's test) §	20	37.2 ± 17.9	47.8 ± 17.8
No Neglect	81	56.5 ± 19.1	64.1 ± 17.0
* Sensation		*0.38 (0.26 to 0.49)*	*0.34 (0.22 to 0.45)*
Normal	44	60.5 ± 18.7	67.5 ± 16.2
Diminished	52	48.2 ± 18.8	56.6 ± 17.9
Absent	4	25.3 ± 18.1	42.9 ± 21.7
* Functioning F3d (0-100)			*0.79 (0.72 to 0.85)*
* Cognition		*0.35 (0.23 to 0.47)*	*0.39 (0.27 to 0.50)*

Abbreviations: DM (Comorbid Diabetes); F3d, (the measure of functioning at three days), F3m, (the measure of functioning at three months); MAP, (mean arterial blood pressure); mmHg, (millimetres of mercury)

*Significant correlations and mean differences at $p<0.03$ or less for the two time points, three months and three days.

† Significant correlations and mean differences at $p<0.03$ or less for one or other of the two time points.

§ N=232 cognitively able to do the test



Reason for Exclusion	**No.**	**%**
Severe illness	149	18
Lived>100 km	141	16
Died	135	15
Stroke unconfirmed<72 hrs	104	12
MMSE <14/22	96	11
Admitted >72 hrs	68	8
Altered LOC for>72hrs	55	6
Not seen within 72 hrs	47	5
TIA	38	4
Brain tumour	15	2
Language barrier	10	1
SAH/SDH	9	1

11 **Figure 6.1 The Screening Process, Participants and Reasons for Exclusion.**

Figure 6.1 Legend: Exclusion table abbreviations: hrs, (hours); km, (kilometer); LOC, (level of consciousness); MMSE, (Mini-Mental State Exam); TIA, (Transient Ischemic attack); SAH, (subarachnoid haemorrhage); SDH,(subdural hematoma).

Chapter 7 Manuscript 5 *Early Predictors of Individual Functioning Three Months Post-Stroke*

Preface to Manuscript 5

This manuscript combines the work to date: (1) the development of global measures that conceptualized defined and quantified functioning in Manuscripts 1 to 3; and (2) the important factors associated with functioning identified in Manuscript 4.

Neural effects and musculoskeletal factors interact in individual stroke survivors in the recovery of functioning. Recovery is influenced by the amount of remaining healthy brain tissue (166), the characteristics of the individual (12) (286), the care received (101) (100), and the initial level of functioning post-stroke (81) (32). To optimize the recovery of functioning is the ultimate goal of rehabilitation. Although studies and reviews have varied, the rehabilitation literature highlights (160) (13) the fact that to improve functioning the earlier an intervention is provided the better the outcome.

Interventions that focused on the early modifiable determinants of functioning might be more beneficial in improving recovery. A study of factors related to functioning may lead to interventions that are more targeted to suit a specific patient's factor profile. Adequate prediction of recovery depends on the definition and quantification of functioning and the variables used to outline the associations. The functioning measure at three months, the F3m, provides the outcome for the objective of this manuscript: to define a set of anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that will predict the extent of an individual's recovery at three months.

The influencing variables were selected based on the literature, (31) (81) (32) (30) their availability within 24 to 72 hours post-stroke and on the strength of their association to functioning in Manuscript 4, Chapter 6. The variables were classified into four groups related to: the person, the stroke event, the process of care and baseline functioning.

If a set of early strong factors could be identified and uniquely linked to the comprehensive F3m measure of functioning, they might prove useful to evaluate and develop more focused early interventions to enhance functioning, to provide a method for the stratification of subjects for research trials and to act as covariates to explain the recovery of functioning.

Multiple linear regression was used to link important factors and functioning with consideration given to the interactions and interrelationships between all the factors. The modeling proceeded in stages to define the best predictive model. The details on the development of this predictive model are in the following manuscript to be submitted to the *Archives of Physical Medicine and Rehabilitation*

Title Page

Title: Early Predictors of Individual Functioning Three Months Post-stroke

For Submission to: *Archives of Physical Medicine and Rehabilitation*

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Keywords: Functioning, Post-stroke, Prediction, Early factors

Abstract

Objectives: To identify parameters measurable at three days post-stroke predictive of the recovery of functioning at three months.

Design: A prognostic study with an inception cohort measured at three days and followed up at three months post-stroke.

Participants: A cohort of 235 subjects hospitalized in a tertiary acute care hospital following an acute stroke.

Main outcome measures: Functioning at three days and three months was measured by new measures, the Functioning measure at three months (F3m) and the Functioning measure at three days (F3d). Both measures were conceptualized using the International Classification of Functioning. Information on variables with prognostic importance related to the person, stroke event, process of care and post-stroke ability was collected within 24-72 hours post-stroke.

Results: The subjects were on average 71.6 (standard deviation: 12.5) years old, and predominately male (62%). Seven characteristics at three days post-stroke predicted 75% of a higher F3m: a higher F3d score, a less severe stroke, a first stroke, higher pre-stroke physical function, absence of pre-stroke diabetes, male sex, and younger age. The most important influential predictor was the F3d, uniquely explaining 26% of the F3m with the largest standardized beta (0.65) coefficient.

Conclusion: A predictive model of functioning with seven variables collected within 72 hours post-stroke explained 75% of the variance in functioning at three months.

Introduction

Functioning has an intensely personal meaning; the loss or recovery of such a broad individual construct can not be easily conceptualized. This has hampered the measurement of recovery. Functioning and its recovery, have neither a precise nor a universally accepted definition. Proposed definitions have varied depending on the level at which recovery was measured: cell, organ, behaviour or satisfaction with a global outcome (293) (175).The most common meaning of recovery is an improvement towards a previous level of functioning. In the present context, using this definition, the extent and course of recovery of physical ability or function post-stroke is markedly individualized with a rapid initial physical improvement that reaches a plateau after three months (34). Recovery occurs even when there is extensive brain damage (60) or if the person is of an advanced age (286). The brain recovers spontaneously through resolution of the secondary effects of stroke, prevention of further neuronal loss, and neural plasticity. That physical functioning recovers suggests that the brain has the capacity to adapt to injury and reorganize (169) (8), but a causal link between the capacity of the brain for reorganization and recovery, as yet, has not been made.

Reducing the impact of stroke by optimizing recovery is the ultimate goal of rehabilitation and, hence, functioning is the outcome of greatest import measured during rehabilitation (31) (30) (76) (56).The rate and extent of the recovery of functioning varies and is influenced by the amount of remaining healthy brain tissue (166), the characteristics of the individual (12) (286), and the care received (101) (100). The most influential factor related to recovery identified, to date, has been the initial level of functioning no matter how or when it has been evaluated (30) (31) (32). This presumably is a proxy measure for the amount of healthy brain tissue remaining after the acute effects of the stroke have waned.

Animal models of stroke (6), theories of brain plasticity and recovery (442) (459), and the rehabilitation literature highlights (160) (13) (167) a common aspect in the quest to improve functioning: the earlier an intervention is provided, the better the outcome. Although when results of studies of early interventions have been summarized the effects are small, but they remain positive. The evidence of the impact of early interventions can be diluted by the manner of care delivered, and the varied types and intensities of therapy compared (126) (144) (129) (146) (147) (142) (15) (80) (125) (141). In some studies, covariates have not been adequately controlled (148) (149), and functioning has been inadequately quantified (13) (12) (129). The effectiveness of early interventions has been tested by comparing groups on the average value of an index of functioning (13) (12) (129) (132) (131), or by categorizing functioning into different levels such as "independent" or "dependent" (68) (12) (57) and examining the proportions of people classified.

A recently developed measure, the F3m, covers the components of functioning outlined by the World Health Organization International Classification of Functioning, Disability and Health, and quantifies functioning with a single total score (24). If a set of early factors could be identified and uniquely linked to this more comprehensive measure, these factors might prove useful in the stratification of subjects to evaluate the efficacy and effectiveness of early interventions, in developing more focused interventions to enhance functioning, and to act as covariates to explain the recovery of functioning.

Objective

The objective of this study was to identify a set of anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that predict the extent of an individual's recovery of functioning at three months.

Methods

Details of the methodology and outcomes for the stroke survivors have been reported elsewhere (Chapters 4-5). Subjects were evaluated within three days of their stroke by observing their performance on tasks and by asking the subjects to rate how difficult it was for them to perform certain activities, such as walking, climbing stairs and bathing (75). Participants were subsequently reassessed at three months on the same tasks complemented by self-report indices gauging their perception of their activities and participation. Information on variables with potential prognostic importance was also collected. The study had ethical approval from McGill University Institutional Review Board and from the Research Ethics committees of all participating hospitals and all participations provided informed consent

Subjects

The subjects were hospitalized from June 2002 to March 2005 following a cerebrovascular accident (33). Patients were excluded if a stroke diagnosis was not confirmed within 24–72 hours. Also excluded were those diagnosed with a transient ischemic attack, those admitted to hospital more than 72 hours after stroke, those with a hemiplegia from non-vascular causes, a subdural hematoma, or subarachnoid hemorrhage, or those with a severe illness and those with severe cognitive or comprehension impairments. For these analyses, only subjects with data from both time points (at three days and at three months) were included.

Measurement

The outcome was functioning at three months, as measured by the Functional Measure at 3- months, the F3m. This measure was developed by combining items on existing functional indices and tests through Rasch analysis. (Details of this were presented in Chapter 4.) Briefly, Rasch analysis is a statistical approach which transforms ordinal observations from items onto an interval scale to produce a unidimensional measure on which items and people are organized hierarchically, by difficulty and ability respectively, on the same measurement scale in natural logarithm linear units or logits (25) (230). A Rasch analysis relates the probability of a person's response to a specific item to the interaction between the amount of functional ability the person has and the level of functioning that item represents (25) (253). This quantifies the amount of recovery a person can achieve based on their position in relation to the item's level of difficulty represented in the measure of functioning.

The International Classification of Functioning, Disability and Health (24) was the conceptual model underlying the F3m and, thus the measure covers a wider range of abilities and levels of functioning than any single index currently employed. Items from self-report questionnaires and items based on observed performance broadens the scope and spread of the measure (293) (288). The F3m includes 44 items: 15 items evaluate movements of the affected arm and nine the affected leg; four items evaluate balance, four self-care activities, 10 items evaluate mobility, and three items are related to participation in life roles. The F3m is scored from 0 to 51, and is internally reliable (0.99). Its validity was judged as excellent based on the fit to the Rasch model and high correlations between the F3m and other indices. The logit scores from the Rasch analysis were linearly transformed to scores ranging from a low of 0 to a high of 100.

Table 7.1 contains the descriptions and scoring options of the items defining the F3m, listed by level of difficulty based on the threshold values for each item's response option. The threshold value is the pivot point in an item's response option where the probability of answering with a higher or lower response is 50%. The different colours in the columns represent a hierarchy of increasing levels of functioning, 20 points apart, from the green representing the highest level of functioning to red the lowest.

The information was collected from the patient's chart, through interviews, and by assessing the subject's performance within 24-72 hours post-stroke. Data abstracted from the chart included variables related to stroke and the organization of services. The influencing variables were selected based on their relationship to functioning in the literature (see Appendix), their availability within 24-72 hours post-stroke and on the strength of their association to functioning at three months estimated in a previous paper (Manuscript 4, Chapter 6.) They were classified into four groups related to; the person, the stroke event, the process of care and baseline functioning and their characteristics are presented in Table 7.2. (Details on the potential predictive variables are in Manuscript 4, Chapter 6.)

Also considered as a predictive variable was baseline functioning at three days, the F3d. The F3d was developed (see Manuscript 3, Chapter 5 for details) in a manner similar to the F3m and has also excellent reliability (0.98) and validity. The F3d is a 38 item measure scored from 0 to 52. The items contained in the F3d are listed in Table 7.1. The logits scores from the Rasch analysis have been linearly transformed to range from a low of 0 to a high of 100.

Analysis

Descriptive statistics were used to characterize the cohort on the F3m outcome measure and all predictor variables and analysis of variance, $\chi 2$ and t-tests were used to contrast participants and non-participants.

Except for the amount of therapy, missing data were less than 5% of the sample; the subjects with missing data were excluded from the analyses. The therapy values, missing for 9% of the sample, were imputed using predictive mean matching with the monotone mean matching method (308) (307).

As the outcome, functioning at three months was measured on a continuous scale; multiple linear regression was used to define the best predictive model. The modeling proceeded in stages. First, the variables characterizing the persons were entered into a regression model followed sequentially by each set of factors outlined in Table 7.2, stroke related factors, process-of-care, and finally the baseline functioning factors

Before the multivariate analysis, a univariate association was estimated between each set of factors and the F3m. The strength of the association between each variable and the F3m was estimated using Spearman's correlation and associated 95% confidence intervals. General linear models with the Tukey post hoc test were used to compare functioning across level of the selected factors.

The significant variables were then entered into four multivariate predictive models one model representing each set of factors. As some of the variables were highly correlated (e.g. amount of therapy and the F3d, rho: 0.61), different combinations of the variables were explored to determine the best fitting model with $p<0.10$ as an initial criteria for keeping the variables in the model. Variables with low prevalence (<5% of the subjects) were eliminated. After the variables for the four models were selected, these variables combined with the significant variables from the univariate analysis were entered into a final functioning model. The best predictive model of functioning at three months combining all significant variables was determined with the variables selected based on the highest adjusted R^2 and Akaike's information criterion statistics. All covariates were checked for collinearity and interaction effects. Significance was set at $p<0.05$ and the analyses were performed using SAS version 9.1 (SAS institute, 100 SAS Campus Dr, Cary NC 27513).

The final regression model was used to predict a value for functioning for each individual at three months on the F3m. Regression estimation lines relating functioning at three days to functioning at three months were drawn for typical persons with stroke.

Results

A total of 1216 patients were screened at three days post-stroke for entry into the study. Of these 262 accepted to participate, 77 refused and 877 were excluded; 89% of eligible participants were reassessed at three months (10 died, 10 refused, 4 moved, 1 was lost to follow up and 2 had accidents). Figure 7.1 illustrates the screening process, participants and reasons for exclusion. Of the 235 evaluated at three months, 89% were assessed within three months ± 10 days, and 11% were evaluated at four months. As there were no differences between persons assessed as scheduled and those assessed later, these data were merged.

Table 7.3 lists the baseline characteristics of the 235 participants common to both time points, assessed within 24 to 72 hours of stroke (mean time to assessment: 71.5 hours; SD: 40.8). The average age of the subjects was 71.6 (SD: 12.5), they were predominately male (62%), and lived at home (94%) with their families (59%) prior to their stroke. Their average level of functioning prior to having a stroke measured on the Physical Functioning scale of the SF-36 (PF, mean: 74.6; SD: 29.4) is comparable to Canadian norms for men aged 65 to 74 (mean: 78.6; SD: 20.5) (265). Seventy nine percent of the subjects had had a first stroke, 86% of the strokes were ischemic in origin, and 41% of the subjects had a moderately severe stroke. Their median hospital length of stay was 11 days (mean: 15.9; SD: 20.9), the majority were discharged to rehabilitation (53%) or to home (39%) and, at the time of the three month interview, 75% were at home and 13% were in long term care. The average early impact of stroke at three days, measured by the F3d, was 52.5 (SD: 20.5; maximum: 100) and the average level of functioning at three months on the F3m, 60.8 (SD: 18.4; maximum: 99.8), was only 8 points above the average F3d score.

Table 7.4 reports the results of the four multiple regression models for the sets of factors associated with functioning post-stroke. All models were adjusted for age and only the variables significant at $p< 0.05$ were kept in each model.

The five-variable, personal factors model explained 25% (R^2=0.25) of the variance in functioning at three months and included: age, income, education level, prior functioning level on the PF, and prior health evaluated with the Charlson Comorbidity Index. In the final model the specific comorbid conditions of the subjects fit the model better than the Charlson index and were easier to determine than the calculation of an index. The conditions, other than comorbid diabetes and prior stroke that were significantly related to functioning in a univariate model, were excluded because of low prevalence (Chronic Heart Failure 5%, Leukemia 0.04%).

The three-variable stroke factors model explained 44% of the variance in functioning at three months and included: stroke severity, presence of neglect, and evidence of white matter disease on imaging. Those with white matter disease were older (mean difference: 6 years; 95% CI: 2.8 to 9.1) than those without white matter disease. A number of post-stroke symptoms significantly related to functioning in the univariate analysis were either collinear with stroke severity or with each other. Of two variables highly related to functioning univariately, admission for a first stroke and the presence of neglect, only neglect was retained as significant in the multivariate model, despite a slight collinearity with stroke severity

The three-variable process-of-care factor model related to functioning at three months explained 35% of the variance and included: the number of medical interventions, the presence of diabetes (as a proxy for glucose control), and the amount of therapy received over the first three days. The control of blood glucose (glucose less than 10mmol/l) was a significant factor, but was confounded by the subjects who had diabetes and poor glucose control. Neither variable, control of glucose nor diabetes was significant when both were entered into the model. As the presence of pre-stroke diabetes is an easier variable to collect than control of blood glucose over 72 hours, diabetes was retained in the model.

The two-variable ability factors model related to functioning explained 68% of the variance and included the F3d and cognition.

Six personal factors, 13 factors related to the stroke, five variables related to process of care and two variables related to the person's baseline functioning along with all previously significant variables were considered for entry into the final model. The best predictive overall model of functioning at three months based on the combination of all relevant variables is given in Table 7.5.

This final seven-factor model related to functioning explained 75% of the variance and included: baseline ability measured with the F3d, stroke severity, admission for a first stroke, prior functioning level, age, gender, and the presence of pre-stroke diabetes. One person with unfavourable levels on these factors, a female, aged 85, with a severe stroke, with pre-stroke diabetes, admitted for a second stroke, with an F3d baseline functioning score of 40, with a PF score of 40, and a Charlson Comorbidity Index greater than three, would be predicted to have a level of function at three months of 15.

The importance of baseline functioning to the prediction of outcome is seen in the amount of variance in the F3m explained by the F3d. The size of the F3d standardized regression beta coefficient reinforces this fact. The F3d accounted for 1/3 of the variance (squared semi-partial correlation of 0.26 with the explained variance of other factors in the model removed) and the F3d standardized beta coefficients had the highest value in the model (see Table 7.5). A comparison of standardized regression coefficients is equivalent to performing a t-test (460).

As the expected improvement in functioning depends on the factor profile of the individual person, estimates of predicted functioning at three months were calculated based on the F3d with scores categorized into 20 point intervals. It is expected that individual subjects will vary about the average line, but be close to the line. The twenty point categories (Table 7.1) were based on what the items in each category represented in relation to actual meaningful functioning. The functioning categories could have been represented by as little as a one point change in the F3m score, or by a specific goal of therapy. Figures 7.2 to 7.5 illustrate the estimated relationships between observed functioning at three days on the F3d and predicted functioning at three months on the F3m according to various factor profiles ± 1 standard error. The relationship between the predicted outcome and the observed baseline score correlated at 0.91 (Spearman's correlation: 95% CI: 0.89 to 0.94). (The figure depicting this relationship is included in the Appendix.)

Figures 7.2 and 7.3 depict the relationships for men separated into age groups from 65 years old and less, in Figure 7.2a, to older than 90, in Figure 7.3b. Figures 7.4 and 7.5 depict the same relationships for women. The horizontal axis represents the observed values on the F3d measure, while the vertical axis represents the predicted values on the F3m. The coloured rectangles along the regression estimation lines correspond to the colours in Table 7.1 and represent at three days and three months a hierarchy of functioning in 20 point increments, from the lowest red level of functioning at the bottom left, to the highest dark green level of functioning at the top right.

Whether the predicted F3m scores, based on the initial observed F3d scores, would increase, remain stable or decrease is depicted by the position and colour of the boxes in the tables and figures. A predicted improvement is indicated by a colour and position change in the figures. Thus, a predicted improvement would be a change from the dark orange box (F3d score 20-40), to the light yellow box above it (F3m score 40-60), or a change from the dark yellow box (F3d score 40-60), to the light lime green box above it (F3m score 60-80). A predicted deterioration is indicated by a colour and position change in the opposite direction, that is, from a dark yellow box (F3d score 40-60), to a light orange box below (F3m score 20-40), or from a dark lime green box, to a light yellow box below. A predicted stable score on the F3d and F3m is represented by the lines in the dark coloured boxes without a position change.

An example of persons predicted to improve follows. Any subject initially in the yellow box, in Table 7.1, or in the figures, with an F3d score of 40-60 would have successfully completed the tasks on the first 14-22 items in Table 7.1. If a subject was predicted to improve to a score of 60-80 on the F3m, s/he would successfully complete the first 30 to 45 item tasks in Table 7.1 on the F3m, and be in the light green box above the yellow box, in Figures 7.2 to 7.5. The improvement would be represented by an increase in functioning from, at three days, being just able to stand and have some arm, hand and leg movement, to being able, at three months, to walk several blocks in the community and move limbs with dexterity. This individual would still be incapable, at 3months, of doing physically demanding tasks or have the motor skills to drive a car.

Any subject in the yellow box, who remained with a score between 40-60 on both the F3d and F3m, would function at a similar level at both times. That is, s/he would be able to walk in the house slowly (item 20, at 3days and items 15, 25, 28, at three months). S/he might be able to perform a few more advanced items at three months, and would rate him/herself able to climb a flight of stairs and take a bath (item 19) without difficulty compared to the ability at three days (item 47). The improvement in functioning, at three months, might result from a behavioural compensation, for example, the use of wall bars to get into and out of the bath. This compensation for the permanent loss of ability, rather than an actual improvement in ability, might explain why the person rated the task with a lower level of difficulty. The lack of a "true" indication of a person's capacity has been a criticism of other measures of functioning such as the Barthel Index (65) (77) (61) (383). The F3m, however, combines capacity or items where performance is observed, and items from questionnaires where the subjects rate their difficulty in performance. Thus, an individual's capacity can be judged by the items in the F3m measure that relate to observed performance, such as items number 20, 21 or 24, in Table 7.1.

The combined effects of the significant factors related to the F3m are illustrated in Figures 7.2-7.5 by the estimated regression lines. There are four graphs in each figure; the lower graphs depict the same information as the ones above, with the coloured rectangles removed, to allow a clearer impression of the relationships between the factors in the estimated regression lines.

The value for prior functioning entered into the regression equation was the mean Canadian, normative, age and gender standardized PF score (265). Low level functioning was defined as two standard deviations below these norms. All regression equations were checked for biological plausibility. As a result, the green lines representing the unique relationship of age to functioning, do not fall below a score of 40; the yellow lines representing low physical functioning do not reach above 80; the red line representing a combined second, severe stroke and diabetes, and the dark red line representing the most unfavourable case, a second stroke, and a severe stroke with a low level of prior functioning, are not seen above 80. It is highly unlikely that a person with a PF score of 20 out of 100, represented by the yellow line, would be able to climb stairs at three months post-stroke, as would be expected of a person on the green line with an F3d score of 80-100.

In the Figures 7.2-7.5, the regression lines are aligned as expected according to the factor profiles, from high to low functioning. The lines progress from higher functioning levels related to single factor profiles in green, to lower functioning levels related to the combined factor profiles in red of diabetes and second stroke, diabetes and a second severe stroke and finally diabetes, a second stroke, a severe stroke, and a low level of prior functioning.

Age as a factor has the least impact on functioning. The order of inverse impact on stroke is diabetes, low functioning, a second stroke and finally a severe stroke.

In the figures 7.2-7.5, estimation lines predictive of improvement are seen in the top lighter coloured boxes. There are more lines reflective of a possible improvement for the men aged 65 and 75 than for women. The number of lines suggestive of improvement, in the top boxes, declined with age. A larger proportion of 65 year old men, with a single risk factor profile, are predicted to improve, in comparison to women with the same profile. The regression lines for 65 year old women resemble those of the 85, or even 90 year old men. The estimation of improved functioning at three months for those with a multiple risk factor profile, no matter what level of functioning they had at three days, is poorer compared to those with a single factor.

An analysis of the standardized residuals of the final model indicated all subjects met the critical values used to indicate model fit; but on further inspection, 6% of subjects had higher (n=9) or lower residuals (n=4) than expected, although remained within the criterion limits. (The criteria are listed in the Appendix.) The subjects with higher than expected residuals had suffered a haemorrhagic stroke and those with lower residuals had unexpected complications during their acute care hospital stay. No significant interactions were found in the model.

Discussion

Seven characteristics known by three days post-stroke were identified as predictors of a higher level of functioning at three months namely: a higher F3d score, a less severe stroke at onset, admission for a first stroke, a higher level of pre-stroke physical function, absence of comorbid diabetes, male sex, and younger age. Not only are the variables plausible, but they are listed as strong predictors throughout the literature (28) (77) (31) (29).

Adequate prediction of an outcome depends on the definition and quantification of that outcome. In recent (452) (30) (14) and previous reviews (28;77;461) (462) of predictive models of functioning post-stroke, the outcome "functioning" has been dichotomized or defined by arbitrary thresholds (337) (80) on various motor impairment or stroke scales (14) (383): the CNS, the Functional Independence Measure (FIM), the Barthel Index (375) (28;77), and the Modified Rankin Scale (MRS) (31) (463), (12) (68). Stroke impacts on more than a single activity or ability at a time; it impacts on all the activities of a person or their functioning (93).

The outcome the F3m, defining functioning for this paper, provides a unique opportunity to discern the relationships between functioning across the components of the ICF (24). Because the F3m measure was developed through a Rasch analysis, the items are arranged hierarchically by difficulty, and the final score provides a transparent indication of the tasks a person can successfully complete, as seen in Table 7.1. For example, a person with a F3m score of 49 would probably be able to open the affected hand, rate him/herself able to walk in the house and climb stairs, (some of the 22 items representing that score). Not only would it be possible to predict a functioning level such as "independent" but the meaning of "functioning independently" would be apparent by the tasks related to the score defining "independent".

Currently, there is no agreed upon method of quantifying improvement in functioning inherent in any indicator of recovery. An attempt at quantifying recovery (175) showed that the range of successful or unsuccessful functioning needed for recovery differed between the indices used and relied on the various cut-points for quantification. The proportion of subjects counted as functioning successfully varied from 57% with the BI as the outcome, to 25% with the global MRS index as the outcome. An increase in functioning measured globally by the MRS does not provide much information, beyond generalities, as to the actual tasks a stroke survivor improved on, whether the person perceives the score as meaningful, or how the score is related to independent functioning.

Another method of defining and quantifying functioning is through an improvement in a score on a specific activity or task (464). The F3m measures more than a specific outcome, such as walking competency, balance or hand dexterity. Clinically relevant specific outcomes can be defined by an F3m score. Because the items are ordered hierarchically by difficulty, it would be possible to prediction a specific functioning outcome relevant to an individual, such as hand dexterity. For example, walking ability with a score of 62 can be defined by items number 32, and 33, that indicate the individual is capable of walking in the community. A score of 48 would indicate the person has a high level of balance ability (item 43), and a score of 73, that the person has a dexterous hand.

The quality and usefulness of a model also depends on the influencing variables. In this paper, they were selected based on reviews of variables predictive of and relevant to functioning post-stroke (31) (452) (30) (14), collectible within 72 hours of stroke onset. The set of variables related to the F3m: age, gender, first stroke, presence of diabetes, severity of stroke, previous level of functioning and baseline functioning, are known to be associated with functioning (28;77;465) (30) (31) (14).

Univariately, a number of variables were significant, but when considered in combinations with others proved no longer significant. The exploratory models based on the factors related to the person, the stroke event, the process of care, and baseline functioning, helped understand the combinations of variables related to functioning post-stroke. Although together the personal factors explained the least amount of functioning, three of them, age, gender and prior functioning, appear in the final model. Personal factors tend to be un-modifiable, but point to areas where additional services could be put in place to augment a person's functioning.

The definition of prior health used in a model can be problematic. Whether a comorbid index or a specific condition should be used is debatable. Diabetes and previous stroke were included as separate indicators of comorbid conditions in our model rather than the Charlson Comorbidity Index. The Charlson Index was developed to predict survival rather than functioning (304), consequently restricting the relationship to functioning post-stroke. Other researchers have included specific conditions rather than an index to adjust for prior health with varying results. Arboix et al.(463) studied 1473 post-stroke subjects and found that congestive heart failure, a previous stroke, and nephropathy were not significant predictors of recovery (MRS <2). A number of prior comorbid conditions in our subjects may already be accounted for in the model through their relationship with age. Pre-stroke levels of functioning and stroke severity have previously been related to pre-morbid health conditions, such as arthritis, genitourinary and heart conditions (77) (466) (286).

Stroke severity was the only stroke factor in the final predictive model. The presence of neglect and the number of medical interventions were confounded by stroke severity, while the presence of white matter disease was related more to age and vascular risk factors than functioning (467) (438). Neglect was measured twice in this study, once during the neurological exam and again using Albert's test; neither variable was retained in the final model. Although neglect has been shown to be a strong predictor of functioning, it has an association with stroke severity (468) (469).

Only the white matter variable seen on the CT scans was related to functioning. This variable appears more reliably on scans within the 72 hours post-stroke in a majority of subjects, but has been shown to be correlated with age (467). The type of stroke, ischemic or haemorrhagic, did not influence functioning. Nevertheless, at three months functioning was overestimated in 4% of the subjects with smaller haemorrhagic strokes and an uneventful hospitalization, compared to the subjects with larger haemorrhages and a complicated hospital stay.

A person's previous level of functioning had a small, but persistent impact on functioning at three months. This is consistent with the literature. Counsell et al. (411) included pre-stroke independence, defined as MRS ≤ 2, as one of six variables in a validated model predicting a functional outcome (alive and MRS ≤ 2) at six months. Although, patient reported outcomes of functioning, the Physical Functioning scale (PF) of the SF-36 for example, are not easily assessed in subjects that are drowsy, cognitively impaired or dysphasic, a proxy version of the index might be useful. Proxy versions of the PF have been found to correlate well enough with the patients' perceptions to be considered adequate for modeling pre-stroke functioning of subjects, but not the post-stroke functioning abilities (470) (471) (472).

The scores used to define levels of prior functioning on the PF of the SF-36 in the regression equations were related to Canadian norms(265) The values are in line with those suggested in the literature (473). Weimar et al. (473) used a single cut point, 60/100 on the PF, to differentiate independent from dependent prior functioning. Dichotomizing the score did not prove adequate to define prior functioning levels in their study. In retrospect, they felt that age and gender standardized PF scores might reflect the level of prior functioning better than a single cut-point. This is especially relevant as these scores differ clinically and significantly across the standardized norms in the elderly (265). The subjects here with a higher PF score were, on average, 10 years younger, mostly male, with fewer comorbid conditions than those with lower scores.

Figures 7.2-7.5 illustrate the dramatic impact of poor prior functioning, on the F3m three months after stroke. Low pre-stroke activity has an impact equivalent to that of having a second stroke or being diabetic. A more active pre-stroke lifestyle is essential to lessen the impact of stroke (427). Walking several blocks a day, climbing a few stairs and carrying groceries seems to have had lasting benefits for subjects in a number of studies (473) (411). The objective of stroke care should be to return patients to their prior level of activity, and to get them to maintain healthier levels. Rehabilitation programs with more intensive training are needed. Presently, the levels of cardiovascular stress needed to induce training are often not provided in rehabilitation sessions (474). An increase in activity is especially important for women and the elderly. On average, these groups tend to have lower levels of prior functioning and would benefit from even small amounts of increased activity (418) (326) (427).

In this study, the inclusion criterion mental competency limited the association between cognition and the F3m, despite the significance of cognition as a variable in previous studies (475) (476). Fewer than 9% of the subjects had a MMSE score less than 13/22, and they were expressively dysphasic.

The relationships between age and functioning are diverse and depend on which function is predicted, at what time point post-stroke function is predicted, and the definition of age used. Being older than 85 was the most relevant age related to a decrease in functioning in this study, as seen in Figures 7.2-7.5.

Despite the advanced age, 85 to 99 years, of 11% of the subjects in this study, only those elderly subjects at three days with the best prior functioning level (those in the top green box) were predicted to have a consistently lower score at three months on the F3m. More elderly men, those in the yellow and orange boxes, were predicted to improve or maintain their three day functioning level at three months more than the most functional ones in the green boxes. One hypothesis to explain this phenomenon may be related to the inactivity experienced by patients during rehabilitation post acute care. Two previous studies stated that subjects in rehabilitation centers only spent 11%-28% of their time in physical and occupational therapy (477) (408). Inactivity may be more detrimental to the more functional elderly than others subjects. Another hypothesis is that the higher functioning elderly may be too depressed or unmotivated post-stroke to participate in therapy (91) (29). Or it may be that the more active elderly take longer to regain their high former levels of activity (286).

The role of gender as a predictive factor in explaining functioning is less clear than age. Some consensus exists for the negative association between women and functioning even when adjusted for stroke severity and age (28) (77) (29)The hypothesized factors responsible for the poorer levels of functioning in women post-stroke are a lack of a support system, (31) a reluctance to demand services (29), and a gender bias in the assessments used (418). The poor variation in the subjects' perception of their support system was probably responsible for the lack of relationship between social support and functioning here. If anything the women tended to have a more favourable perception of their support system than the men. There were no interaction effects found to explain poor functioning in women and the items in the F3m were not found to differ in their performance based on gender (see Chapter 4).

That baseline functioning measured with the F3d was the most important predictor variable of the F3m is not surprising. Baseline functioning has been, and still is, the greatest predictor of function after stroke (28) (29) (77), whether it be at 1-week, 1-month or 1-year post-stroke. The baseline functioning data normally used as early predictors of later functioning are garnered through chart abstraction (30;31) or from the performance on neurological stroke scales, (426) (173) (478) motor impairment scales, (14) and self-care indices such as the BI (28) and the FIM (149) . Each of these indices when used to represent baseline functioning, assess but a single element. The F3d was developed as a comprehensive measure of the early impact of stroke on functioning and can provide estimates of the probability of recovering specific abilities of functional import to an individual. It covers both observed performance on tasks, as well as the person's self-rating of the difficulties encountered in performing activities. It includes all the physical elements necessary for functioning relevant to a stroke survivor during the early period post-stroke, and those needed by health care professionals to plan therapeutic interventions.

The advantage of using the two set of indices for prediction has been demonstrated previously (288) (293) (18). Combining self-report and performance-based indices to study physical functioning status in the elderly improved the prognostic information on mortality and functioning. The indices were not combined into a single measure; the subjects were cross-categorized by the scores on the two indices to improve the definition of functional status (293). A single measure would have made the categorization easier.

Incorporating numerous elements of functioning into one measure may account for the amount of variance the F3d explained at three months. The F3d uniquely explained 26% of the functioning in the F3m measure and was the most influential factor in the model, based on the standardized betas (Table 7.5). Previous preliminary results on the predictive ability of the F3d (see Manuscript 3), reinforce its ability to explain later functioning. The F3d explained 66% of the BI at discharge, adjusted for age, stroke severity and length of stay. The 66% is more than that seen in other models using early baseline predictors (173) (426) that explained 50% of the variance in impairment outcomes. But, the 26% in the F3m explained by the F3d is similar to the variance explained in participation or quality of life indices models by early baseline variables (between 33% (173) and 15% (426)).

There is growing evidence that rehabilitation interventions need to start earlier (160) (6) (13). In recent papers extolling the benefits of the early initiation of rehabilitation, the time delay from stroke onset to admission to rehabilitation varied from a mean of 11.4 days (SD: 12.7) (145) to 13.8 days (SD: 18.7) (144). In this study, the delay between stroke onset and admission to rehabilitation was, on average, 18.4 days (SD: 15.7). If rehabilitation is to start earlier, organized rehabilitation programs for stroke must start in the acute care setting and be more intense (145). The risks and benefits of very early increased levels of the relevant evidence-based therapies (see Table 1.4 in Chapter 1)

(129) (77) (142) (126) have only been examined in a few clinical studies. Few have started within three days (153) (359). To investigate the efficacy of early rehabilitation effects requires an adequate comprehensively defined outcome. The F3m, a continuous, equal interval outcome, could be one. The F3m may improve the ability to detect change compared to the more ordinal outcomes and allow the quantification of recovery based on meaningful scores.

The adequate testing of early interventions also requires a stratification strategy based on early factors related to functioning. Similarity of groups in a randomized control trial of early rehabilitation interventions is essential to define the benefit of any intervention and reduce bias. This can only be achieved if stratification is on a strong prognostic variable such that the balance across groups is equal and large enough to define a statistical and meaningful difference between the interventions. The scores on the F3d may prove useful in stratifying subjects for clinical trials, assist in developing early interventions and/or assist in clinical decision making. The greatest variance in the F3m was explained by the F3d measure even when adjusted for the other covariates in the model- age, gender, stroke severity, pre-stroke diabetes and prior functioning- are all readily and reliably collectible within 24 to 72 hours post-stroke. Additionally, the transparent nature of the F3d and F3m allow for a better understanding of which tasks a person with a certain score is capable of performing.

Another factor with a strong predictive relationship to functioning post-stroke is stroke severity assessed via stroke scales. The function predicted or the predictor variables reflected within these scales is but a single component of functioning. The F3d measures early functioning comprehensively and would make an ideal factor on which to stratify subjects. As it is related to early functioning within three days, it may also represent the measure closest in time to the effects on the brain and its capacity to reorganize.

The relevance of the predictive models and factor profiles based on the F3d scores and related to the F3m is apparent in the previous examples in Table 7.1 and illustrated by Figures 7.2 through 7.5. Targeted therapies could be developed to suit the individual in any strata according to his or her relevant factor profile. A person in the red strata could be considered for more compensatory types of therapy, while an individual in the yellow strata more constraint induced therapies (479), and an individual in the green strata more intensive therapies, possibly on an outpatient basis.

To date, upwards of 50 different variables have been combined in various models to predict a number of outcomes post-stroke. The methodology used has limited their accuracy, and made them difficult to apply in practise. The best models have simple, interpretable and clinically useful variables that can help in set therapeutic goals, stratify for balanced research designs and plan necessary services (28). The F3d fulfills this role.

Limitations

The functioning predictive model is based on a small, but comprehensively measured group of persons affected by stroke representative of a broad spectrum of stroke survivors (except for those with severe cognitive impairments or receptive dysphasia). The sample represents a diverse group at three months living in the community, in nursing homes and in long term care facilities.

The major drawback to this model is the lack of validation. The size of this sample prevented cross validation of the model.

Only a snapshot of the functioning of a group of stroke survivors as a result of usually care is provided; there is no indication of what occurred between three days and three months that could have influenced the level of functioning at three months. There may be variables of clinical significance, after 72 hours, which impact on later functioning, such as: the number of complications, depression, motivation or the withdrawal of support systems. Although these factors would not be available early enough to stratify subjects for early interventions, they would be relevant to later interventions.

The functioning of persons after stroke continues to evolve for upwards of a year (1), but is most pronounced within the first three months (56) (57). Additional indications of functioning, at one and six months post-stroke, could allow for other analytical techniques to assist in defining the trajectories of the recovery of functioning.

The outcome, the F3m, and the major predictor, the F3d, were developed separately. A combined measure might prove beneficial. This would require that the difficulty level of the items remain stable across these two measures. Preliminary indications of stability are seen in Table 7.1. Combining all the items and co-calibrating across both time points into a common pool from which only the necessary items would be drawn should be the objective of future research. A combined measure of functioning across two or more time points might prove to be a better measure for change. However, an objective here was to develop a measure to define early interventions and on which to stratify patients for early research trials: the F3d is such a measure and it can be used to stratify subjects for any early intervention with functioning as an outcome, no matter how functioning is defined.

The goal here was to determine the early indicators, (at three days), of functioning at three months. Strong early acute care indicators are needed to define better, interventions that impact more on earlier functioning and that can act as prognostic stratification factors. The F3d as a strong predictor of functioning at three months is such an indicator.

Functioning as defined by the F3m is based on physical functioning elements only, measured at three months. Consequently, only the early factors related to physical functioning at three months were determined. Additionally, the improvements in functioning post-stroke depend on other facets of human functioning, e.g., motivation, depression and pharmaceutical interventions, factors not dealt with in this model. These factors should be included in future research on the recovery of functioning.

Conclusions

A predictive model of functioning based on seven variables with known relationship to functioning collected within 24 to 72 hours post-stroke explained 75% of the variance in functioning at three months. The most important influential predictor of functioning was the measure of early functioning, the F3d, which can now be used to stratify subjects into homogeneous groups which will facilitate the evaluation of the effects of early interventions, to aid in the development of interventions to enhance function, and to explain the recovery of functioning.

41 7.1 Transformed and Raw Scores for the Functioning measure at three days (F3d) and the Functioning measure at three Months (F3m)

		F3d	F3m		
0-100	0-51	38 Items	44 Items	0-52	0-100
			† Gait speed >1.3 m/s	52	[redacted]
[redacted]	51	Bounce a ball	† Do demanding activities as before	51	[redacted]
[redacted]	50	Tandem Walk for 2 m	Tandem Walk for 2 m	50	[redacted]
[redacted]	49	Trace leg pattern quickly	Bounce a ball	49	[redacted]
[redacted]	48	Walk on toes 2 m	† Able to do activities/ work as before	48	[redacted]
[redacted]	47	Bath independently	Drive a car any where	47	[redacted]
[redacted]	46	†Stand on one foot > 10 s	Quick ankle circumduction	46	[redacted]
[redacted]	45	Heel forward & toe back quick	Trace pattern with leg quickly	45	[redacted]
[redacted]	44	Touch fingertips quickly	Do heavy housework without difficulty	44	[redacted]
[redacted]	43	Walk 50 feet independently	Stand on affected leg for 5s	43	[redacted]
[redacted]	41	† Climb one flight of stairs no difficulty	*Unable to do physically demanding activities	41	[redacted]
[redacted]	42	Quick ankle circumduction	Touch fingertips quickly	42	[redacted]
[redacted]	40	† Walk down 3 stairs normally	Stand with one foot in front 30sec	40	[redacted]
[redacted]	39	Trace pattern with leg	External rotation of the arm	39	[redacted]
[redacted]	38	†Get on & off toilet independently	Clip toe nails without difficulty	38	[redacted]
[redacted]	37	*Stand on foot >5 s	† Walk in the community as need to	37	[redacted]
[redacted]	36	† Walk down 3 stairs with assist	Pour water into a glass	36	[redacted]
[redacted]	35	*Climb one flight of stairs with difficulty	Tap foot quickly	35	[redacted]
[redacted]	34	Personal hygiene independently	Do arms scissors	34	[redacted]
[redacted]	33	Tap foot quickly	Walk several blocks	33	[redacted]
[redacted]	32	Pour water into a glass	† Gait speed >0.8 <1.3 m/s	32	[redacted]
[redacted]	31	*Walk down 3 stairs with deviation	*Unable do activities/ work as before	31	[redacted]
[redacted]	30	Draw an 8 with your arm	Draw an 8 with your arm	30	[redacted]
[redacted]	28	† Reach forward >25 cm	*††Gait speed >0.5 <0.8 m/s	28	56
[redacted]	29	Hand to forehead	Lace shoes without difficulty	29	56
[redacted]	27	Ankle eversion	Fully abduct arm	27	55
[redacted]	26	† Turn look behind & shift weight	Tap finger quickly	26	54
[redacted]	25	† Stand to sit without hands	Walk sideways	25	53
[redacted]	24	Fully abduct arm	Hip flexion & knee extension	24	51
[redacted]	23	†No difficulty standing	Turn a doorknob without difficulty	23	50

Table 7.1 continued Transformed and Raw Scores for the F3d and the F3m

		F3d	F3m		
0-100	0-51	38 Items	44 Items	0-52	0-100
57	22	*Reach forward =12 cm	Climb one flight of stairs	22	49
57	21	*Turn to look behind turn only	Finger extension & abduction	21	48
56	20	*Walk 50 feet with assistance	Flex arm 90 supinate & pronate	20	44
53	19	*Get on & off toilet with help	Bathe without difficulty	19	44
52	18	*Some difficulty standing	Lift foot off floor quickly in sitting	18	44
49	17	Oppose little finger and thumb	*Get to the toilet on time without difficulty	17	43
45	16	Toe ext & ankle plantarflexion	Oppose little finger and thumb	16	41
44	15	† Stand to sit with hands	*Walk in the house	15	[redacted]
41	14	† Fully put hand on sacrum	Dress top half of body	14	
[redacted]	13	*Stand to sit uncontrolled	Open hand from closed	13	
	12	Dynamic righting feet on floor	† Full knee flexion	12	
	11	Finger flexion & extension	*Toilet on time with some difficulty	11	
	10	*Partially put hand on sacrum	† Full hip flexion lying	10	
	9	Ankle inversion	Ankle inversion	9	
	8	† Full knee extension	Bridge	8	
	7	Bridge	*Partial knee flexion	7	
	6	Finger/wrist flex >1/2 range	Finger/wrist flex >1/2 range	6	
	5	Touch opposite knee	Log roll	5	
	4	*Partial knee extension in sitting	Dorsiflexion of foot	4	
	3	Facilitate finger flexion	*Partial hip flexion lying	3	
	2	Resist Trunk rotation	Sit unsupported	2	
	1	Facilitate hip flexion	Facilitate finger flexion	1	
	0			0	

Abbreviations: F3d, (the functioning measure at three days measure); F3m, (the functioning measure at three months); m, (meter); m/sec, (meters per second).

The scores have been linearly transformed from the original logits to a scale ranging from 0 to 100 for comparison.

The items have been placed by level of difficulty from top to bottom by the threshold values for each response option.

The different colours in the outside columns for each measure represent increasing categories of difficulty 20 points apart and correspond to the colours in Figures 7.2 to 7.5. The inner columns represent the actual item scores and item names. The highest category of functioning is coloured green and the lowest red. The inner columns represent the actual item scoring options and names. Shaded items represent self rating of performance items; unshaded items represent items where actual performance is observed and rated.

* Items with more than one response option, the first response option.

† Items with more than one response option, subsequent response options.

††Walking speed in meters per second per category: 0:0-0.5; 1:0.6-0.8; 2:0.9-1.3; 3: >1.3.

42 **7.2 Potential influencing Factors collected within 24-72 hours**

CONSTRUCT		VARIABLE	INDEX USED	ADJUST- MENT VARIABLES
Personal factors	Health Status	Accident, level of health	Questionnaire, Sf-36 Q2 (292) Co-morbidity index*	Risk factors (smoking, drinking)
	Social Support	Social network	OARS-Social Q3,6,9 (277;278) (279)	Gender, Finance
	Prior Function		SF-36 PF (292)	
	Participation experience and skills	Type and level of work, sports, hobbies	Questionnaire	Education
Stroke factors	Symptoms, Neuro signs,	Symptoms of stroke, orientation, consciousness, weakness	CNS(250), & standardized data collection form with variables marked as present or absent	
	Lesion description	Size, Site, Side, Atrophy, # of lesions, Swelling, first stroke	Standardized form for CT/MRI Imaging (395)	Stroke type: ischemic or hemorrhagic
Provision-of-care factors	Stroke intervention	Medical, Surgical	Standardized form: #,	
	PT; OT	Number of days and hours of therapy	Departmental Statistics	
	Expertise of care	Location, Approach, Complications	Standardized chart audit abstraction instrument (396) (397)	
	Physiological factors	Hydration	# with IV	
		Glucose level	# with glucose >10 mmol/l	
		Temperature	# >38 ° C	
		Oxygen saturation	# saturation <95%	
		Mean arterial blood pressure (MAP)	# with MAP <100; or MAP>220	
Ability	Clinical abilities	Self-care, mobility, neglect, sensation, impact of stroke, motor control, balance, cognition	F3d (Manuscript 4), MMSE, (305) (306) Fugl-Meyer sensation (46)	Memory, orientation, language comprehension

Abbreviations: CNS, (Canadian Neurological Stroke scale); OARS, (Older Americans Resources and Services Questionnaire); MMSE, (Mini Mental State Exam); OT, (occupational therapy); PF,(physical function scale of the SF-36); PT, (physical therapy); SF-36, (Medical Outcomes Trust Short Form-36 questionnaire); #, (number).

*Charlson Comorbid Index

43 7.3 Baseline Characteristics of the Participants

Characteristic	Participants (n=235)
Age at stroke onset (years) Mean ± SD	71.6 ± 12.5
64>/ 65-74 / 75-84 / ≥85 (%)	29 / 25 / 35 / 11
Men/ Women (%)	62 / 38
Level of Education Finished (%)	
None/ Grade school / High school / College	18 / 39 / 14 / 29
Living where pre-stroke† (%)	
Home/ Residence /Other	94 / 5 /1
Living with who pre-stroke† (%)	
Family/ Alone / Other	59 / 34 /6
Living where three months post-stroke (%)	
Home/ Rehabilitation / Residence/ LTC	75 / 9 / 2 /13
***Finances** (%)	
Ample/ sufficient / insufficient	53 / 42/ 5
Discharge Destination (%)	
Rehabilitation / Home / Transferred / LTC/ Died	53 / 39 / 2 / 6 / 0
Ischemic/Hemorrhagic/Other (%)	86 / 14 /<.1
First stroke (%)	79
Length of stay in acute care (days) Mean ± SD	15.9 ± 20.9
† †**Stroke severity score at admission**	
CNS Mean ± SD	8.2 ± 2.6
Very Mild / Mild / Moderate / Severe (%)	18 / 22 / 41 /19
Charlson Comorbidity Index (%)	
0 / 1 / 2, 3 / >3	30 / 28 / 31 /11
Pre-Stroke Physical Functioning† (SF-36, PF: 0-100)	
Mean ± SD	74.6 ± 29.4
F3d (F3d:0-100) Mean ± SD	52.5 ± 20.5
F3m (F-3m:0-100) Mean ± SD	60.8 ± 18.4

*Finances categorized as the amount of money left over at the end of the month: more than enough (ample), enough (sufficient), or not enough to make ends met (insufficient).

Abbreviations: F3d, (the measure of functioning at three days); F3m, (the measure of functioning at three months); N/A, (not available); SD, (standard deviation); BI, (Barthel Index, basic activities of daily living); LTC, (Long term care); Sf-36 PF, (Medical Outcome Study (MOS) 36-Item Short Form Health Survey (SF-36), the physical functioning scale (PF) (292)); †CNS, (Canadian Neurological Stroke scale); ††Best score: 11.5; with: Very Mild: ≥11.0; 9.5 ≥Mild <11; 5 ≤Moderate <9.5; Severe: <5,

* Significantly different; p<.01

†Pre-stroke for all variables prior to stroke is based on information one month prior to stoke

44 **Table 7.4 Best Predictive Factor Models for Functioning At Three Months Post Stroke**

Models	Parameter estimate	95% CI for parameter estimate	R^2
Personal factors and Functioning			0.25
Level of education (college or not)	1.9	0.04 to 3.8	
PF score for the month prior (0-100)	0.15	0.08 to 0.23	
Age (y)	-0.35	-0.54 to -0.17	
Charlson comorbid index >3	-10.84	-17.70 to -4.00	
*Monthly income inadequate	-14.80	-24.60 to -5.00	
Intercept	73.8	57.2 to 90.3	
Stroke factors and Functioning (with age)			0.45
†Severe Stroke	-25.40	-30.10 to -20.70	
Presence of white matter disease	-5.25	-9.00 to - 1.55	
Presence of Neglect	-7.53	-12.93 to - 2.14	
Intercept	100.3	89.8 to 110. 85	
Process of care factors and Functioning (with age)			0.35
Amount of therapy (hours/day)	29.7	21.8 to 37.5	
More than 2 medical interventions	-6.95	-12.6 to -1.3	
Not Diabetic	4.5	0.07 to 9.0	
Intercept	76.4	64.1 to 88.6	
Ability factors and Functioning (with age)			0.68
F3d (0-100)	0.67	0.60 to 0.74	
Cognition (MMSE)	0.57	0.15 to 1.0	
Intercept	33.4	21.5 to 45.4	

Abbreviations: CI, (Confidence Interval); F3d, (Functioning measure at three days); MMSE, (Mini Mental State Exam); PF, (Physical Functioning Index of the SF-36). R^2 the proportion of the variability in functioning explained by the model.

* Finances categorized as the amount of money left over at the end of the month: more than enough (ample), enough (sufficient), or not enough to make ends meet (insufficient).

† Stroke severity categorized with Canadian Neurological Stroke scale (CNS); Best score: 11.5; with: Very Mild: ≥ 11.0; $9.5 \leq$ Mild < 11; $5 \leq$ Moderate < 9.5; and Severe < 5.

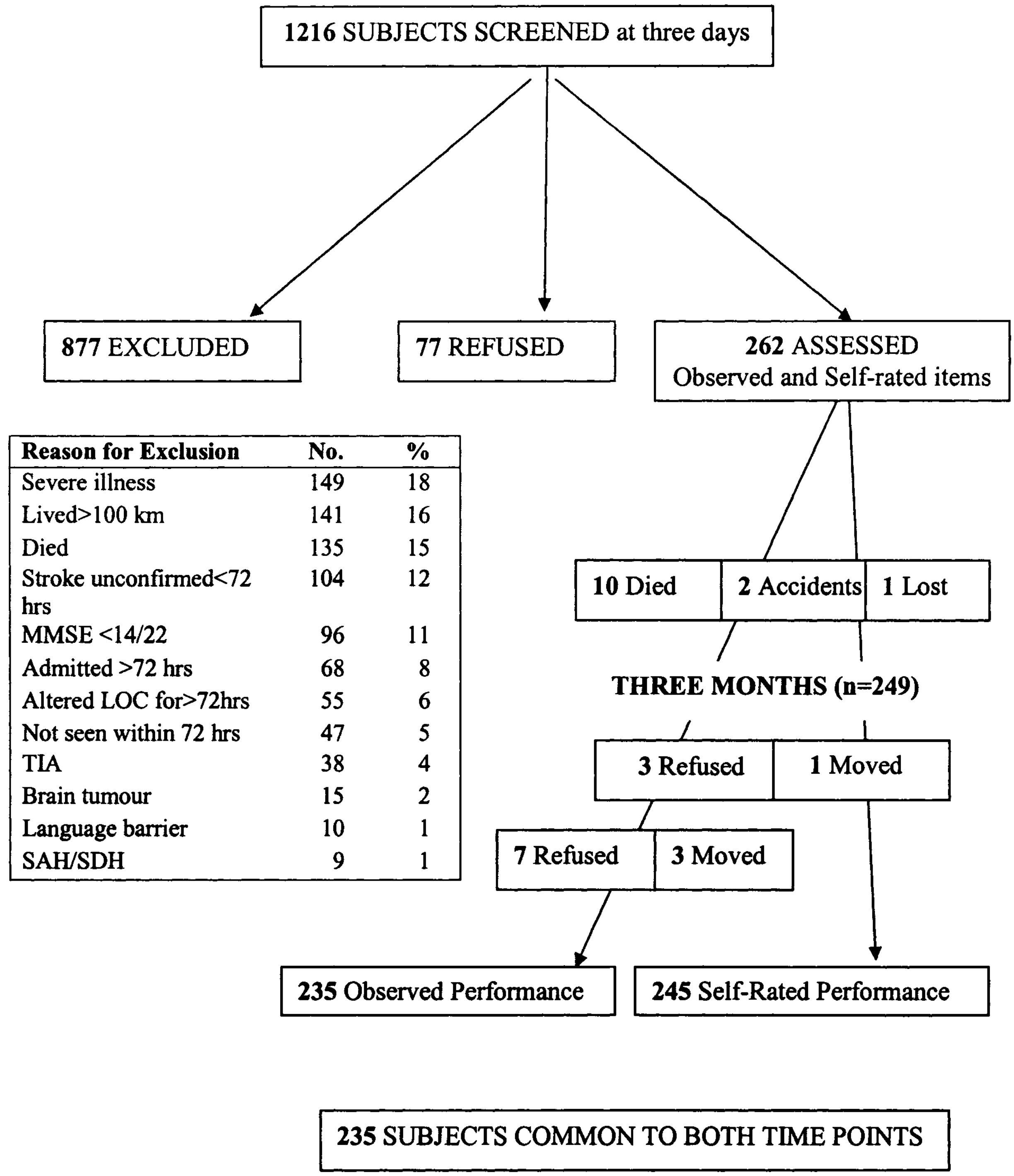
45 **Table 7.5 Best Predictive Models for Functioning At Three Months Post Stroke**

Models	Parameter estimate	95% CI for parameter estimate	R^2
Functioning at Three Months			0.75
F3d (0-100)	0.59 (0.65)[†]	0.51 to 0.66	
Severe Stroke *	-8.05	-11.88 to -4.15	
Admission for first stroke	-5.77	-8.80 to -2.74	
PF score for the month prior (0-100)	0.09 (0.15)[†]	0.05 to 0.14	
Not Diabetic	3.03	0.20 to 5.90	
Gender (male = 0)	-3.3	-6.00 to 0.62	
Age (y)	-0.20 (-0.13)[†]	-0.30 to -0.09	
Intercept	32.9	22.0 to 43.8	

Abbreviations: CI (Confidence Interval), F3d (early impact of stroke on functioning measure), PF (Physical Functioning Index of the SF-36). R^2 the proportion of the variability in functioning explained by the model.

Stroke severity categorized with Canadian Neurological Scale (CNS); Best score: 11.5; with: Very Mild: $\geq$11.0; 9.5 $\leq$Mild <11; 5 $\leq$Moderate <9.5; and Severe <5.

[†]standardized β s (460)



Reason for Exclusion	No.	%
Severe illness	149	18
Lived>100 km	141	16
Died	135	15
Stroke unconfirmed<72 hrs	104	12
MMSE <14/22	96	11
Admitted >72 hrs	68	8
Altered LOC for>72hrs	55	6
Not seen within 72 hrs	47	5
TIA	38	4
Brain tumour	15	2
Language barrier	10	1
SAH/SDH	9	1

12 **Figure 7.1 The Screening Process, Participants and Reasons for Exclusion.**

Figure 7.1 Legend: Exclusion Table abbreviations: hrs, (hours); km, (kilo meter); LOC, (level of consciousness); MMSE, (Mini-Mental State Exam); TIA, (Transient Ischemic attack); SAH,(subarachnoid haemorrhage); SDH,(subdural hematoma).

13 Figure 7.2 a-d Regression Estimation Lines Relating Functioning at Three Days (F3d) to Functioning at Three Months (F3m) for Men Aged 65 (7.2a,c) and 75 (7.2b,d) According to Factor Profiles ± 1 Standard Error

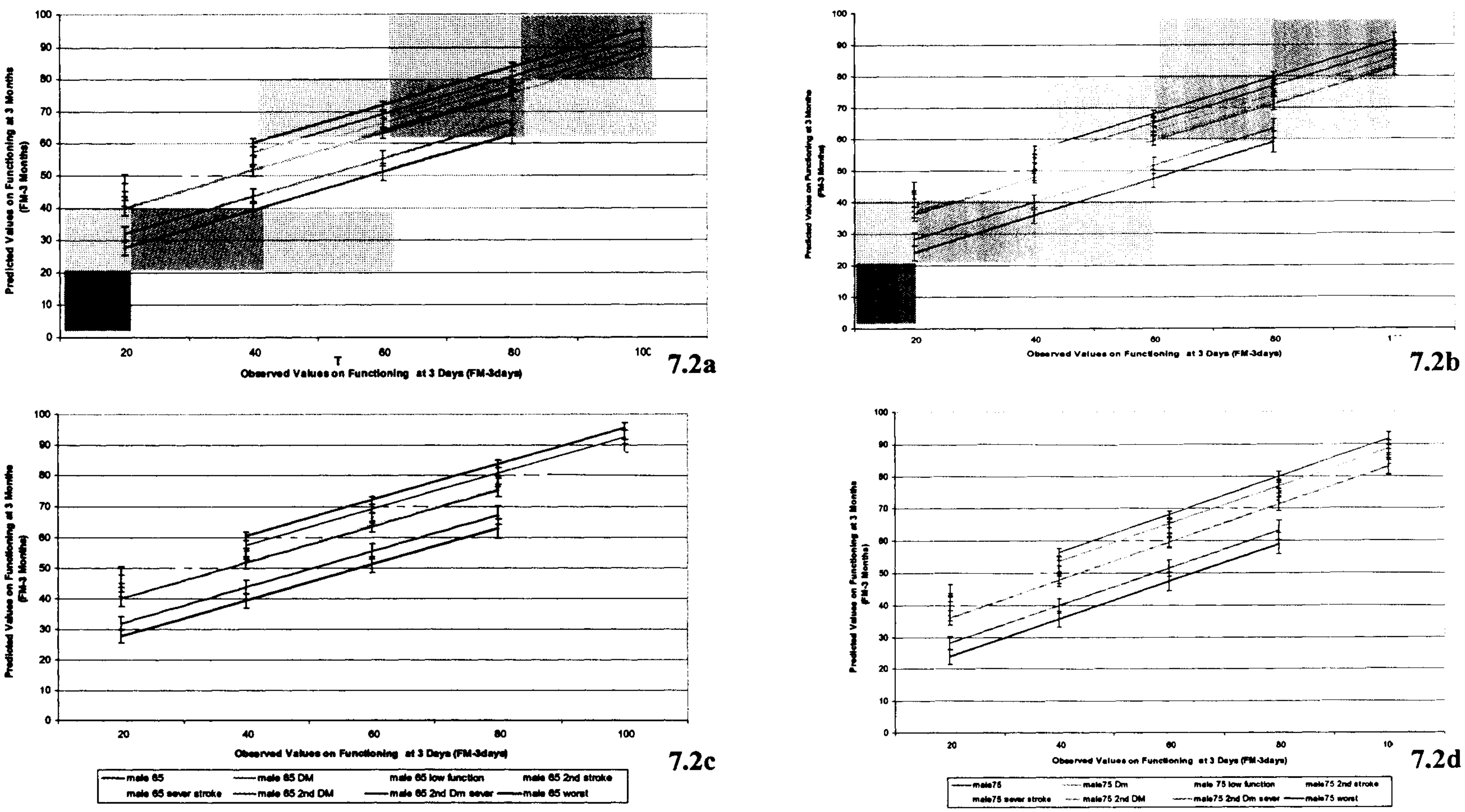


Figure 7.2 Legend. The lines in each figure represent the estimated regression lines based on the factor profiles. The horizontal axis represents the observed values on the F3d measure; the vertical axis represents the predicted values on the F3m. The coloured rectangles along the regression estimation lines correspond to the colours in Table 7.1 and represent at three days and three months a hierarchy of functioning in 20 point increments, from the lowest red level of functioning at the bottom left, to the highest dark green level of functioning at the top right. The lower Figures 7.2c and 7.2d depict the same information as the Figure immediately above it (7.2a and 7.2b), but with the coloured rectangles removed.

14 **Figure 7.3 a-d Regression Estimation Lines Relating Functioning at Three Days (F3d) to Functioning at Three Months (F3m) for Men Aged 85 (7.2a,c) and 90 (7.2b,d) According to Factor Profiles ± 1 Standard Error**

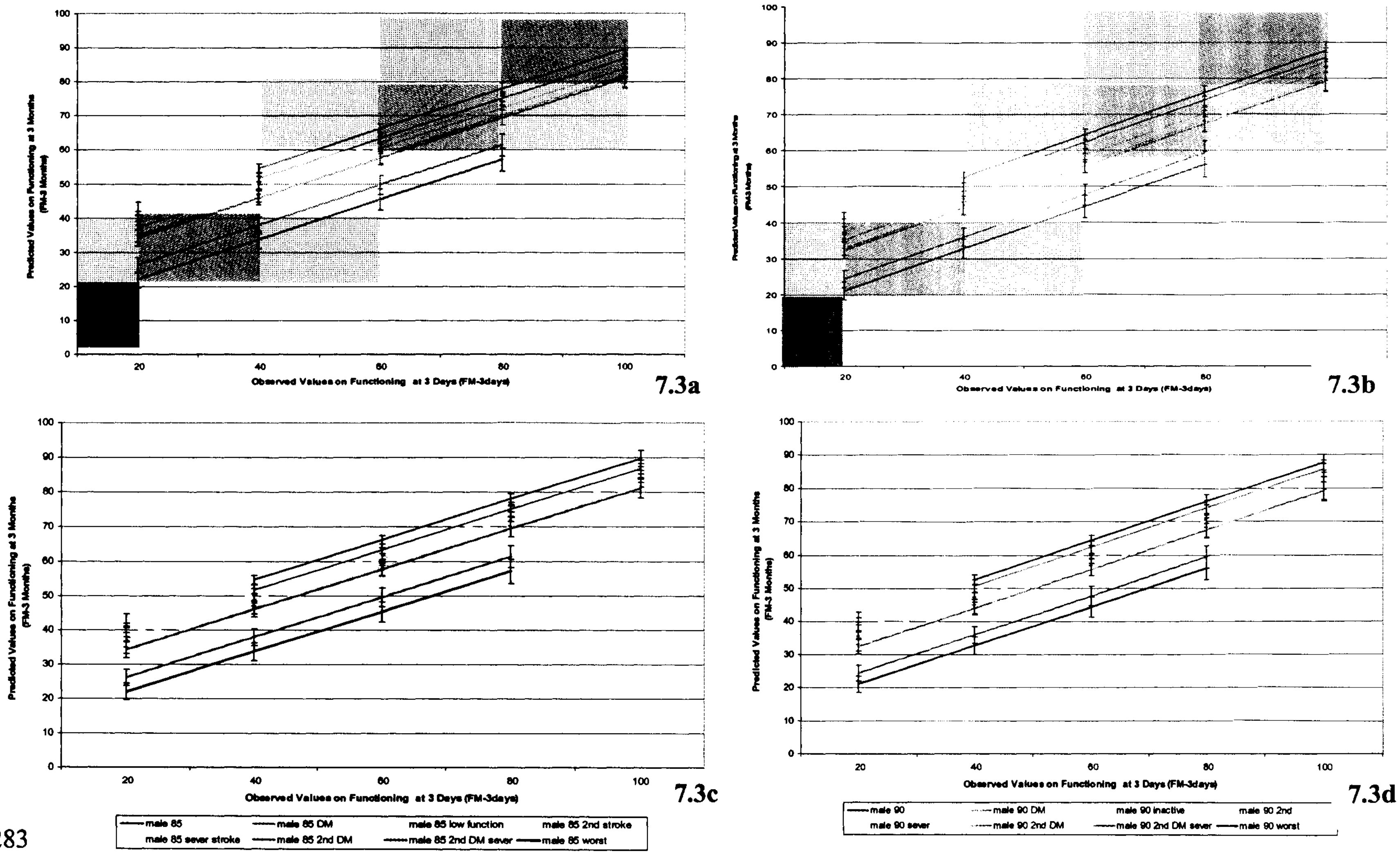


Figure 7.3 Legend. The lines in each figure represent the estimated regression lines based on the factor profiles. The horizontal axis represents the observed values on the F3d measure; the vertical axis represents the predicted values on the F3m. The coloured rectangles along the regression estimation lines correspond to the colours in Table 7.1 and represent at three days and three months a hierarchy of functioning in 20 point increments, from the lowest red level of functioning at the bottom left, to the highest dark green level of functioning at the top right. The lower Figures 7.3c and 7.3d depict the same information as the Figure immediately above it (7.3a and 7.3b), but with the coloured rectangles removed.

15 Figure 7.4 a-d Regression Estimation Lines Relating Functioning at Three Days (F3d) to Functioning at Three Months (F3m) for Women Aged 65 (7.3a,c) and 75 (7.3b,d) According to Factor Profiles ± 1 Standard Error

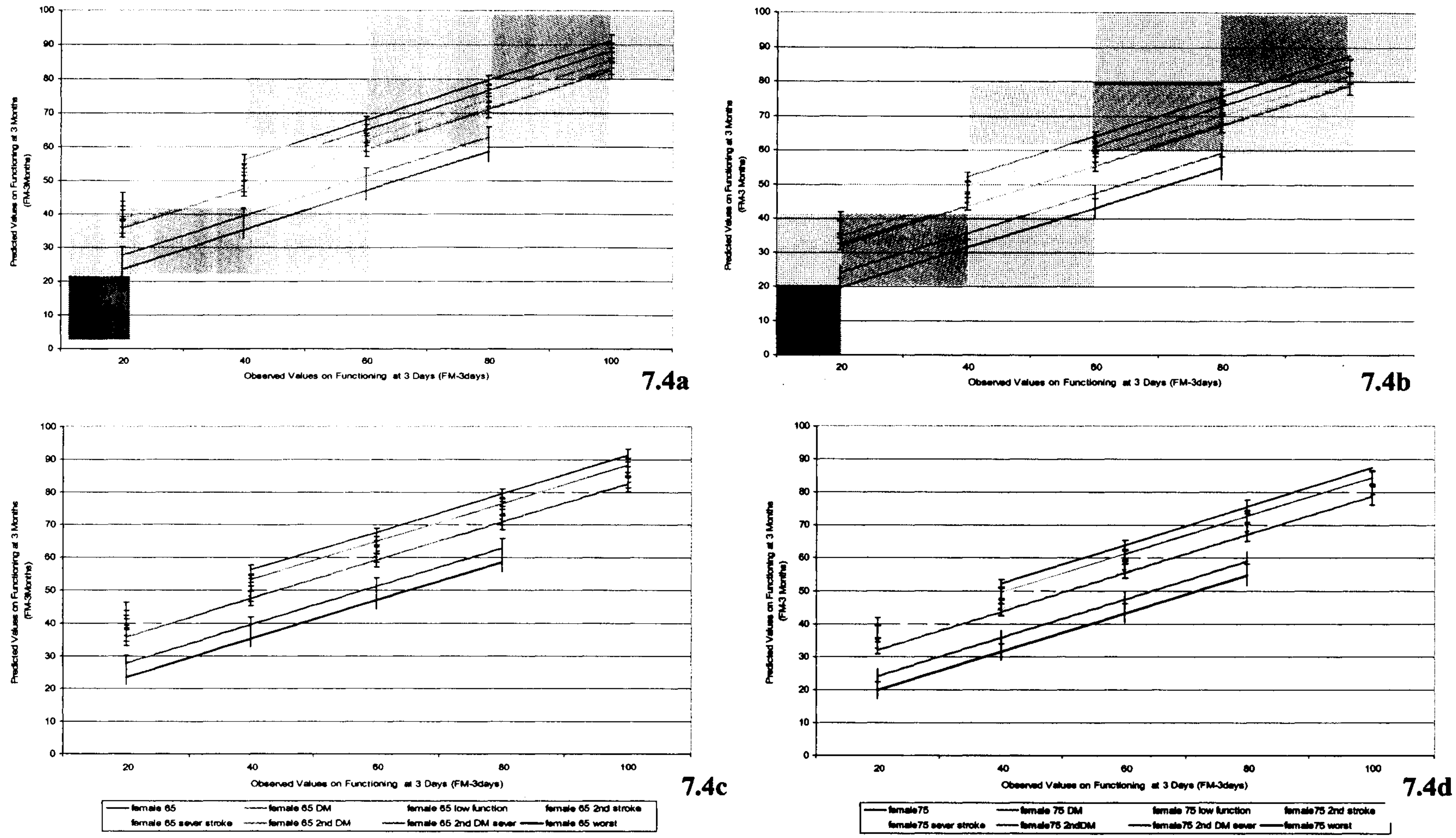


Figure 7.4 Legend. The lines in each figure represent the estimated regression lines based on the factor profiles. The horizontal axis represents the observed values on the F3d measure; the vertical axis represents the predicted values on the F3m. The coloured rectangles along the regression estimation lines correspond to the colours in Table 7.1 and represent at three days and three months a hierarchy of functioning in 20 point increments, from the lowest red level of functioning at the bottom left, to the highest dark green level of functioning at the top right. The lower Figures 7.4c and 7.4d depict the same information as the Figure immediately above it (7.4a and 7.4b), but with the coloured rectangles removed.

16 Figure 7.5 a-d Regression Estimation Lines Relating Functioning at Three Days (F3d) to Functioning at Three Months (F3m) for Women Aged 85 (7.4a,c) and 90 (7.4b,d) According to Factor Profiles ± 1 Standard Error

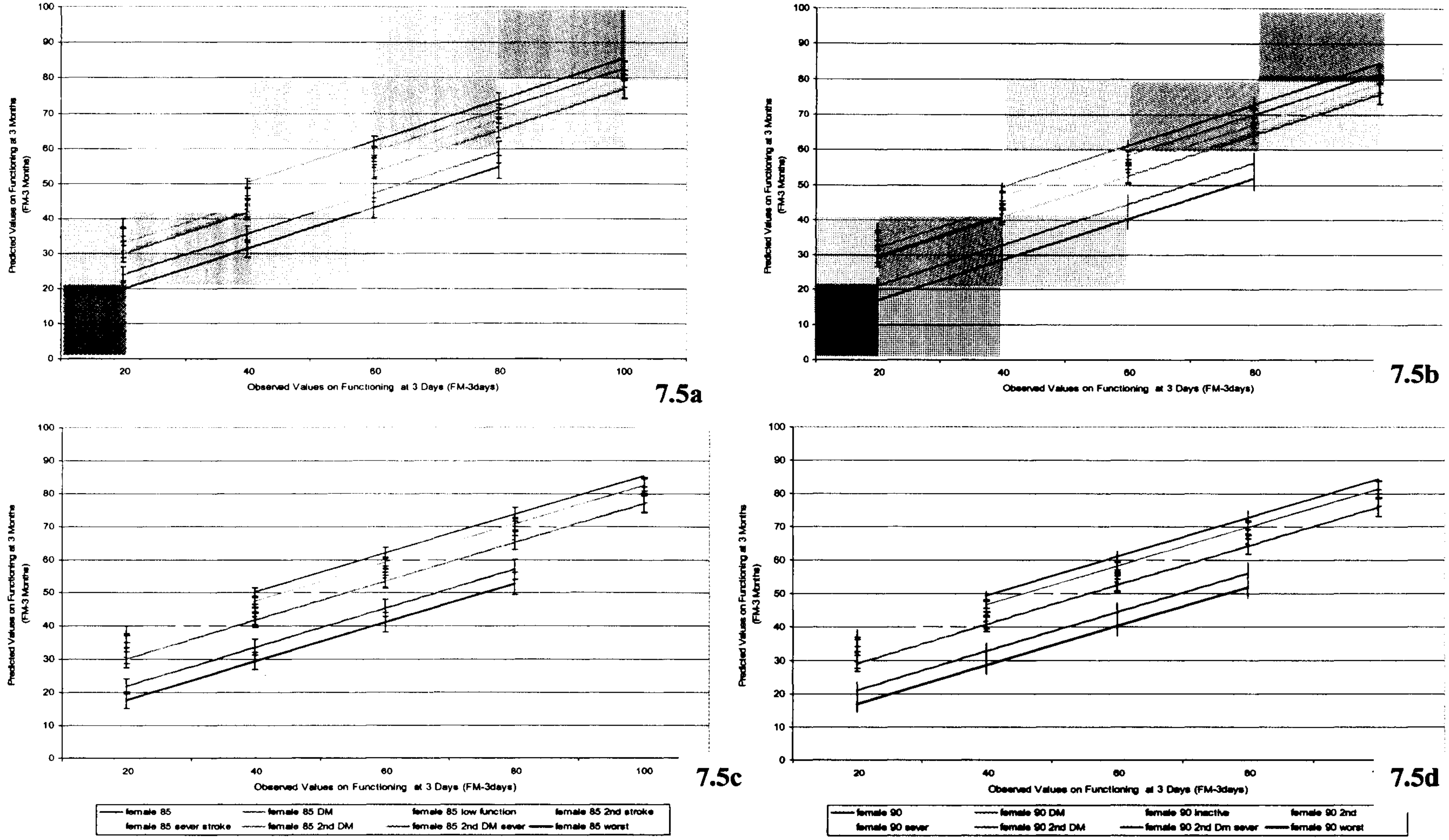


Figure 7.5 Legend. The lines in each figure represent the estimated regression lines based on the factor profiles. The horizontal axis represents the observed values on the F3d measure; the vertical axis represents the predicted values on the F3m. The coloured rectangles along the regression estimation lines correspond to the colours in Table 7.1 and represent at three days and three months a hierarchy of functioning in 20 point increments, from the lowest red level of functioning at the bottom left, to the highest dark green level of functioning at the top right. The lower Figures 7.5c and 7.5d depict the same information as the Figure immediately above it (7.5a and 7.5b), but with the coloured rectangles removed.

Chapter 8 Summary and Conclusion

Summary

The overall objective of the thesis was to identify a set of anatomical, physiological, clinical and behavioural parameters measurable at three days post-stroke that could predict the extent of an individual's recovery of functioning at three months. A longitudinal prognostic study of 262 patients admitted to an acute hospital following a cerebrovascular accident and followed up at three months was undertaken. Two measures of functioning were defined using Rasch analysis, one at three days, the Functioning measure at three days, the F3d, and one at three months, the Functioning measure at three months, the F3m. An additional prototype measure was also developed. The prototype measure was validated qualitatively via expert opinion, and quantitatively with factor analysis and Rasch analysis on a representative sample from a number of clinical sites. It forms the basis of a measure of functioning at six months that combined activity and participation indices, an essential component of the ICF. These measures represent functioning as conceptualized by the International Classification of Functioning, Disability and Health (24).

The F3m includes 44 items, scored from 0 to 51, that evaluate movement of the affected arm, and of the affected leg, balance, self-care activities, mobility, and participation in life roles. It is internal consistent with a reliability coefficient of 0.99 and valid as judged by the fit to the Rasch model and high correlations between other indices. The person and items aligned on a single measure with a sufficient total score allows for the quantification of a person in terms of their functioning, given their total score. It has the capacity to assist in directing and assessing therapeutic interventions and defining the services needed to meet the needs of stroke survivors three months post-stroke.

The acute F3d, a 38-item measure, scored from 0 to 52, measures the physical impact of acute stroke on early functioning. The F3d was also developed through a Rasch analysis and has excellent internal reliability (0.98) and validity. The F3d expands the range of assessment in acute stroke by including observational tasks and self-rating of performance items and covers a broad spectrum of difficulty. The F3d does not demonstrate floor or ceiling effects, discriminates across three levels of stroke severity and shows good predictive qualities.

The heterogeneous impact of stroke on an individual requires the understanding of all the factors related to functioning. The two measures, the F3d and the F3m, and variables with a known relationship to functioning collected within 24 to 72 hours post-stroke were used to define a predictive model of functioning that explained 75% of the variance in functioning at three months. The model included the following variables: baseline functioning, age, gender, presence of pre-morbid diabetes, admission for a first or subsequent stroke, stroke severity and prior physical functioning level, the most important influential predictor of functioning was the F3d.

Conclusions

This thesis produced measures of functioning and linked them to prognostic factors.

The first measure developed was a 12-item prototype measure of functioning that, after further validation, can be used to quantify recovery six months post-stroke. To fully conceptualize functioning the impairment component of the ICF should be incorporated and by not including it, this prototype measure was limited in scope.

The second measure progressed from the first, the Functioning measure at three months, the F3m, and covers all the components of the ICF. The F3m has the capacity to assist in directing and assessing therapeutic interventions and defining the services needed to meet the needs of stroke survivors three months post-stroke.

The final measure, the Functioning measure at three days, the F3d, measures the impact of stroke on early functioning. The F3d has good psychometric properties and is the first comprehensive measure of early functioning. The hierarchy of the items in the F3d could aid in understanding the process of recovery of early functioning, what is needed to successfully complete each stage in the recovery process and assist in the development of treatment plans.

Of the multiple factors evaluated that were related to both the F3d and the F3m, 18 were univariately associated with functioning at both times. All but one was associated with the process of care reinforcing the necessity of good early clinical care.

A predictive model of functioning with seven variables related to functioning collected within 72 hours post-stroke explained 75% of the variance in functioning at three months. The most important influential predictor was the measure of early functioning, the F3d. The F3d can now be used to stratify subjects into homogeneous groups which will facilitate the evaluation of the effects of early interventions, to aid in the development of interventions to enhance function, and to explain the recovery of functioning.

Future Work

This thesis has set the stage for future research into the quantification of and treatment of early functioning. The F3d and the F3m measures point the way for a more efficient method of assessing patients, but they require refinement. The internal consistency and separation indices for the measures are excellent, which suggest that the psychometric properties of reliability and responsiveness will be adequate. Nevertheless, a confirmation of the changes in rating scale efficiency, test retest reliability and sensitivity to change are required. Whether a better picture of the difficulties encountered in post-stroke functioning could be improved by the addition of harder IADL and participation self-report items at three months should be tested. Additionally, an objective of future research should be to assess whether combining all the items and co-calibrating them across all time points into a common pool should be tested. The predictive model requires validation in a separate sample of stroke survivors.

Finally, once refined, the Functioning measure at three days, the F3d, should be used to stratify subjects. This would facilitate designing a randomized trial of early interventions.

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Appendix Table A1 Definitions for Recovery Used By the Health Care Professionals

The Extent of Recovery		Definitions with Examples
Normal	*Definition* for selection of items	Performance of a variety of complex activities has been regained with due regard for age related factors such as, timing, coordination, strength and endurance
	Example subjects must perform all functions	**MOS SF-36** (292)not limited in walking one kilometer *and* not limited in climbing one flight of stairs **Stroke Impact Scale (SIS)** (209)no difficulty in remembering
Near Normal	*Definition*	A partial return of ability with a change in strategy or performance of that ability
	Example	**OARS-IADL**(279): preparing meals with some help **SIS:** climbing a few stairs with a little difficulty and getting in and out of a car with a little difficulty
Compensation	*Definition*	An adaptation to a permanent loss of ability. A new behavior develops to compensate for the lost one, for example switching writing ability from the right hand to the left, or reading by Braille rather than by eye (188) (189) (480)
	Example:	**Balance Scale** (334): require assistance to move from sitting to standing **Barthel** (211): eating with assistance
Minimal	*Definition*	None provided generated by the therapists
	Example	**Balance Scale:** can only stand for 3 seconds **RNL**(84): I do not move around my living quarters as I feel necessary

Appendix Table A2 The Item Pool for the Functioning Measure at three Months (F3m)

Index	Items (89)	Difficulty	SE	Fit- resid	χ^2	F-stat
CMSA	Facilitate hip flexion	-5.30	0.62	-0.06	0.54	0.14
CMSA	Resistance to trunk rotation	-4.79	0.54	-0.18	0.26	0.18
CMSA	Facilitate finger flexion	-4.65	0.52	-0.36	0.47	0.34
CMSA	Hip abduction: adduction to neutral	-4.49	0.50	-0.23	0.26	0.34
BS	Sitting unsupported	-4.20	0.47	-0.44	0.67	0.55
CMSA	Facilitate dorsiflexion or toe extension	-4.15	0.46	-0.15	2.32	0.05
CMSA	Facilitate finger flexion	-3.40	0.39	-0.38	0.89	1.06
CMSA	Facilitate log roll to side lying	-3.39	0.39	0.05	1.22	0.51
CMSA	Plantarflexion >½ range	-3.21	0.37	-0.04	1.05	0.42
CMSA	Touch opposite knee	-3.16	0.37	-0.64	1.92	1.95
STREAM*	Hip flexion in lying	-3.02	0.24	-0.28	0.63	0.08
CMSA	Hip flexion to 90° in sitting	-2.85	0.34	-0.78	2.80	3.05
CMSA	Finger/ wrist flexion>½ range	-2.66	0.33	-0.62	1.90	2.17
CMSA	Shoulder shrugging>½ range	-2.43	0.32	-0.48	0.77	0.31
CMSA	Bridging hip with equal weight bearing	-2.32	0.31	-0.56	2.10	2.48
STREAM*	Elbow extension	-2.24	0.22	-0.41	0.33	0.07
BS	Standing to sitting	-2.19	0.30	-0.43	1.29	0.79
STREAM*	Hip flexion in sitting	-2.17	0.21	0.44	2.29	0.45
STREAM*	Knee flexion in sitting	-1.90	0.20	0.65	5.08	0.97
CMSA	Ankle inversion	-1.84	0.28	-0.43	0.81	0.38
CMSA	Sitting-to standing	-1.65	0.27	0.08	5.39	0.88
STREAM*	Some dorsiflexion in sitting	-1.32	0.18	0.15	1.95	1.37
CMSA	Elbow at side, 90° flexion: supination, then pronation	-1.28	0.26	-0.65	1.90	1.00
BS	Standing with eyes closed	-1.22	0.26	-0.98	2.03	1.62
CMSA	Pronation: finger abduction	-1.11	0.25	-0.77	0.56	0.34
CMSA	Legs crossed: toe extension with plantarflexion	-1.08	0.25	-0.24	1.50	0.97
STREAM	Open hand from fully closed position	-1.04	0.25	-0.35	0.99	0.45
EQ-5D*	Self-care	-1.00	0.17	-1.16	3.99	1.77
SIS*	Get to the toilet on time	-0.95	0.17	1.29	6.89	1.48

Appendix continued A2 Item Pool for the F3m

Index	Items (89)	Difficulty	SE	Fit resid	χ^2	F-stat
STREAM	Raise arm overhead to fullest elevation	-0.72	0.16	-0.20	1.16	0.36
CMSA	Sitting with knee extended: ankle plantarflexion, then dorsiflexion	-0.70	0.24	-0.61	0.89	0.31
STREAM	Supination and pronation of forearm	-0.70	0.24	0.01	1.94	0.44
CMSA	Dynamic righting backward and sideways with displacement, feet off floor in sitting	-0.64	0.23	-0.19	6.47	2.30
BS	Retrieving shoe from floor	-0.63	0.24	-1.16	4.74	3.08
SIS	Dress the top part of your	-0.62	0.23	-0.13	0.90	0.38
CMSA	Stand with equal weight bearing	-0.53	0.23	-0.62	5.60	2.64
CMSA	Hand unsupported: opposition of thumb to little finger	-0.44	0.23	0.07	2.70	0.46
STREAM*	Abduction: hip adduction to neutral	-0.44	0.16	0.53	2.40	0.53
CMSA	Sitting legs crossed: ankle plantarflexion, with toe extension	-0.42	0.23	0.24	4.28	0.63
SIS*	Cut your food with a knife and fork	-0.22	0.15	0.81	5.06	1.57
CMSA	Lift foot off floor 5X in 5 sec in sitting	-0.22	0.22	0.15	1.48	0.42
SIS	Bathe yourself	-0.21	0.22	-0.77	5.40	2.21
EQ-5D*	Mobility	-0.19	0.16	-0.63	1.70	0.61
CMSA	Full range: hip internal rotation	-0.13	0.22	-0.20	3.38	0.98
CMSA	Shoulder flexion to 90°:supination, then pronation	-0.10	0.22	-0.42	5.34	1.69
SIS	Walk one block	0.06	0.15	0.65	3.49	0.77
BS*	Turning to look behind	0.09	0.15	0.20	0.43	0.04
STREAM	Standing ankle dorsiflexion	0.17	0.15	-0.85	3.55	0.31
CMSA	Pistol grip pull trigger then return	0.22	0.21	-0.52	1.30	0.40
PF	Walk one block	0.27	0.21	-1.07	1.81	0.99
CMSA	Pronation: wrist and finger extension with finger abduction	0.27	0.21	-0.79	0.39	0.30
PF	Climb one flights of stairs	0.28	0.21	0.25	0.43	0.10
SIS	Turn a doorknob	0.38	0.20	0.03	1.10	0.16
CMSA	Hip extension with knee flexion	0.54	0.20	-0.32	2.13	0.89
PBSI*	Walking in the community	0.76	0.14	-1.33	3.29	1.20

Appendix A2continued The Item Pool for the F3m

Index	Items (89)	Difficulty	SE	Fit resid	χ^2	F-stat
STREAM	Walk 3 steps sideways	0.77	0.19	-1.34	3.66	1.88
SIS*	Walk fast	0.81	0.19	-0.61	3.29	1.30
CMSA	Pronation: tap index finger 10x in 5 sec	0.85	0.19	-0.17	0.06	0.01
CMSA	Arm resting at side of : raise your arm over head with full supination	0.91	0.19	-0.73	1.52	0.48
SIS	Tie a shoe lace	1.02	0.19	0.10	2.68	0.69
CMSA	Heel on floor: eversion	1.25	0.19	-1.01	3.80	2.19
BS	Turning 360°	1.27	0.19	-0.95	7.20	3.23
CMSA	Shoulder flexion to 90°: trace a figure 8	1.36	0.18	-0.89	2.51	1.02
STREAM	Walk 3 steps backwards	1.55	0.18	-1.29	4.41	2.85
PF	climb several flights of stairs	1.56	0.18	0.41	4.42	0.99
SIS	Go shopping	1.63	0.18	-0.25	2.37	0.91
CMSA	Shoulder flexion to 90°: scissors in front 3 x in 5 sec	1.74	0.18	-1.01	3.89	2.19
PF	Walk several blocks	1.75	0.18	-0.95	4.30	2.16
PF	Walk a kilo meter	1.84	0.18	-1.10	4.36	2.43
CMSA	Heel on floor: tap foot 5x in 5 sec	1.85	0.18	-0.62	3.76	1.56
CMSA	Pour water from pitcher to cup, then reverse	2.01	0.18	-0.09	2.18	0.55
SIS	Clip your toenails	2.08	0.18	-0.33	1.46	0.55
CMSA	Elbow at side 90° flexion: resisted shoulder external rotation	2.19	0.18	0.13	0.47	0.28
BS	Standing with one foot in front	2.55	0.18	0.97	4.61	1.52
CMSA	Thumb to fingertips, then reverse 3x in 12 sec	2.59	0.18	-0.13	1.21	0.47
CMSA	Clap hands overhead, then behind back 3x in 5 sec	2.70	0.18	-0.38	1.09	0.51
BS	Standing on one foot	2.71	0.18	0.39	7.54	2.25
Speed*	Walking speed	2.74	0.12	-0.84	2.06	0.77
PF*	Perform moderate activities	2.74	0.12	0.16	5.68	1.45
PBSI*	Ability to perform work or other activities	2.82	0.13	0.95	5.63	1.89
CMSA	Heel forward toe backward	3.03	0.18	-0.51	4.60	2.36

Appendix A2 continued The Item Pool for the F3m

Index	Items (89)	Difficulty	SE	Fit resid	χ^2	F-stat
CMSA	Stand on weak leg for 5 sec	3.19	0.18	-0.50	2.08	1.16
SIS	Do heavy household chores	3.33	0.18	-0.31	2.25	1.10
CMSA	Trace a leg pattern: forward, side, back, return	3.61	0.19	-0.42	3.86	1.96
CMSA	Foot off floor: foot circumduction	3.68	0.19	-0.10	3.34	1.01
PBSI	Drive a car	3.88	0.19	-0.18	5.41	2.35
PBSI*	Perform physically demanding activities	3.90	0.14	0.05	2.56	0.79
CMSA	Bounce a ball 4x in succession, then catch	4.38	0.20	-0.22	4.11	1.72
CMSA	Tandem Walking 2m in 10 sec	4.57	0.21	-0.28	1.45	0.93

Items are listed in order of difficulty, from easy to hard from top to bottom

*Polytomous items.

Walking speed in meters per second per category: 0: 0-0.5; 1: 0.6-0.8; 2: 0.9-1.3; 3: >1.3

Abbreviations: BS, (Balance Scale); CMSA, (Chedoke McMaster Stroke Assessment); DF, (degrees of freedom); Fit resid, (standardized fit residuals); F-stats, (the F-statistic from a one way analysis of variance); SE, (standard error); SIS, (stroke Impact Scale); STREAM, (Stroke Rehabilitation Assessment Measure); χ^2, : (Chi-Square),

Degrees of freedom for: Fit residuals: 225.68; χ^2: 3: F-statistic: 228.

Appendix Table A3 The Item Pool for the Measure of Functioning at Three days (F3d)

Index	Items (92)	Difficulty	SE	Fit resid	χ^{2+}	F-stat
CMSA	Arm not yet stage 2	-8.36	0.84	-0.05	0.22	0.01
CMSA	Hand not yet stage 2	-7.56	0.62	-0.06	0.51	0.03
CMSA	Facilitate hip extension	-6.66	0.47	-0.12	1.83	0.47
CMSA	Resistance to passive hip or knee flexion	-6.25	0.42	-0.10	0.24	0.22
CMSA	Facilitate hip flexion in lying	-5.94	0.40	-0.04	0.37	0.17
CMSA	Resistance to trunk rotation	-5.49	0.37	0.00	3.64	1.25
CMSA	Facilitate elbow flexion	-4.47	0.31	-0.23	2.05	1.41
CMSA	Hip abduction: adduction to neutral	-4.13	0.30	-0.23	1.29	2.05
CMSA	Hip flexion to 90° then extension synergy	-3.55	0.28	-0.10	0.74	0.33
CMSA	Resistance to passive wrist or finger extension	-3.41	0.28	-0.05	8.29	3.57
CMSA	Plantarflexion >½ range	-3.36	0.28	0.08	4.91	0.89
CMSA	Facilitate finger flexion	-3.14	0.27	0.02	7.05	1.95
CMSA	Touch opposite knee	-2.80	0.26	-0.33	2.55	1.79
CMSA	Positive Hoffman	-2.77	0.26	-0.20	3.09	1.50
STREAM*	Hip flexion in lying	-2.73	0.18	-0.36	4.58	1.21
CMSA	Some dorsiflexion	-2.47	0.26	-0.18	0.29	0.06
STREAM	Extends Knee in sitting	-2.43	0.18	-0.30	0.91	0.26
CMSA	Wrist extension >½ range	-2.36	0.25	-0.04	0.46	0.16
STREAM	Shoulder shrugging>½ range	-2.36	0.17	0.28	6.30	0.62
CMSA	Finger extension, then flexion	-2.34	0.25	0.11	2.46	0.85
STREAM	Hip flexion in sitting	-2.30	0.18	-0.29	0.74	0.29
CMSA	Bridging hip with equal weight bearing	-2.24	0.25	-0.44	3.06	2.30
CMSA	Extension of toes	-2.12	0.25	-0.30	0.56	0.04
CMSA	Ankle inversion	-1.80	0.24	-0.29	1.96	1.01
CMSA	Lateral prehension	-1.68	0.23	-0.14	1.32	0.57
CMSA	Knee flexion beyond 100°	-1.60	0.23	-0.67	4.26	4.20
CMSA	Hip Extension then flexion synergy	-1.57	0.23	-0.17	4.46	2.29
STREAM	Bridging with equal weight bearing	-1.55	0.23	-0.02	1.54	0.20
BS	Sitting unsupported	-1.52	0.23	0.40	8.56	3.99
CMSA	Heel on floor: eversion	-1.47	0.23	-0.33	1.21	0.21

Appendix A3 continued The Item Pool for the F3d

Index	Items (92)	Difficulty	SE	Fit resid	χ^2	F-stat
STREAM*	Sitting with knee extended: ankle dorsiflexion	-1.43	0.16	-0.30	3.33	1.29
CMSA	Finger flexion with lateral prehension	-1.37	0.22	-0.33	0.68	0.58
CMSA	Finger flexion, then extension	-1.29	0.22	-0.31	1.58	0.59
STREAM*	Placing hand on sacrum	-1.27	0.16	-0.33	3.06	1.82
CMSA	Legs crossed: dorsiflexion, then plantarflexion	-1.25	0.22	-0.55	0.78	0.51
CMSA	Dynamic righting feet on floor	-1.17	0.22	-0.07	5.56	0.57
STREAM	Plantarflexion>½ range in sitting	-1.15	0.22	-0.49	0.45	0.27
STREAM*	Raising hand to touch top of head	-1.13	0.15	-0.02	0.87	0.24
CMSA	Stand for 5sec	-0.92	0.21	-0.02	7.77	2.39
CMSA	Elbow at side, 90° flexion: supination, then pronation	-0.90	0.21	0.56	7.46	1.62
CMSA	Arm flexion then extension	-0.72	0.21	0.44	9.50	2.36
CMSA	Pronation: finger abduction	-0.69	0.21	-0.23	5.54	2.06
STREAM*	Raise ram overhead to fullest elevation	-0.61	0.15	-0.06	3.38	1.26
CMSA	Legs crossed toe extension with ankle plantarflexion	-0.55	0.20	-0.09	2.48	0.43
STREAM	Opposes thumb to index finger	-0.48	0.20	0.41	5.10	1.03
STREAM	Open hand from fully closed position	-0.45	0.20	0.40	6.48	1.30
STREAM*	Rises to standing from sitting	-0.10	0.12	1.06	1.03	0.08
CMSA	Sit to stand	-0.08	0.19	-0.40	4.71	1.89
BS*	Standing to sitting	-0.06	0.11	1.39	5.65	2.52
CMSA	Hand unsupported: opposition of thumb to little finger	0.10	0.19	-0.20	5.13	1.27
CMSA	Full range: hip internal rotation	0.10	0.19	-0.16	7.91	2.52
CMSA	Shoulder flexion to 90°:supination, then pronation	0.34	0.19	0.05	9.10	3.08

Appendix A.3 continued The Item Pool for the F3d

Index	Items (92)	Difficulty	SE	Fit resid	χ^2	F-stat
BI*	Transfer bed to chair	0.55	0.14	-1.17	4.91	1.85
STREAM*	Abducts affected hip with knee extended	0.62	0.13	-0.21	8.80	2.38
STREAM*	Dorsiflex ankle with knee extended in standing	0.79	0.13	-1.04	4.81	2.74
SIS*	Stand without losing balance	0.87	0.13	0.50	0.96	0.22
BI*	Dressing and undressing	0.90	0.14	0.31	2.68	1.15
STREAM*	Knee flexion in standing	1.04	0.13	-0.66	4.63	1.43
BS*	Stand with eyes closed	1.11	0.12	-0.98	5.22	2.48
BS*	Turning to look behind	1.24	0.13	-0.88	5.21	2.13
STREAM*	Places affected leg on first step	1.29	0.10	-1.03	1.18	0.81
BS*	Retrieve shoe from floor	1.34	0.13	-1.02	3.39	1.69
BS*	Reach forward with out stretched arm	1.38	0.13	-0.80	2.53	0.82
CMSA	Full abduction of arm	1.44	0.18	-0.33	2.77	1.13
SIS*	Walk a block	1.46	0.18	-0.16	6.04	1.94
CMSA	Heel on floor: eversion	1.79	0.18	-0.19	2.87	0.89
CMSA	Hand from knee to forehead 5X in 5seconds	1.84	0.18	-0.17	1.00	0.21
BI*	Getting on and off the toilet	1.84	0.13	-0.54	1.35	0.34
CMSA	Shoulder flexion to 90°: trace a figure 8	2.05	0.18	0.00	0.72	0.22
BI*	Walk on a level surface	2.32	0.14	-0.95	6.21	2.96
BS*	Turning 360°	2.55	0.13	-0.59	2.83	1.37
CMSA	Pour water from pitcher to cup, then reverse	2.57	0.19	-0.09	1.15	0.12
CMSA	Shoulder flexion to 90°: scissors in front 3 x in 5 sec	2.64	0.19	0.01	1.39	0.23
CMSA	Heel on floor: tap foot 5x in 5 sec	2.74	0.19	-0.33	0.50	0.11
BI	Doing personal toilet	2.79	0.19	0.07	5.49	1.55
STREAM*	Walk down 3 stairs alternate feet	2.98	0.11	-0.44	4.84	1.54
BI*	Ascending and descending stairs	3.04	0.14	-0.53	4.62	1.86
SIS*	Climb one flight of stairs	3.21	0.14	0.28	5.74	2.41
CMSA	Trace a pattern: forward, side, back, return	3.23	0.20	-0.37	3.64	1.83
BS*	Stand with one foot in front	3.47	0.15	-0.30	2.34	0.66
CMSA	Foot circumduction	3.57	0.20	-0.26	0.28	0.07
BS*	Standing on one foot	3.74	0.15	-0.07	0.82	0.03

Appendix A3 continued The Item Pool for the F3d

Index	Items (92)	Difficulty	SE	Fit resid	χ^2	F-stat
CMSA	Thumb to fingertips, then reverse 3x in 12 sec	3.84	0.21	0.14	7.25	2.53
CMSA	Clap hands overhead, then behind back 3x in 5 sec	4.14	0.22	0.19	9.45	0.73
CMSA	Up on toes, then back on heels 5x	4.27	0.22	-0.32	2.04	1.85
CMSA	Ankle circumduction quickly	4.80	0.24	-0.28	4.78	4.43
BI	Bathing self	4.94	0.25	-0.04	0.57	0.56
CMSA	Walk on toes 2 meters	5.21	0.26	-0.20	3.66	2.28
CMSA	Trace a pattern: forward, side, back, return	5.48	0.28	-0.19	2.30	2.18
CMSA	Bounce a ball 4x in succession, then catch	5.95	0.31	0.15	3.59	0.91
CMSA	Tandem Walking 2m in 10 sec	6.18	0.32	-0.18	4.46	4.02
SIS	Getting in and out of a car	10.3	1.15	-0.03	0.07	0.07

Items are listed in order of difficulty, from easy to hard from top to bottom shaded items are self report of difficulty

*Polytomous items.

Abbreviations: BI, (Barthel Index); BS, (Balance Scale); CMSA, (Chedoke McMaster Stroke Assessment); DF, (degrees of freedom); Fit resid, (standardized fit residuals); F-stats, (the F-statistic from a one way analysis of variance); SE, (standard error); STREAM, (Stroke Rehabilitation Assessment Measure); SIS, (Stroke Impact Scale-16); χ^2, : (Chi-Square),

Degrees of freedom for: Fit residuals=257.5, χ^2 =3, F-statistic=258

+Bonferroni corrected significance level p <0.0013

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

Review; Author, Methods [illegible]	Factor groupings [illegible]				Definition of functioning, outcome, time of assessments and strengths of studies
	Personal	Stroke	Process	Ability	
Jongbloed (1986) (77)					
Summary of methods: selective review of 33 papers from 1950 to 1986. **Inclusion criteria:** those with a systematic measure of function within 3 months of stroke **Purpose:** critical review of prediction of function at 3 months to describe recovery, define factors and determine the value of single factors **Results:** poor measurement and timing of assessment make interpretation of results and conclusions for papers difficult	1.Age; Unclear relationship except for those of an older age which is not defined, 2. Previous stroke adverse relationship, NOT related: Gender	1. side with right side worse outcome, NOT related Hemisphere of stroke	Time to admission inconclusive	1.Incontinence adverse relationship, 2. Baseline severity linear relationship but depends on index used, 3. Visuo-spatial adverse relationship, 4. Baseline functioning linear relationship	**Functioning:** ability to perform ADL. **Outcomes:** ADL measured by various indices from individual tasks to standardized indices most of unknown reliability and validity **Factors:** reliability not stated **Drop outs:** not stated **Timing:** factors assessed from 48 hours to 3 months, FU several weeks to 3 months **Strengths:** all studies listed with their characteristics, strength of association listed if present. Good critiques of papers **Weakness**: studies varied greatly in purpose, outcome, timing of assessments, sample size, and statistics used, could have grouped them by characteristics or strength of evidence

Appendix A 4 Table Reviews of Predictive Factors Related To Functioning

Review, Author, [illegible]	Factor groupings [illegible]				Definition of functioning, outcome, time of assessments and strengths of studies
	[illegible]	Stroke	Process	Ability	
Kwakkel et al (1996) (28)					
Summary of methods: Electronic and manual search methods listed. Selected 8 out of 78 from initial 142 dated 1966 -1994 against internal, external and statistical validity criteria. **Inclusion criteria:** Studies with disability as an outcome. **Purpose:** 1.review quality of studies 2. identify factors consistently related to outcome **Results:** 9 factors listed need for simple models	1.Old age, 2.Prior stroke, 3. Trend for social support NOT related: gender, ethnic origin	1. LOC within 48 hours, 2. disorientation, Not related: side of lesion	1.Results of cerebral metabolic rate on PET sample too small	1.Baseline functioning, 2. urinary incontinence, 3.severity of paralysis, 4.poor sitting balance,	**Functioning:** ADL as defined by ICIDH codes 30-46 (self-care and ambulation) no specific outcomes **Indices:** 52% of 78 papers used valid reliable indices, BI most used **Factors:** 37% of 78 papers evaluated reliable factors **Drop outs:** only stated in 79% of studies **Timing:** several days to several months **Outcomes:** ADL **Strengths:** 10 validity criteria scored per paper, numerous factors assessed Ranked studies by scores on criteria **Weakness:** limited electronic search, only 1 reviewer, no strength of association

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

[illegible]					Definition of functioning, outcome, time of assessments and strengths of studies
[illegible]	[illegible]	Stroke	Process	Ability	
Hoffman et al. (2001) (29)					
Summary of methods: Electronic and manual search methods listed. Selected 40 out of 49 dated 1986 -1999 including 7 descriptive papers. **Inclusion criteria:** 1 or more functional status outcomes or Q of L with socio-demographic, clinical, and patient characteristics factors **Purpose:** considered the evidence for 10 factors impacting on functioning and Q of L post stroke **Results:** methodological issues prevented generalizabililty of factors	1.Older age unclear relationship, 2.Gender unadjusted for other covariates but women worse outcome, 3.Social support relationship depended on definition, 4.Comorbidity depended on the condition examined, 5.Prior stroke inconsistent relationship	1.Hemisphere of stroke ambiguous left appears poorer, 2.stroke severity linear relationship depended on definition of severe and index used		1.Baseline functioning linearly related, 2.Depression limited number of subjects, 3.Cognition inconsistent relationship	**Functioning:** 1. The ability to perform ADL. 2. Quality of life: satisfaction with aspects of life important to the person **Indices:** standardized ADL indices Katz, BI or FIM Q of L varied NHP,SIP and non standardized questions **Factors:** reliability not stated **Drop outs:** not stated **Outcomes:** 1. Functional status 2. Quality of life **Timing:** factors varied from 48 hours, to on admission, to 7 days, FU for function, discharge from acute care or rehabilitation, FU for Q of L 6 months-4 years **Strengths:** Papers listed with characteristics **Weakness:** selective review only limited electronic search, reliability or validity of papers not stated, no criteria for assessing papers stated Strength of relationship not presented

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

[illegible] Methods	[illegible]	Stroke	Process	Ability	Definition of functioning, outcome, time of assessments and strengths of studies
Counsell et al (2001) (30)					
Summary of methods: Electronic search and manual search methods listed. Selected 78 out of 238 dated 1996 -1997 against internal, external and statistical validity criteria. **Inclusion criteria:** 3 or more factors studied multivariately; sample size greater than 100. **Purpose:** 1.review quality of studies 2. identify factors consistently related to outcome **Results:** Only 4 models met all criteria to evaluate outcome being alive and home	For survival and independent At 30 days NOT related age, sex, HTN, At 2-12 months NOT related: gender, HTN, Other relationships less clear including age, For alive and at home age, urinary incontinence	For survival and independent at 2-12 months LOC, absence of SA blood in haemorrhagic		For survival and independent at 30 days less severe at baseline, For survival and independent at 2-12 months weakness, less impairment	**Functioning:** dichotomized 1.survival and independent /dependent state, 2. alive and at home/ dead **Indices:** not stated **Factors:** looked at **Drop outs:** looked at **Outcomes:** 1. Survival and independent state 2. alive and home **Timing:** factors assessed within 30 days, FU minimal 30 days **Strengths:** 8 validity criteria numerous factors assessed **Weakness:** limited electronic search, reliability or validity of papers not stated. Included all models adequate or not in analysis of factors consistently related to outcome. Strength of relationship not presented

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

[illegible]					Definition of functioning, outcome, time of assessments and strengths of studies
[illegible]	Personal	Stroke	Process	Ability	
Weimar et al (2002) (31)					
Summary of methods: electronic and manual search in 1998 for past five years. Selected best papers per factor out of 33 against criteria. **Inclusion criteria:** factors within 72 hours, representative sample, and sufficient follow up outcome, objective and blindly evaluated outcome, analysis adjusted for important factors **Purpose:** identify and confirm predictive factors of outcome. **Results:** appropriate models for prognosis in stroke are missing, 38 factors defined as possible indicators	1.Age, 2.Gender, 3. Prior stroke, 4.Diabetes mellitus	Lenticulo-striatial infarcts	1.Fever>38, 2.neurological complication within 72 hours	1. Baseline neurological impairment, 2. functional impairment at baseline on MRS	**Functioning:** not stated in search but goal of search defined outcome as complete restitution. Any outcome related to functioning as defined by the ICF was included in the search. **Indices:** not stated in search **Factors:** reliability not stated **Drop outs:** not stated in search **Timing:** factors within 24-72 hours **Outcomes:** Function **Strengths:** factors very well defined included control groups of RCTs. **Weaknesses:** total number of papers assess not stated, operational definition of inclusion poor, strength of association not stated, only ischemic strokes

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

[illegible]	[illegible]	[illegible] Stroke	[illegible] Process	[illegible] Ability	Definition of functioning, outcome, time of assessments and strengths of studies
Hendricks et al (2002) (32)					
Summary of methods: electronic and limited manual search. Selected 14 papers out of 174 from 1966-2001 against criteria scored 0-18. 64% evaluated arm/hand, 28% global weakness, 5% leg. **Inclusion criteria:** factors within1 week of stroke, outcome motor recovery, FU 3 months, Lost<20%, subject to variable ratio>10. **Purpose:** Asks and answers two questions. The extent of timing of motor recovery **Results:** 1. Extent of Motor recovery Leg 65%, arm unable to assess; 15% if completely paralysis. 2. Time to recover 2 times longer for severely affected.	1.Age, NOT related: gender	Suggestive secondary factors with a relationship hemisphere vs. brainstem, lacunar infarcts fare better	Evoked potential better than clinical factors but sample size too small	**Strongest predictor:** 1.Initial weakness Depended on index OR varied from 4.58 to 24 by level of severity depended on time of assessment if later than 1 day better predictor, 2. Some evidence for early movement return related to better outcome	**Functioning:** motor deficits after stroke. **Indices:** Stroke scales 36% MRC grades 21% standard motor assessments 2%, paper defined outcome 14% **Factors:** reliability not stated **Drop outs:** <20% **Timing:** factors assessed at 1 week, FU at least 6hours to 3 months **Outcomes:** 1. extent of motor recovery 2. time to recover **Strengths:** validity criteria scored 0-18, included control groups of RCTs. Calculated factor ORs and *z*-scores for comparison of papers. **Weaknesses:** biased towards papers on evoked potentials, meta analysis not done even on similar papers. Included papers outside criteria

Appendix Table A 4 Reviews of Predictive Factors Related To Functioning

Review, Author, Methods	Factor groupings				Definition of functioning, outcome, time of assessments and strengths of studies
	Personal	Stroke	Process	Ability	
Meijer et al. 2003 (81)					
Summary of methods: Used Cochrane Collaboration search criteria. Selected 26 papers out of 135 to 2002 against previously used internal, external and statistical validity criteria scored by 2 reviewers (28). **Inclusion criteria:** defined inception cohort, factor s within 2 weeks, Outcome 6-12months, N>50. **Purpose:** identify evidenced based factors in subacute phase of stroke **Results:** insufficient evidence for factors related to ADL/ ambulation. Factors related to outcome vary by strength of study	3.age, living alone before stroke, ethnic origin, residence	6. Size of haemorr-age or edema, LOC	5. Complications of ischemic stroke	*Numbered by Best evidence for relationship* 1. Urinary incontinence, 2. Baseline severity ADL ambulation and 4. weakness and swallowing difficulties 7. Apraxia	**Functioning:** ADL and ambulation ICIDH codes 30-46 **Indices:** BI 27%, MMSE 19%, FAI 19% MRS GCS each 15%. **Factors:** looked at **Drop outs:** looked at **Timing:** factors assessed within 2 weeks, FU at least 6months **Outcomes: 1.** ADL or Ambulation as coded by ICIDH codes 30-46 **2.** Only 'A' evidence factors presented **Strengths:** determination of sample size needed to detect difference of 20% in dichotomous factors. Ranked studies by scores on criteria 'A-C'. **Weaknesses:** no meta analysis as did not have raw data, heterogeneity large. Strength of association not stated.

Abbreviations: CT, (Computed Tomography); FIM, (Functional Independence Measure);FU, (Follow up period); HTN,(hypertension); ICIDH, (International Classification of Impairment, Disability and Handicap; now the International Classification of Functioning, Disability and Health); MRC, (Medical Research Council manual muscle testing grades from 0 none to 5 normal); MRS, (modified Rankin Scale); LOC, (level of consciousness); SA, (Subarachnoid space in the brain); PET, (Positron Emission Tomography); OR, (odds ratio); Q of L, (Quality of Life); RCT, (Randomized Controlled Trials).

Appendix Table A5 Summary of Activity Levels and Metabolic Units (N=262)

Activity	Activity Time Frame		Number of subjects (N)	
	Previous	**Present**	**Previous**	**Present**
	Mean ± SD	Mean ± SD		
Number of activities	3.8 ± 1.3	2.6 ± 1.2	262	259
Metabolic activity units	59.7 ± 31.1	19.2 ± 19.3		
Hours spent on activities	18.4 ± 7.8	11.8 ± 13.5		
Work			234	71
Retired			0	176
Unemployed or not working			29	21
Metabolic units used per week	104.5 ± 65.0	24.0 ± 48.0		
Hours spent working per week	42.2 ± 13.8	36.0 ± 19.0		
Volunteering			91	60
With more than 1 activity			3	2
Metabolic units used per week	8.6 ± 19.3	4.3 ± 14.0		
Hours spent per week	9.4 ± 11.0	6.9 ± 8.3		
Sports			180	88
With more than 1sport			80	24
Metabolic units used per week	40.3 ± 65.1	7.6 ± 16.6		
Hours spent per week	6.3 ± 5.7	6.4 ± 5.5		
Housework			210	262
Doing more than 1 task			5	14
Metabolic units used per week	27.0 ± 44.0	2.5 ± 1.4		
Hours spent per week	10.5 ± 14.7	7.4 ± 16.0		
Hobbies			162	262
With more than 1 hobby			9	21
Metabolic units used per week	10.2 ± 17.3	10.7 ± 19.5		
Hours spent per week	7.7 ± 8.6	6.2 ± 10.7		

Only one example of one set of activities with metabolic units is given (Housework).

Activity levels were calculated from the energy expended on the activities related to hobbies, sports, household chores, volunteer activities or work. The energy cost in metabolic equivalent units (Met) is from the Compendium of Physical Activities classification 2000. Mets for unlisted activities were determined from the units of similar activities. The average energy cost per activity was determined by multiplying the average Mets by the number of hours spent per week on an activity. Two time periods are: Present, the month prior to stroke and Previous, the period between the ages of 20 and 30.

Table A5 of Present and Previous Hobbies (N=262)

Activity	Hours	N	Category Items
Hobbies		N	
Previous	7.7 ± 8.6	157	
Present	9.6 ± 12.0	150	
Reading			
Previous	11.4 ± 9.8	27	Reading
Present	12.5 ± 16.5	49	Reading
Music			
Previous	9.0 ± 11.6	17	Listening to music, playing an instrument, singing
Present	4.4 ± 3.2	16	Listening to music, playing an instrument, singing
Crafts			
Previous	6.5 ± 7.4	68	Crocheting, knitting, sewing, leatherwork, needle point, woodwork, painting, photography, jewellery, model building, doll making, handiwork
Present	6.7 ± 8.3	34	Crocheting, knitting, sewing, leatherwork, x-stitching, woodwork, painting, photography, jewellery, model building
Watching TV			
Previous	-	-	In other categories as too few
Present	15.7 ± 13.4	12	Watching TV
Shopping			
Previous	-	-	In other category as too few
Present	8.0 ± 5.6	3	Mall shopping
Playing games			
Previous	8.0 ± 7.8	14	Cross word puzzles, cards, chess,
Present	8.4 ± 6.5	27	Bingo, bridge, cross word puzzles, cards, chess, snooker, darts
Computer			
Previous			In other category as too few
Present	14.2 ± 13.0	8	Playing on the computer, surfing the net
Gamble			
Previous	-		In other category as too few
Present	8.5 ± 13.3	8	Casino, horseracing, lotteries
Playing sports			
Previous	7.3 ± 7.4	21	Dancing, body building, bowling, camping, fishing, hunting, dragon dancing, hiking, lawn bowling, climbing, motorcycle- riding, walking, racing cars, horseback riding
Present	10.5 ± 11.6	14	Horseback riding, fishing, hunting, camping, hockey, walking, workout, lawn bowls, driving 4x4 trucks
Gardening			
Previous	8.6 ± 7.1	10	Gardening
Present	9.9 ± 8.1	6	Gardening

Table A5 Continued of Present and Previous Hobbies

Variable	Hours		Category Items
Socialize			
Previous	-	-	In other category as too few
Present	12.4 ± 16.8	4	Socializing with friends and family
Cooking			
Previous			In other category as too few
Present	4.9 ± 1.8	4	Cooking for pleasure and entertaining
Other			
Previous	7.5 ± 10.2	20	Wild mushroom collecting, movies, business presentations, performance for radio, clubbing, electronics, collecting hockey stats, playing the stock market, TV watching, cooking, cross-word puzzles, poker, roulette, studying
Present	7.2 ± 6.4	8	Taking courses, movies, mushroom gathering, renovations, stock market

Table A5 Present and Previous Housework Activities

Variable	Hours	N	Items in category
Housework			
Previous	10.5 ± 14.5	215	
Present	9.2 ± 17.1	214	
Dishes			
Previous	3.2± 2.5	24	
Present	4.1 ± 3.7	18	
Cooking and Cleaning			
Previous	13.8 ± 21.4	17	
Present	9.0 ± 10.2	28	
Heavy house work			
Previous	6.4 ± 6.0	37	
Present	15.2 ± 37.5	37	Maintenance, painting, renovations, gardening, taking care of children, scrubbing floors, shovelling snow, full time caregiver
Light housework			
Previous	3.9 ± 3.8	19	
Present	4.7 ± 3.7	26	Dusting, making beds, tidying, helping husband/wife around the house
Vacuum			
Previous	7.2 ± 4.9	9	
Present	8.3 ± 6.9	21	
Shopping			
Previous	5.0	1	
Present	2.5 ± 1.1	4	
Laundry			
Previous	10.9 ± 12.9	12	
Present	8.2 ± 6.4	9	
Everything			
Previous	15.6 ± 17.7	92	
Present	10.5 ± 8.0	77	
Taking out the garbage			
Previous	2.0 ± 0.8	9	
Present	2.3 ± 1.0	9	

Table A5 Present and Previous Housework Activities Metabolic Units

Variable	Mean Hours ±SD	N	Items in category with metabolic units
Housework			
Previous	10.5 ± 14.5	215	
Present	9.2 ± 17.1	215	
Dishes			
Previous	3.2 ± 2.5	24	2.3
Present	4.1 ± 3.7	18	
Cook and Clean			
Previous	13.8 ± 21.3	17	Cooking 2.0 prep for cooking 2.5 Light cleaning 2.5 general 3.0
Present	8.5 ± 11.4	21	
Heavy house work			
Previous	6.4 ± 6.0	37	4.0 renovations (average of 6 carpentry/painting plumbing)gardening 4.0 caregiver elder 4 children 3.3
Present	15.2 ± 37.5	37	
Light housework			
Previous	3.9 ± 3.84	19	Light cleaning 2.5 general 3.0 bed 2.0
Present	4.7 ± 3.8	25	
Vacuum			
Previous	7.2 ± 4.9	9	3.5 scrubbing 6 sweeping 3.3 mopping 3.5
Present	8.4± 6.9	21	
Shopping		1	
Previous	5.0		Food shop 2.3 groceries 2.5 carrying 2.5
Present	2.5 ± 1.1	4	
Laundry			
Previous	10.9± 12.9	12	2.0 laundry 2.3 ironing 2.3
Present	6.1 ± 4.1	7	
Everything			
Previous	15.6 ± 17.7	92	Light 3.5 heavy 4.0
Present	10.5 ± 8.0	77	

Table A5 of Present and Previous Sports Activities

Variable	Hours	N	Items in category
Sport			
Previous	6.3 ± 5.7	184	
Present	6.4 ± 5.5	89	
Golf			
Previous	8.5 ± 7.2	23	
Present	7.5 ± 5.5	16	
Ski			
Previous	6.2 ± 4.6	44	Alpine and cross-country
Present	8.0 ± 5.4	10	
Tennis			
Previous	6.5 ± 5.2	30	
Present	9.3 ± 7.3	7	
Soccer			
Previous	7.6 ± 5.4	21	
Present	1.0	1	
Curling			
Previous	5.0	1	
Present	4.7 ± 1.5	3	
Walking			
Previous	6.4 ± 4.9	14	
Present	6.8 ± 5.7	31	
Exercise			
Previous		0	
Present	7.0 ± 6.5	7	cardiac exercise, YMCA exercises, aerobics
Bowling			
Previous	6.1 ± 6.7	23	
Present	5.5 ± 5.7	11	
Swimming			
Previous	6.2 ± 5.2	15	
Present	8.5 ± 7.9	10	
Cycling			
Previous	4.8 ± 3.5	21	
Present	9.6 ± 8.4	14	
Hockey			
Previous	8.6 ± 7.6	25	
Present	7.0	1	
Other vigorous sport activities			
Previous	4.4 ± 2.6	7	running, tap dancing, track & field, volleyball, horseback riding, exercises at work, jogging, weights
Present	11.9 ± 8.9	9	gymnastics, hiking, camping, x-county hiking, horseback riding hunting, boating, kung fu, gym, senior citizens tai che, weight lifting

Table A5 of Present and Previous Volunteering Activities

Variable	Hours	N	Items in category
Total Volunteering			
Previous	9.4 ± 11.0	92	
Present	6.8 ± 8.2	62	
Church groups			
Previous	9.5 ± 9.5	13	Helping at church or synagogue functions: bazaars, bible study, bingo, dinners
Present	7.5 ± 11.4	13	Helping at church or synagogue functions: bazaars, bible study, bingo, dinners
Sports groups			
Previous	7.6 ± 4.4	9	*Coach sports:* boxing, hockey, soccer, football, baseball,Amateur boxing league president *Organized sports:* bowling leagues, triathlon with kids, swimming club
Present	12.1 ± 15.8	4	*Coach sports:* baseball, hockey, curling club president, *Organized sports:* bowling leagues
Community work			
Previous	9.0 ± 10.3	24	*Ethnic communities:* Greek, Ghanaian, Pan Africa, teaching at Russian school. *Neighborhood activities*: garden work, Verdun community work, town councilor, charity events, planting trees, flowers, landscaping, community center president, organizing social events. *Area schools activities*: bus mother, helping at performances, telephone, primary school helper, *Other organizations*: meals on wheels, scouts, political, salvation army, *Welfare rights group*: foster children, baby photographer
Present	7.0 ± 9.1	13	*Ethnic communities:* Jewish day center, society of Greek holocaust center. *Neighborhood activities*: community activities, condo president, organizing activities, fund raising, helping at institute, board of complex president *Other organizations:* counseling, memorial association Quebec, anti-defamation league, men's club V.P, funeral association
Elderly			
Previous	4.6 ± 3.3	5	visiting and helping the elderly
Present	5.8 ± 3.7	3	visiting and helping the elderly

Table A5 Continued Volunteering Activities and Metabolic Units

Variable	Hours	N	Items in category
Hospital			
Previous	11.2 ± 13.8	10	*Adults:* various tasks: transport, visits, counseling for alcoholics *Children:* children's suicide line
Present	7.3 ± 7.6	12	*Adults:* assisting in various tasks: transport, visits *Children*: emergency at Montreal children's hospital *Community:* meals on wheels, caring for friend with leukemia, VON, administration Red Cross telephone helpline
Organizations			
Previous	11.3 ± 15.1	23	*Adult:* Lions, legion, mason, rotary, moose, vets meetings, optimist, old age committee, womens' association *Children:* brownies, boy scouts, junior league *Community:* army, library, SPCA, fireman , foster home president MTL, political activities, Bnae Brith association president, refugees rehabilitation
Present	5.3 ± 6.2	10	*Adult:* legion, mason, moose, Red cross, optimist, old age committee, women's association *Community*: library
Other			
Previous	7.1 ± 5.6	11	*Home help*: helping mother with children, farm hand *Other:* singing, helping different organizations, office work, volunteering
Present	6.9 ± 7.7	9	*General help:* delivering: boxes, referendum circulars, general aid: animal rescue, money lending, office work, painting

Table A5 Present and Previous Work Activities and Metabolic Units

Variable		N	Items in category
Work	**Hours**		
Previous	42.2 ± 13.8	239	
Present	36.0 ± 18.9	71	
Retired			
Previous		1	
Present		149	
Not working			
Previous		29	
Present		48	
Professional			
Previous	42.3 ± 12.4	46	Architect, accountant, physician, Engineer, lawyer, professor/teacher, pharmacist, psychiatrist, psychologist, researcher, social work, stock broker, veterinarian, chemist, nurse, respiratory technician, laboratory technician, library clerk
Present	32.4 ± 17.0	19	Accountant, developer, computer analyst, professor/teacher, lawyer, psychiatrist psychologist, pharmacist, social worker, respiratory technician, benefits consultant, stock broker
Artistic			
Previous	41.4 ± 15.1	9	Artist, photographer, jeweler, reviewer, photographer, dancer,interior designer, model, musician, CBC announcer, fashion designer
Present	42.5 ± 23.6	5	Artist, dresser, photographer, jeweler, reviewer
Construction			
Previous	38.2 ± 10.1	11	Construction superintendent, construction, cement, finishing
Present	37.5 ± 10.3	9	Carpenter, contractor, electrical, painter, saw operator, renovator
General Office			
Previous	34.6 ± 11.9	19	Office work, secretary, clerical, computers
Present	35.5 ± 17.0	6	Secretary, general office work
Transportation			
Previous	48.0 ± 18.5	14	Truck driver, taxi driver, flight attendant, Derailleur, CNR/CPR kitchen help, Canadair, CPR shops, aircraft worker, airport work, CNR work, CPR work, VIA auto parts
Present	30.7 ± 25.7	3	Truck driver, taxi driver, flight attendant
Housekeeping			
Previous	41.7 ± 4.1	6	Housekeeping, caretaker,
Present	29.8 ± 18.9	6	Caretaker, cleaning, housekeeper, janitor

Table A5 continued of Present and Previous Work Activities

Variable	Hours	N	Items in category with metabolic units
Management			
Previous	46.8 ± 16.6	38	Administration, section head, director, manager, foreman ,self employed, supervisor, commercial union policy, credit department, printer, import export, quality control, payrolls, sales tax consultant, employee benefits consultant
Present	48.0 ± 9.0	8	Systems manager, company president management, self-employed business owner, administration
Skilled labour			
Previous	42.8 ± 10.5	35	Machinist, welder, steel worker, Toolmaker, butcher, dressmaker, electrician, mechanic, painter, dressmaker, gardener
Present	36.1 ± 19.3	8	Dressmaker, machinist
Sales			
Previous	41.3 ± 14.0	12	Salesperson
Present	34.5 ± 21.4	4	Salesperson
Student			
Previous	32.3 ± 15.4	8	Worked as a student (MD, Pharmacist, general work)
Present		0	
Military work			
Previous	47.9 ± 16.8	7	Air force crew, military work, merchant navy, slave work- Germans, army office work, air force technical work, teaching women to prepare for war
Present		0	
Service			
Previous		0	
Present	39.8 ± 14.7	14	Cinema, post office, waitress, waiter, swimming teacher, cook, martial arts, hockey teacher, Northern telecom producer, TV technician, cable cutter, radio distributor, civil worker
Other			
Previous	42.8 ± 12.5	19	Factory worker, cashier, clothes presser, delivery, farmer, odd jobs, saw mill, livestock purchaser, shipping receiver, sailor
Present	32.5 ± 13.0	3	Shop keeper, waiter, delivery, switch board operator

Appendix Table A6 Imaging Characteristics for Subjects within 24-72 Hours Post-Stroke (N=262)

Lesion variables	Percent	Lesion variables	Percent
Mass effect	15%	**Lesion site**	
Atrophy	31%	Right	37
Leukoaraiosis	43%	Left	30
Other abnormalities	33%	Posterior	14
Lesion burden		Bilateral	7
No lesion seen	9%	**Lesion Pathology**	
No infarcts	18%	Superficial	12
A single infarct	36%	Deep	55
Two infarcts	35 %	Both	9
Three infarcts	2%	**Lesion Anatomy**	
Previous lesion	49%	Cortical	20
Only one previous	19%	Subcortical	38
Two previous	32%	Posterior	14
New Hemorrhagic lesion	14%	Multiple	14
Hemorrhagic plus 1 infarct	2%	**Size**	
Hemorrhagic plus 2 infarct	2%	Small	33
		Medium	11
		Large	16

Appendix Table A7 Distribution of Signs and Symptoms With in First Three Days of Stroke (N=262)

Stroke Signs and symptoms	Percent	Stroke Signs and Symptoms	Percent
Deviation of mouth	59	Dysphagia	10
Dysarthria	49	Confusion	8
Sensory impairment	38	Tongue deviation	7
Ataxia	23	Ptosis	5
Loss of balance	22	Blurred vision	3
Hyperactive reflexes	21	Vertigo	3
Headache	18	Diplopia	3
Dysphasia	17	Unconscious	2
Hemianopia	15	Seizures	2
Neglect	14	Fixed gaze	2
Hypoactive reflexes	13	Unresponsive	2
Dizziness	12	Memory impairment	1
Nausea	12	Stupor	0.5
Vomiting	11	Syncope	0.0
Deviation of eyes	11	Coma	0.0

Total Compliance with guide-lines 75%

Dimension Compliance %	Compliance to criteria by institution %		Criterion items and compliance score	
Team coordination 51%	Documentation	4	Document team meeting or rounds	100
	>3 disciplines	94	Disciplines in care = 3	50
Document Patient Condition 97%	Documentation	97	Documentation of Etiology, deficits etc	100
	No Document	3	No Documentation	0
Early initiation of rehabilitation 84%	Early mobilization	84	Reason for delay of mobilization/mobilized	100
	Not mobilized	16	Not mobilized	0
Manage health conditions 87%	Heath managed	87	Swallowing + 3/4 conditions evaluated	100
	3 Conditions evaluated	94	Not evaluated	0
Prevention of Complications 27%	DVT skin and **falls**+ 2/3 others addressed	27	DVT skin and **falls** + 2/3 others addressed	100
	Not done	73	Not done	0
Prevention of Recurrent Stroke 95%	Control risk plus	90	Control risk factors + any secondary prevention	100
	Control risk	10	Control risk factors	50
Use of standardized assessment 66%	CNS used	66	Use of CNS	100
	CNS not done	34	CNS not used	0
Evaluated for Rehabilitation 87% (233)	Control risk plus	90	Evaluated + all factors considered	100
	Control risk	10	Evaluated+ no factors considered	50
Congruence between eligibility and going to rehabilitation 79%	Eligible + to rehabilitation	79	Evaluated for rehabilitation and to rehab	100
	Eligible + not to rehabilitation	31	Evaluated for and not to rehabilitation	0

Appendix Figure A1 Summary of Compliance with the Guidelines (N=262)

Legend. Figure 1 presents the scoring criteria for the Veterans Affairs Structure, Process and Outcomes of Post-Acute Stroke Rehabilitation Abstraction Instrument Acute episode version. The 9 acute care dimensions with their scoring criteria are in the boxes to the far right, the distribution of compliance to each criteria achieved by the Hospitals as a whole are in the central boxes, and the total distribution for compliance per dimension is in the boxes to the far left. The overall compliance to the guides was 75%.

Table A9 Distribution of Medical Interventions During Acute Hospitalization (N=262)

Medical interventions	**N**	**%**	**Details**
Respiratory			
Intubations	19	7	
Ventilatory Support	5	2	BIPAP, CPAP
Miscellaneous	6	2	Bronchoscopy, oxygen, lung perfusion, Pulmonary function test
Nutritional			
Barium Swallow	18	7	
Dobhoff	19	7	
Tpn	1	0.3	
Nasogastric tube	11	4	
Cardiac			
Halter monitor	18	7	
Electro conversion	1	0.3	
Miscellaneous	4	1	External pacemaker, monitor in ICU, assess heart function
Neurological			
Tissue plasminogen activator	17	6	
Electroencelography	3	1	
Angiogram cerebral	7	2	
Vascular			
Transfusion	11	4	
Genitourinary			
Catheter	81	30	
Condom	2	0.3	
Gastrological	4	1	Gastroscope
General Medical			
Consult	12	4.4	Nephrology, Ophthalmology, Geriatric, Psychiatry, Urology, Rheumatology, Hematology, Respirology, Dermatology
X-ray	2	1	Hip, Back
Miscellaneous	4	1	Solumedrol injection shoulder, LP, radiation therapy, hip CT

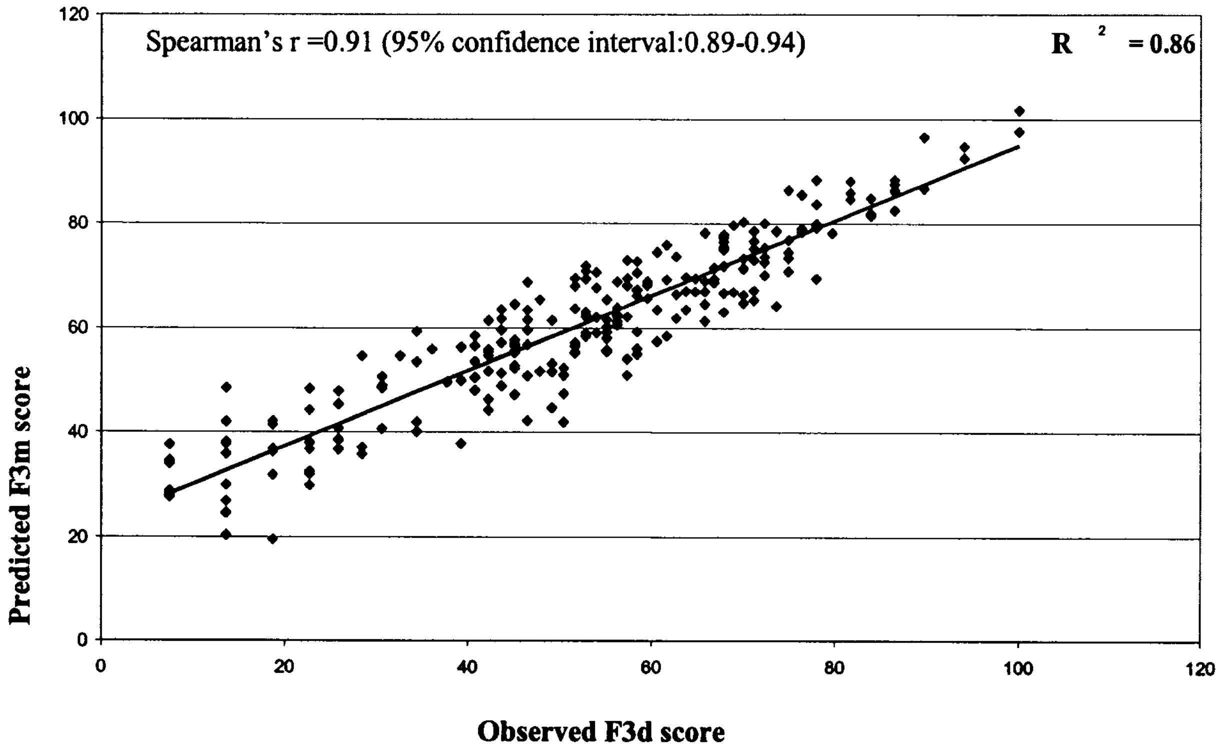
Appendix Table A9 Distribution of Surgical Interventions During Acute Hospitalization Post-Stroke (N=262)

Surgical interventions	N	%	Details
Neurosurgical	5	2	External Ventricular Drain placement or removal, Craniotomy, replacement of bone flap,
Cardiological	8	3	Pacemaker insertion or repair, AVR replacement, MVR for thrombosis on valve
Vascular Surgery	7	3	femoral embolectomy, IVC filter, Lt ICA aneurysm repair, by pass surgery right leg, above knee amputation,hip disarticulation, vascular consult for open wound
General surgical	9	3	Percutaneous Endogastrostomy, Tracheostomy

Appendix Table A10 Physiological Variables, Critical Values and Distribution of Subjects Beyond Critical Value in the First Three Days

Physiological variable and critical value	N	%
Oxygen saturation level less than 95%	97	48
Use of oxygen	74	31
Mean arterial Blood Pressure >140 mm HG	30	13
Mean arterial Blood Pressure <100 mm HG	198	84
Temperature >38° Celsius	19	8
Hydrated (number with Intra Venous)	183	78
Glucose controlled <10 mmol/l	158	67
Glucose not controlled >10 mmol/l	77	33
Glucose controlled <10 mmol/l not diabetic	144	61
Glucose controlled <10 mmol/l diabetic	13	6
Glucose not control>10 mmol/l non diabetic	32	14
Glucose not control >10 mmol/l diabetic	45	19
Diabetic	58	25

Abbreviations: mmHg, (millimeters of mercury); mmol/l, (millimoles per liter)



Appendix Figure A2 Plot of the Observed Functioning at Three Days (F3d) Value Plotted Against the Predicted Functioning at Three Months (F3m) Value

Appendix Table A11 Critical Values to Detect and Evaluate Outliers (N=235)

Parameter	**SAS name**	**Critical Value***	**k (# of predictors)**	**α**
Studentized residuals	"Studentized residuals"	≥3.73	7	0.05
Jackknife residuals	"Rstudent"	≥3.61	7	0.05
Cook's Distance	"Cook's D"	N ≥17.3	7	0.01
Leverage		0.137	7	0.05

hi=0.08

*Taken from Kleinbaum,D.G.; Kupper,L.L.; Muller,K.E. Applied Regression Analysis And Other Multivariable Methods 3rd edition, Duxbury press, New York, 1998.

List of Study Measures
Three days and Three Months

Performance Measures

1. Grip Strength
2. Fugl-Meyer Sensory Test/Orpington test
3. Two Minute Walk Test
4. Box and Block Test
5. Balance Scale
6. Albert's Test of Perceptual Neglect
7. Gait speed
8. Mini-Mental state Examination-Telephone version
9. Chedoke McMaster Stroke Assessment Impairment Inventory
10. Stroke rehabilitation Assessment of Movement (STREAM)

Self-report Measures Day 3

11. Previous Physical Activity (Q3 SF-36 and questions on work and leisure)
12. OARS Social Resources Scale
13. SIS-16

Chart Audit Measures Day 3

14. Barthel
15. Canadian Neurological Stroke Scale (recruiter sheet)
16. Health Related Services Questionnaire
17. Imaging variables

Self-Report Measures three Months (not included in the appendix)

EQ-5D
Preference Based Stroke Index
Stroke Impact Scale
Medical Outcomes Trust Short Form SF-36 Questionnaire

Performance measures are the same Day-3 and Month-3

GRIP STRENGTH Instructions / Data Sheet

No: ________________ Date: _____________Hospital / Hôpital:________________

Subjects are seated on a standard height chair without armrests with their elbow at 90 degrees. Three grip strength measures of each hand are taken using the Jamar dynamometer. The highest score will be retained.

Dominant HAND is__Right______________Left__

Right hand:	1) ________	Left hand:	1) ________
	2) ________		2) ________
	3) ________		3) ________

FORCE DE PRÉHENSION

Instructions / Formulaire des données

Le sujet est assis sur une chaise de hauteur standard, sans appui-bras. Le coude est placé a 90 degrés. Trois mesure de chaque mains sont prises avec un dynamomètre Jamar. La mesure la plus haute sera retenue.

La main dominant est_____Droite_________________Gauche____________

Main droite:	1) ________	Main gauche:	1) ________
	2) ________		2) ________
	3) ________		3) ________

Sensation

Light Touch

The sensation for light touch is only roughly estimated .Ask the patients if s/he feels a light touch on both arms, the palmer surface of the hands, both legs and the soles of both feet. If the patient has an appreciation of light touch ask him/her for the quality does it feel normal to you?

SCORE: 0: anaesthesia; 1: hyperaesthesia/dysaesthia; 2: normaesthesia

ARM Affected side score________

PALMER Affected side score________ TOTAL LIGHT TOUCH_______

LEG Affected side score________

SOLE Affected side score________

POSITION SENSE

The patient should have vision occluded (Blind folded is the best). The patient is asked to locate the affected thumb. Place the thumb within easy reach of the patient but on the affected side. Then ask the patient to:

Locate your (right/left) thumb: accurately (1.2) slight difficulty (0.4) unable (0)

TOTAL SCORE FOR SENSATION=

LIGHT TOUCH + POSITION =_____________

THE TWO MINUTE WALK TEST

Data Sheet / Formulaire des données

No: ________________Date: ______________Hospital / Hôpital: _____________
HEIGHT in METETRS ___________

Data Entry Table for TWO-Minute Walk Test:

FIRST TRIAL

Time (min)	HR	RR
0		
2		

Duration of Rests: (1) __________ (2) __________ (3) __________
(4) __________

Rests: _______

Distance Walked: ________________ metres

Average Walking Speed (distance/120 sec): ________ metres/sec.

SECOND TRIAL

Time (min)	HR	RR
0		
2		

Duration of Rests: (1) __________ (2) __________ (3) __________
(4) __________
Rests: _______

Average Walking Speed (distance/360 sec): ________ metres/sec.

Walking aid/Assistance________________________________

THE BOX AND BLOCK TEST
Instructions / Data Sheet
Date: ______________Hospital/Hôpital:# _____ID#

The evaluator sits in front of the subject. The subject is permitted to have a trial period of 15 seconds. At the signal, the subject is asked to take the blocks, one by one, from the compartment on the side of the hand being evaluated, take them to the other side of the box and release them. Start the test with the dominant hand. Count the number of blocks transferred in 60 seconds.

If the subject picks up two blocks at a time, they are counted as one. If the block is dropped on the table or floor after it is carried across the box, it is still counted but if it is tossed across without the fingertips crossing the partition, it will not be counted.
The Dominant Hand is Right Left

Number of blocks in 60 seconds - right hand _________

Number of blocks in 60 seconds - left hand _________

LE TEST «BOX AND BLOCK»

Instructions / Formulaire des données

L'évaluateur est assis en face du sujet. Le sujet a droit à une période d'essai de 15 secondes. Au signal, le sujet doit prendre les blocs, un par un, d'un compartiment situé du côté de la main évaluée, les transporter et les relâcher dans l'autre compartiment. Commencez le test avec la main dominante. Comptez le nombre de blocs transféré dans un délai de 60 secondes.

Si le sujet prends deux blocs à la fois, ils ne compterons que pour un. Si le sujet échappe un bloc sur la table ou par terre après l'avoir traverser le l'autre côté de la boîte, il sera compté mais si le bloc est lancez sans avoir les bouts des doigts ait traversé la séparation du milieu, il ne sera pas compté.
La main dominante est Droite Gauche

Nombre de blocs - main droite _________

Nombre de blocs - main gauche _________

THE BALANCE SCALE

Instructions

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 are 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.

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

Standing unsupported

Instructions: Please stand for 2 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.

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

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

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 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

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

Standing unsupported with feet together
Instructions: Place your feet together and stand *1 minute* without holding.
( ) 4 able to place feet together independently *and stand safely 1 minute*
( ) 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

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 fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.
( ) 4 can reach forward confidently > 25 cm (10 inches)
( ) 3 can reach forward > 12 cm 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
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 assist to keep from losing balance or falling

Turning to look behind left and right shoulders while standing
Instructions: Turn to look directly behind you over your left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

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

Turn 360 degrees
Instructions: Turn completely around in a full circle. Pause, then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 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

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 needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

Standing unsupported one foot in front
Instructions: (Demonstrate to subject) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead 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

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 assist to prevent fall.

TOTAL SCORE (Maximum = 56): _____

ALBERT'S TEST OF PERCEPTUAL NEGLECT
Instructions / Data Sheet

No: ________________________Date: ______________Hospital: ________________________________

This test requires the patient to draw a line across all of 40 lines evenly distributed on the sheet of paper. The test score is calculated as the percentage of lines that are left uncrossed. If more than 70% of the uncrossed line are on the same side as the patient's motor deficit, lateralized neglect is indicated.

Number of lines left uncrossed on the affected side:_______________

La capacité du cerveau LE TEST DE NÉGLIGENCE D'ALBERT

Instructions / Formulaire des données

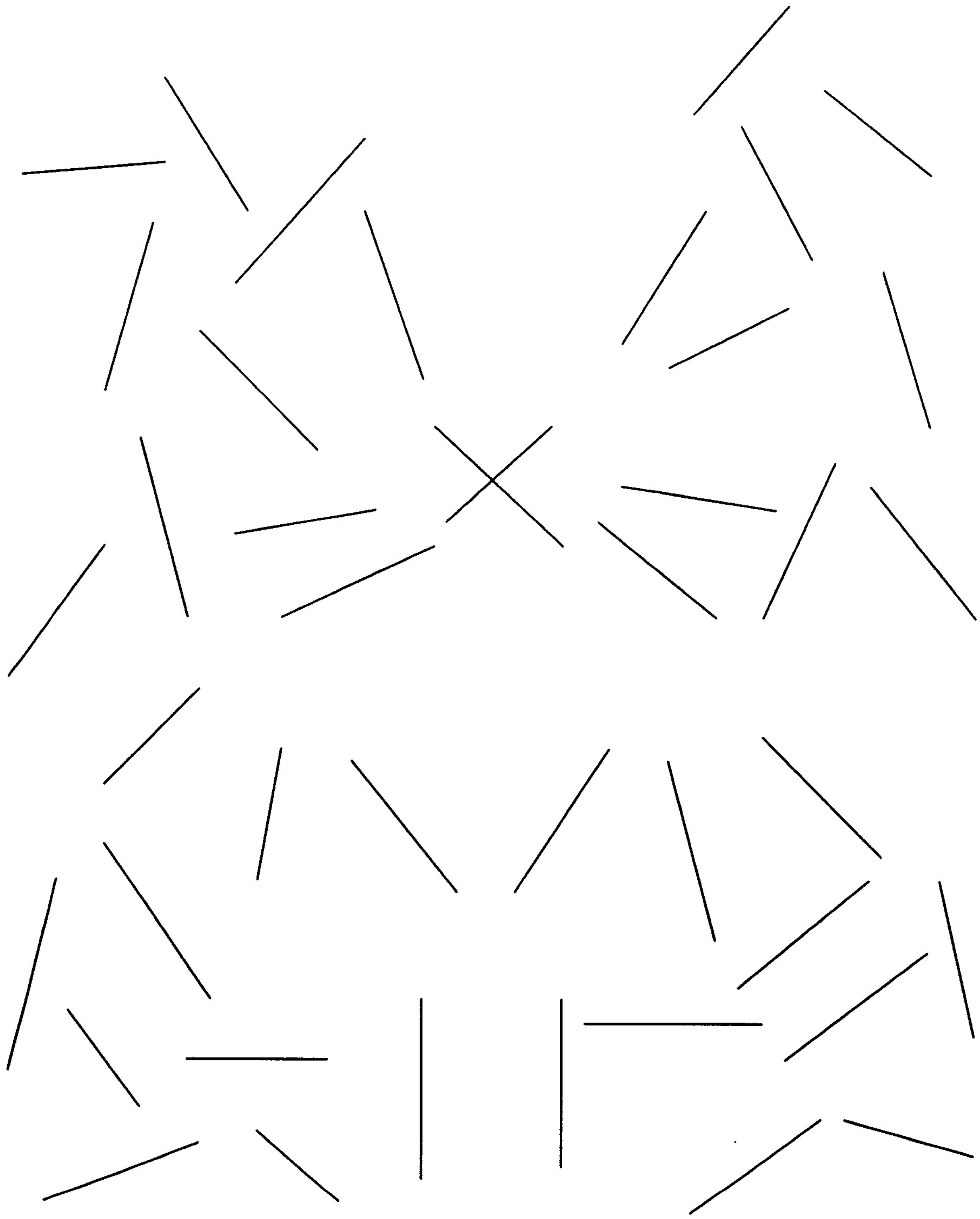
Nom: __________________________________ Date: _______________

Hôpital: ________________________________

Le patient doit rayer les 40 lignes qui sont également distribuée sur la feuille. On calcule le pourcentage de lignes qui n'ont pas été rayées. Si plus de 70% des lignes qui n'ont pas été rayées sont situées sur le côté affecté du patient, celui-ci est considéré comme ayant une héminégligence.

Nombre de lignes non rayées du côté affecté: _________________

Albert's Test



The middle line is crossed out as an example. The patient is instructed to cross out all of the remaining lines on the page.

Comfortable walking speed is determined over a 5 meter distance. 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 portion of the walkway at a comfortable walking speed 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: 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. The following instructions are given:

> "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."

THE MINI MENTAL STATE EXAMINATION Telephone version

Questionnaire

No: ______________\Date: ___________\Hospital:_______________________________

Orientation

What is the: 1. year __________

2. season __________
3. date __________ ___/5
4. day of the week __________
5. month __________

Where are we? 1. country __________
2. province __________
3. city __________ ___/4
4. building __________

Registration

Name 3 objects: LEMON, KEY, BALL. Take one second to say each word.
Then ask the subject to repeat the three words. ___/3
Repeat exercise until he learns all three. Number of trials: ___

Attention and Calculation

Begin at 100 and count backward by 7. Stop after 5 subtractions.
OR
Ask subject to spell WORLD backwards.
Give one point for each correct letter in the right order. ___/5

Recall

Ask the subject to repeat the 3 objects previously mentioned: LEMON, KEY, and BALL. Give one point for each correct response. ___/3

Language

Repeat this phrase "No ifs, ands or buts". ___/1
Name one item: telephone.
"Tell me, what is the thing called that you are speaking into as you talk to me?" ___/1
Total ___

Stroke Rehabilitation Assessment of Movement (STREAM)

No: ______________________________ Date:

Hospital#: ______________________________

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 (extenal 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).
	SITTING (feet supported; hands resting on pillow on lap for items 7-14)
/2	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).

	STANDING
/3	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) 22. Abducts affected hip with knee extended *"Keep your knee straight and your hips level, and raise your leg to the side."*
/2	23. Flexes affected knee with hip extended *"Keep your hip straight, bend your knee back and bring your heel towards your bottom."*
/2	24. Dorsiflexes affected ankle with knee extended *"Keep your heel on the ground and lift your toes off the floor as far as you can."*
	Standing and Walking Activities
/3	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	25. Takes 3 steps backwards (one and a half gait cycles) *"Take 3 average sized steps backwards, placing one foot behind the other."*
/3	26. Takes 3 steps sideways to affected side *"Take 3 average sized steps sideways towards your weak side."*
/3	27. 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	28. 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).

Previous Activity SF-36 HEALTH STATUS SURVEY/CANADA 3-DAY Questionnaire

NO: _____________ Date: _____________Hospital:

INSTRUCTIONS: This survey asks for your views about your health in the last month. This information will help indicate to us how well you did your usual activities in the past.

1. 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

2. The following items are about activities you might do during a typical day. Did your health limit you in these activities in the last month? 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	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

SOCIO-DEMOGRAPHIC three days INFORMATION

3. The following are **questions on activities and work you might have done in the past or when you were young**.

a. Did you work outside the home for an income? (1) Yes (0) No ---
   If yes, a) How many hours per week did you work? ____________________
   b) What kind of work did you do? ____________________________
   c) When did you stop?_____________________________

b. Did you volunteer or help out in the community? (1) Yes (0) No _
   If yes, a) For how many hours per week? ____________________
   b) What did you do? ____________________________
   c) When did you stop?_____________________

c. Did you do your own housework? (1) Yes (0) No
   If yes, a) how many hours per week_________________________
   b) What did you do? ____________________________
   c) When did you stop?_________________

d. Did you have an activity (sport)? (1) Yes (0) No________________
   If yes, a) How many hours per week_________________________
   b) What kind of activity (sport)? _________________
   c) When did you stop?__________________

e. Did you have a hobby? (1) Yes (0) No________________
   If yes, a) How many hours per week_________________________
   b) What kind of hobby? _________
) When did you stop?____________

The following are questions on activities and work you have done in the last month and socio-Demographic Information. Please circle the number that corresponds with the appropriate answer.

1. What is your date of birth? _____ / _____ / _____
   Year Month Day
2. What is the highest level of education you have completed?
   (0) Primary
   (1) Secondary
   (2) College / CEGEP
   (3) University
   (4) No education or only kindergarten

3. . What is your marital status?
   (0) Single
   (1) married/common law
   (2) Separated
   (3) Divorced
   (4) Widowed

4. . Do you have children ? (1)Yes (0) No
   If yes, how many? (1) one (2) two (3) three (4)four (5) >five
   How old are they ? ___________________

5 a. Do you work outside the home for an income? (1) Yes (0) No ---Retired (2)

If yes, a) How many hours per week do you work? ____________________

b) What kind of work do you do? ____________________________

b. Do you volunteer or help out in the community? (1) Yes (0) No _

If yes, a) For how many hours per week ? ____________________

b) What do you do? ____________________________

c. Do you do your own housework? (1) Yes (0) No

If yes, a) how many hours per week__________________________

b) What do you do? ____________________________

d. Do you have an activity (sport) (1) Yes (0) No

If yes, a) How many hours per week__________________________

b) What kind of activity (sport)?_________________

e. Do you have an hobby? (1) Yes (0) No

If yes, a) How many hours per week__________________________

b) What kind of hobby?______________

6. In general, how do your family finances work out at the end of the month? Do you usually have

(0) some money left over (2) not enough to make ends meet

(1) just enough to make ends meet (3) refused to answer

7. Have you fallen during the past 6 months? (1) Yes (0) No

If yes, did you fall: (1) at home (2) outside your home

Where you injured (1) Yes (0) No

What type of injury? ____

8. During the past 6 months, have you had any accidents causing an injury that led to a restriction of activities? (1) Yes (0) No

If yes, a) What type of accident?

____

b) What type of injury?

____

9. Do you currently smoke? (0) No ⇒ go to Question 14
(1) Yes, on a regular basis
(2) Yes, on occasions

10. At what age did you begin to smoke cigarettes daily? _____

11 Currently, approximately how many cigarettes do you smoke a day? _____

12. Which statement best describes your experience with cigarette smoking:

(0) I have never smoked cigarettes
(1) I occasionally smoke cigarettes
(2) I have smoked cigarettes on a daily basis in the past

13. Have you ever consumed beer, wine, liquor or other alcoholic drinks? (0.5% beer is not considered as alcohol)

(1) Yes (0) No ⇒ go to the end

13. Over the past 6 months, have you ever consumed beer, wine, liquor or other alcoholic drinks?

(1) Yes (0) No ⇒ go to the end

13.How often have you consumed alcoholic drinks during the past 6 months?

Did you drink:

(1) Everyday
(2) 4 to 6 times per week
(3) 2 to 3 times per week
(4) Once a week
(5) Once or twice a month
(6) Less than once a month

Comorbidity Index see recruiter sheet and Charleston comorbid index in the chart audit section

Was this questionnaire filled out by the subject (1) or the caregiver/proxy (0)?

____

Stroke Impact Scale –**16** VERSION 3.0

The purpose of this questionnaire is to evaluate how stroke has impacted your health and life. We want to know from YOUR POINT OF VIEW how stroke has affected you. We will ask you questions about impairments and disabilities caused by your stroke, as well as how stroke has affected your quality of life.
These questions are about the physical problems, which may have occurred as a result of your stroke.

In the past few days, how difficult was it to...	Not difficu lt at all	A little difficult	Somewh at difficult	Very difficult	Could not do at all
1. Dress the top part of your body?	5	4	3	2	1
2. Bathe yourself?	5	4	3	2	1
3. Get to the toilet on time?	5	4	3	2	1
4. Control your bladder (not have an accident)?	5	4	3	2	1
5 Control your bowels (not have an accident)?	5	4	3	2	1
6. Stand without losing your balance?	5	4	3	2	1
7. Go shopping?	5	4	3	2	1
8. Do heavy household chores (e.g. vacuum, laundry or yard work)?	5	4	3	2	1
9. Stay sitting without losing your balance?	5	4	3	2	1
10. Walk without losing your balance?	5	4	3	2	1
11. Move from a bed to a chair?	5	4	3	2	1
12. Walk fast?	5	4	3	2	1
13. Climb one flight of stairs?	5	4	3	2	1
14. Walk one block?	5	4	3	2	1
15. Get in and out of a car?	5	4	3	2	1
16. Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1

VA Structure , Process, and Outcomes of Post-Stroke Rehabilitation
Review Criteria - Acute Episode

Facility:____________________ Unit: ____________________

Admit Date:__________ Discharge Date:__________

Admitted to: (service)
___ Medical
___ Surgical
___ Neurology
___ Intensive Care

Did patient have a neurology consult? ________ (Y/N)

Prior Stroke? (Y/N/UTD) ________

Was patient given TPA, streptokinase or urokinase for this stroke? ________ (Y/N)

I. COMORBIDITIES: (check all that apply)

Myocardial infarct ________
Congestive heart failure ________
Peripheral vascular disease ________
Cerebrovascular disease ________
Dementia ________
Chronic pulmonary disease ________
Connective tissue disease ________
Ulcer disease ________
Mild liver disease ________
Diabetes ________

Hemiplegia ________
Mod./severe renal disease ________
Diabetes with end organ disease ________
Any tumor ________
Leukemia ________
Lymphoma ________

Mod/severe liver disease ________

Metastatic solid tumor ________
AIDS ________

Discharge Modified Rankin Score

___ 00 No symptoms at all

___ 01 No significant disability despite symptoms; able to carry out all usual duties and activities

___ 02 Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance

___ 03 Moderate disability requiring some help, but able to walk without assistance

___ 04 Moderate severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance

___ 05 Severe disability; bedridden, incontinent, and requiring constant nursing care and attention

II. Was there evidence of co-ordinated, multi-disciplinary stroke-related evaluation and services?

Is there documented evidence of services provided by (check all that apply):

		Date of initial contact
Mental Health Professional	______	__________
Speech Therapist	______	__________
Occupational Therapist	______	__________
Physical Therapist	______	__________
Nutritionist/ dietician	______	__________
Social Worker	______	__________
Audiologist	______	__________
Recreational Therapist	______	__________
Kinesiotherapist	______	__________

Was patient admitted to a specialized stroke unit? YES NO

Is there documentation of care by a specialized stroke team? YES NO
(nurses, therapists and physician)

III. Complete documentation of patient's condition and clinical course?

a. Stroke etiology & areas of brain involved	YES	NO
b. Types & severity of neuro deficits	YES	NO
c. Changes in clinical status over time	YES	NO
d. Functional status prior to stroke	YES	NO
e. Was diagnostic CT or MRI performed?	YES	NO

IV. Early initiation of rehab-oriented care , and increase in patient's activity?

1. Did patient have any of the following indications for delaying mobilization: Coma or severe obtundation, progressing neuro signs or symptoms, subarachnoid or intracerebral hemorrhage, severe orthostatic hypotension, acute MI, acute DVT (until adequate anticoagulation achieved), cerebral edema?

YES NO

2. If NO to question 1, were the following items documented?
   a. Position changes and ROM within 48 hrs of admission — YES NO NA

   b. Patient out of bed within 48 hours of admission — YES NO NA

V. Management of general health functions:

a. Was swallowing evaluated? — YES NO
   If YES, did patient have dysphagia? — YES NO NA
   If YES, was consult obtained & program initiated (swallow training, modified food and liquid texture, gastrostomy)? — YES NO NA

b. Was food & fluid intake monitored ? — YES NO

c. Was bladder function/ urinary output monitored? — YES NO
   If YES, did patient have persistent urinary incontinence? — YES NO NA
   If YES, was a management program Initiated (catheter, frequent toileting) — YES NO NA

d. Was bowel function monitored? — YES NO
   If YES, did patient have persistent bowel problems? — YES NO NA
   If YES, were bowel management programs implemented? — YES NO NA

e. Was there any assessment of sleep and rest patterns? — YES NO
   If YES, did patient have sleep disturbances? — YES NO NA
   If YES, were they eval. for cause and interventions implemented ? — YES NO NA

VI. Prevention of Complications

a. DVT – Any of the following: early mobilization, low-dose heparin, LMW heparin, warfarin, intermittent pneumatic compression, elastic stockings — YES NO

b. Skin breakdown – (applicable only if patient not independently mobile) Any of the following: Structured risk assessment, daily skin inspection, routine cleansing, minimize exposure to moisture, avoidance of friction, pressure reduction, upright sitting, nutrition/hydration management, increase of mobility — YES NO NA

c. UTI- (applicable only if patient has indwelling catheters)
Catheter care performed — YES NO NA

d. Seizures –(applicable only if patient has had seizures)
Anticonvulsants — YES NO NA

e. Falls –
Any of the following: Structured risk assessment, supervision of high-risk patients, regular toileting specified for fall prevention, supervision of transfer/ambulation, fall prevention program, pt. & family Education for the stated purpose of fall prevention — YES NO NA

f. Contractures – (applicable for patients with paretic limbs with muscle spasticity)
Any of the following: ROM exercises, splints, nerve blocks specified for treatment of spasticity, medication to manage spasticity — YES NO NA

VII. Prevention of recurrent stroke

a. Identification & control of risk factors (hypertension, smoking, diabetes, elevated cholesterol, heavy alcohol consumption) — YES NO NA

b. Oral anticoag. for patients with a-fib or prosthetic heart valves (not if ischemic stroke not attrib to embolism from heart) — YES NO NA

c. Aspirin or ticlid for strokes secondary to arterial diseases — YES NO NA

d. Referral for evaluation for carotid endarterectomy if stenosis >70% — YES NO NA

e. Surgery to clip intracranial aneurysm or resect AV malformation — YES NO NA

VIII. Patient Assessment

Was a standardized stroke neurological scale used (NIH, Canadian Neurological, etc) YES NO

IX. Screening for formal rehabilitation

1. Is there any evidence of evaluation of the patient's eligibilty for rehabilitation? YES NO

   If YES, date of referral for evaluation ____/___/____

2. Does the evaluation include consideration of:
   a. Clinical status YES NO
   b. Home environment, family support YES NO
   c. Patient and family preferences YES NO

X. Is the patient a candidate for rehabilitation?

a. One or more significant disability __Y__(Y/N)
b. Able to learn __Y__(Y/N)
c. At least moderately medically stable ______(Y/N/UTD)
d. Physical endurance to sit unsupported 1 hour ______(Y/N/UTD)
e. Can patient tolerate 3 or more hrs therapy/day? ______(Y/N/UTD)
f. Does patient have caregiver support at home? ______(Y/N/UTD)
g. Can patient manage IADLs, including meals, phone and transportation? ______(Y/N/UTD)

XI. Complications - Check each event that occurred during the stay:

a. Fall – no resulting injury ______
b. Fall – injury other than fracture ______
c. Fall – resulting in fracture other than hip ______
d. Fall – resulting in hip fracture ______
e. Urinary tract infection ______
f. DVT ______
g. Pulmonary embolism ______
h. Pressure Ulcer ______
i. Aspiration pneumonia ______
j. Recurrent stroke ______
k. Shoulder injury/ painful or frozen shoulder ______
l. Depression ______

Recruiter__________________
Subject Number_____________
Hospital_________________
Room Number_____________

Age_____________ Date of Birth _________________ Gender M F

Date of Stroke_________Date of admission________Date of Discharge_____

Destination – Discharge: 1. Home 2. Rehab____3. LTC 4. Transfer 5. Deceased

Name of resourceperson :_____________________________________ __
Telephone number : ___________________________________

Other person to contact : _____________________________

Telephone number : _____Language : 1.English 2.French 3. English and French

4. Neither English or French

Living : 1. Home 2. Other _____________________

Living with whom : 1. Alone2. Spouse3. Members of the Family 4. Other

Description of stroke event :________________________

List of Comorbid Conditions

1. ________________________________ 4.
____
2. ________________________________ 5.
____
3. ________________________________ 6.
____

Type of Stroke ___________________________________

Is this a first stroke ? 1. yes 2. no 3. not noted

Side of lesion 1. Left 2. Right3. Bilateral 4. None

Side of hemiplegia 1. Left 2. Right3. Bilateral 4. None

Circle any of the conditions or symptoms that were recorded at onset of stroke.

Coma Unconscious Stupor Unresponsive Dizziness
Vertigo Syncope Confusion Memory impairment Headache
Convulsions/seizures Fixed gaze Deviation of eyes DiplopiBlurred vision
Neglect Hemianopia Ptosis Dysphasia DysarthriaDysphagia Vomiting Nausea
Deviation/drop of mouth Tongue deviation Sensory impairment
Deep tendon reflexes hyper or depressed Loss of balance Ataxia Scan

Yes No Not noted

Canadian Neurological Stroke scale

Level of conciousness Alert = 3 Drowsy = 1.5
Orientation Oriented = 1 Disoriented or non-applicable = 0
Speech Normal = 1 Expressive deficits = 0.5 Receptive deficits = 0

A1 No receptive deficit				A2 Receptive deficit			
Face :				Face :			
None = 0.5				Symmetrical = 0.5			
Present = 0	R	L	B	Assymmetrical = 0	R	L	B
Arm proximal :				Arms :			
None = 1.5				Equal = 1.5			
Mild = 1.0	R	L	B	Unequal = 0	R	L	
Significant = 0.5	R	L	B				
Flaccidity = 0	R	L	B				
Arm distal :				Legs :			
None = 1.5				Equal = 1.5			
Mild = 1.0	R	L	B	Unequal = 0	R	L	B
Significant = 0.5	R	L	B				
Flaccidity = 0	R	L	B				
Leg proximal :							
None = 1.5							
Mild = 1.0	R	L	B				
Significant = 0.5	R	L	B				
Flaccidity = 0	R	L	B				
Leg distal :							
None = 1.5							
Mild = 1.0	R	L	B				
Significant = 0.5	R	L	B				
Flaccidity = 0	R	L	B				

<u>Barthel Index</u>

Date :_____________

1. <u>Feeding</u>

   10=Independent5=Some help is necessary 0=Unable to

2. <u>Doing personal toilet</u>

   5=Independent 0=Some help is necessary 0=Unable to

3. <u>Bathing self</u>

   5=Independent 0=Some help is necessary 0=Unable to

4. <u>Dressing and undressing</u>

   10=Independent5=Some help is necessary 0=Unable to

5. <u>Getting on and off the toilet</u>

   10=Independent5=Some help is necessary 0=Unable to

6. <u>Continence on bowels</u>

   10=Independent5=Needs some assistance 0=Unable to

7. <u>Controlling bladder</u>

   10=Independent5=Needs some assistance 0=Unable to

8. <u>Chair/bed transfers</u>

   15=Independent10=Minor help 5=Major help 0=Unable to

9. <u>Walking on a level surface</u>

   15=Independent10=Needs some assistance 0=Unable to

10. <u>Ascending and descending stairs</u>

    10=Independent5=Needs some assistance 0=Unable to

11. <u>Propelling a wheelchair</u> (score only if patient receives 0 on walking item(9))

    5=Independent 0=Needs assistance 0=Unable to

CT MRI Form Coding

Identifying information	ID #	Age in years	Gender Male 1 Female 2	
Date of stroke			Y/mm/dd	-9 unknown
First Scan characteristics and lesion variables seen				
Date of first scan			Y/mm/dd	-9 unknown
Hours from stroke to first scan			Time	-9 unknown
Was the scan done within 24 hours from stroke date?			Yes 1	No 2
Scan is	CT 1	MRI 2	Both done 3 (a second scan is done)	
General Abnormalities on first scan				
Vascular lesion found			Yes 1	No 2
Evidence of mass effect			Yes 1	No 2
Evidence of atrophy			Yes 1	No 2
IS this a silent infarct			Yes 1	No 2
Evidence of leukoaraiosis (any white matter dx)			Yes 1	No 2
Evidence of other abnormalities			Yes 1	No 2
Type of lesion found per new lesion seen on the first scan (if more than one lesion the largest is considered the first lesion)				
Infarct likely causing the indexed stroke 1	Infarct likely prior to the stroke 2	Primary intra cerebral Haemorrhage 3	Vascular abnormality other than 1, 2 or 3 4	No lesion seen 5 see second CT as appropriate
Hemorrhagic infarct 6	Other infarct in the scan 7	Other haemorrh-age in the scan 8		
Lesion site per new lesion seen on the first scan				
Left hemisphere 1	Right hemisphere 2	Cerebellar 3	Brainstem 4	Bilateral hemispheres 5
None 6				
Pathology per new lesion first scan				
Superficial infarct not deep 1	Deep not superficial infarct 2	Both deep & superficial infarct 3	Abnormality other than 1, 2 or 3 4	Not reported 5
No lesion 6				
Anatomy per new lesion first scan				
Frontal 1	Parietal 2	Temporal 3	Occipital 4	Subcortical 5
Cerebella 6	Brainstem 7	Not stated 8	OTHER 9	None 10
Multiple numbers indicates multiple lobes				

CT MRI Form Coding Page 2

Size of the lesion per new lesion first scan				
Small:<0.5cm) 1	Intermediate 2(0.5-1.5cm)	Moderate:1.6-3cm 3	Large:>3cm 4	Massive (multilobar) 5
Not reported 6	No lesion 7			
Second and third new lesion characteristics				
2^{nd} type	Site	Pathology	Anatomy	Size
3^{rd} type	Site	Pathology	Anatomy	Size
Previous lesion seen on the first scan characteristics as per first lesion				
Previous lesion	Yes 1	No 2		
Type	Site	Pathology	Anatomy	Size
Second scan characteristics and lesion variables seen				
2^{nd} scan (CT or MRI) done within 24-72 hours			Yes 1	No 2 //no scan-9
Type of second scan		No second scan -9	CT 1	MRI 2
Hours from first stroke to second scan			**hours**	-9 not done
Lesion seen on second scan not seen on first			Yes 1	No 2// no scan -9
Type of lesion found per new lesion seen on THE SECOND SCAN not seen on the first scan				
Infarct stroke 1	Primary Hemorrhage 2	Vascular abnormality other than 1 or 2 3		No lesion seen 4
Hemorrhage infarct 5		Extension of first lesion 8		No scan -9
Lesion site per new lesion seen on the SECOND SCAN				
Left hemisphere 1	Right hemisphere 2	Cerebellar 3	Brainstem 4	Bilateral hemispheres 5
None 6	No scan -9			
Pathology per lesion SECOND SCAN				
Superficial infarct not deep 1	Deep not superficial infarct 2	Both deep & superficial infarct 3	Abnormality other than 1, 2 or 3 4	Not reported 5
No lesion 6	No scan -9			
Anatomy per lesion SECOND SCAN				
Frontal 1	Parietal 2	Temporal 3	Occipital 4	Subcortical 5
Cerebellar 6	Brainstem 7	Not stated 8	Other 9	None 10// no scan -9
Size of the lesion per lesion SECOND SCAN in cm				
Small <0.5 1	Intermediate 0.5-1.5 2	Moderate 1.6-3 3	Large >3cm 4	Massive (multilobar) 5
Not reported 6	No lesion 7	No scan -9		
Second /third new lesion characteristics on the second scan// if no scan –9				
2^{nd} type	Site	Pathology	Anatomy	Size
3^{rd} type	Site	Pathology	Anatomy	Size

Appendix Ethic Approvals Forms