THE RELIABILITY AND VALIDITY OF THE PSFS IN PEOPLE WITH PD

THE RELIABILITY AND VALIDITY OF THE PATIENT SPECIFIC FUNCTIONAL SCALE INPEOPLE LIVING WITH PARKINSON'S DISEASE.

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A Thesis Submitted to the School of Graduate Studies in Partial Fulfillment of the Requirements for the Degree Master of Science

TITLE: The Reliability and Validity of the Patient Specific Functional Scale in People Living with Parkinson's Disease

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Abstract

Objectives: To assess the reliability and validity of the Patient Specific Functional Scale when administered to people living with Parkinson's Disease.

Methods and Materials: Twenty six people living with Parkinson's Disease from Hamilton and Burlington were interviewed four times within a four month period. The participants answered the Movement Disorders Sponsored Unified Disease Rating Scale part II, the Parkinson's Disease Questionnaire 39, and the Patient Specific Functional Scale. Reliability assessment addressed test-retest reliability and reliability of the change scores using Intraclass Correlation Coefficients. Validity assessment focused on convergent construct validity and longitudinal validity by correlating the Patient Specific Functional Scale with the other measures administered.

Results: The test retest reliability of the scores yielded by the PSFS was ICCpre= 0.72 (95%CI=0.47-0.86); ICCpost=0.83 (95%CI=0.66-0.92). The reliability of change scores was 0.50. In relation to the validity, no significant correlations were found between the Patient Specific Functional Scale and the other measures.

Conclusions: The PSFS yields reliable scores when it is administered to people living with PD. The Patient Specific Functional Scale does not target the same

outcomes as the MDS-UPDRS part II and the PDQ-39. The PSFS does not detect change in functioning in people living with PD within a four month period.

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List of Abbreviations

ADL: Refers to the dimension of “Activities of Daily Living” from the PDQ-39

ADLs: Activities of daily living

BOD: Refers to the dimension of “Bodily Discomfort” from the PDQ-39

COG: Refers to the dimension of “Cognition” from the PDQ-39

COM: Refers to the dimension of “Communication” from the PDQ-39

EMO: Refers to the dimension of “Emotion” from the PDQ-39

ICC: Intraclass Correlation Coefficient

ICF: International Classification of Functioning, Disability, and Health.

MDS-UPDRS: Movement Disorders Society Sponsored Unified Parkinson’s Disease Rating Scale

MOB: Refers to the dimension of “Mobility” from the PDQ-39

PADLS: Parkinson’s Disease Activities of Daily Living Scale

PDQ-39: Parkinson’s Disease Questionnaire 39

PROM: Patient Reported Outcome Measure

PSFS: Patient Specific Functional Scale

PSI: Patient Specific Index

PSI-PD: Patient Specific Index for Physiotherapy in Parkinson's Disease

QoL: Quality of Life

SOC: Refers to the dimension of "Social" from the PDQ-39

SPDDS: Self-Assessment Parkinson's Disease Disability Scale

STI: Refers to the dimension of "Stigma" from the PDQ-39

Declaration of Academic Achievement

I, Gabriela Burgos-Martinez wrote this manuscript and had editing input from Lori Letts, Paul Stratford and Laurie Wishart. The work from other people is properly referenced within the text. The questionnaires in the appendices are appropriately referenced and permission to use them was provided by the corresponding authority.

Chapter I: Introduction

Parkinson Disease (PD) is a neurodegenerative condition classified as an extrapyramidal movement disorder of unknown cause. The main clinical manifestations of PD are bradykinesia, resting tremor, rigidity, and postural instability. As a consequence of the clinical manifestations, people with PD may present a variety of impairments, activity limitations and participation restrictions (Morris, 2000). People with PD usually face increasing disability (Jankovic & Aguilar, 2008; Keus, Munneke, Nijkrake, Kwakkel, & Bloem, 2009). The effect of PD in a person's level of functioning is not only related to the clinical manifestation but to the contextual factors of each individual. Therefore, a comprehensive and individualized assessment of the effect of the disease is necessary for health providers to understand the patient's needs.

In general, health professionals assess the traits of PD with a wide variety of outcome measures. There are a wide variety of measures utilized for the assessment of people with PD. However, there is not a measure available that targets functioning status. Measuring functioning with patient oriented instruments is likely to provide reliable information about the impact of the disease on Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs) and fulfillment of life roles. Functioning is an umbrella term referring to the interaction between body functions, activities and participation. As explained with the ICF, such interaction can be described as level of functioning (World

Health Organization, 2001). Assessment of functioning rather than just impairment recording (problems in body function and body structures), allows health professionals to understand the impact of disease on a person (Hagell, Reimer, & Nyberg, 2009; Lohr & Zebrack, 2009; Martinez-Martin, Rodriguez-Blazquez, & Frades-Payo, 2008). Currently, the assessment of functioning is done through the clinical assessment and application of questionnaires (mostly rater based) focused on the ability to perform ADLs in the clinical setting (Martinez-Martin et al., 2008). The measurement of functioning is complex because it is a concept composed by various factors, body functions, contextual factors and personal factors. In addition when utilizing rater-based outcome measures, these reflect the perspective of a third party, as opposed to the perspective of the person being assessed. Therefore, when attempting to obtain a measurement with as much veracity as possible, it is preferable to approach the source, specifically the patient. For example, the level of functioning of three people with the same impairments will vary according to their roles in life and contextual factors. It is therefore necessary to use a patient-centred approach to assess functioning. This understanding may result in a better health care for the person.

Due to the increased recognition that patient-centred care is a good approach for the management of health, measures that assess traits from the patients' perspectives have been increasing in popularity and number. These

measures are known as Patient Reported Outcome Measures (PROMs) (Martinez-Martin et al., 2008). The Patient Specific Functional Scale (PSFS) is a PROM that assesses the level of disability. The PSFS was created to gain insight into the functioning limitations and their level of difficulty caused by certain musculoskeletal conditions as perceived by the respondent. The nature of the PSFS allows its adaptation to different populations (Stratford, Gill, Westaway, & Binkley, 1995). Additionally, the burden of its administration is very low for the rater and for the respondent, an important characteristic of outcome measures. Therefore, the PSFS seems to be an outcome measure suitable for the assessment of functioning in people with PD.

This thesis provides a description of the validation of PSFS in people living with PD. Chapter 2 contains a description of the background and rationale for the research question. In chapter 3, the study design is described as well as the procedures for the completion of the study. Chapter 4 provides study results. Chapter 5, the discussion chapter, expands on the previous chapters and provides the interpretation of results. The discussion chapter refers also to the limitations of the study, implications and suggestions for future work, and finally the concluding remarks of this work.

Chapter II: Background and Literature Review

Chapter Introduction

The purpose of this chapter is to provide the background for the project that is described in this thesis. This chapter first provides an overview of functioning as explained by the International Classification of Functioning, Disability, and Health. Second, the effect of Parkinson's Disease on functioning is described. Following is an overview of the measurement of functioning in people with Parkinson's Disease. Finally, the Patient Specific Functional Scale is introduced.

2.1 Functioning

The International Classification of Functioning, Disability, and Health (ICF) is a multipurpose classification that provides a framework for the description of health (WHO, 2001). The ICF facilitates the communication between professionals with the use of the classification scheme that allows use of a standardized language. The ICF can be utilized as a descriptive tool, to inform outcome measurement, to inform clinical assessments, facilitate social policy planning, and to elaborate educational curricula (WHO, 2001). The ICF contains health and health-related domains described by categories. Such categories refer to an individual's situation described from a biopsychosocial perspective, thus considering not only biological characteristics intrinsic to the person but also

environmental and personal factors. The ICF framework (Figure 2.1) is formed by two parts and each is divided further into various components. Part one, Functioning and Disability, contains the “Body” component in which body structures and body functions are described. These two components describe body parts and their functions from a physiological perspective. Contained also in Part I is the component of “Activities and Participation”. This component describes a wide range of activities that range from simple tasks to complete participation activities. The second part, Contextual Factors, contains the “Environment” component and a “Personal Factors” component (WHO, 2001). The environment component describes everything that is external to the human including things, places and other persons. The description of these four components allows a comprehensive view of the functioning level of a person. Functioning as defined by the ICF refers to the positive interaction between body structures, body functions, activities and participation, and the contextual factors. When such interaction is negative, the term utilized is disability (WHO, 2001). Consequently, functioning and disability can be seen as part of a continuum, where the positive end is the maximum level of functioning and the negative end is the maximum level of disability. It is pertinent to clarify that the word “function” is sometimes used in literature and in oral communication to denote what according to the ICF framework is functioning. However, within the ICF framework “function” is only used in association with body structures and refers to physiological processes of the human body. When there is something

pathological interfering with body function or a body structure it can be referred to as impairment.

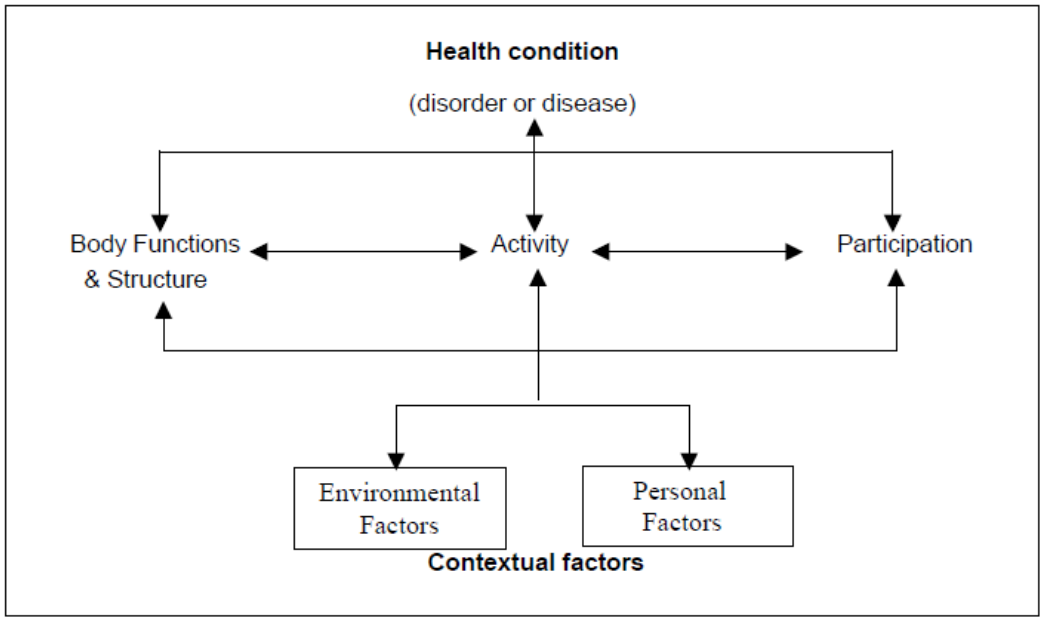

Figure 2.1 Internation Classification of Functioning, Health and Disability from: WHO, "Towards A Common Language For Functioning, Disability and Health", 2002, electronic resource, http://www.who.int/classifications/icf/training/icfbeginnersguide.pdf.

2.2 Parkinson's Disease and Functioning

Parkinson's disease (PD) is a neurodegenerative condition characterized as an extrapyramidal movement disorder of unknown cause. PD affects 1% of the adult population with a median of nine years between diagnosis and death (Clarke, 2007). PD pathogenesis involves the basal ganglia (the globus pallidus, putamen, caudate and subthalamic nuclei) and the brain stem. The pathological hallmarks are the loss of dopaminergic neurons and the inclusion of Lewy bodies

(spherical, palid structures with an eosinophilic nucleus also found in other diseases) in the brainstem and cerebral cortex (Greenfield, Love, Louis, & Ellison, 2008). The loss of dopaminergic neurons in the substantia nigra pars compacta results in reduced excitation of striatal neurons due to decreased dopaminergic input. The inefficient striatal neurons cause a lessened inhibition of the subthalamic nucleus by the globus palidus. Without an adequate inhibition of the subthalamic nucleus, the basal ganglia-motor cortex neurotransmission loop disorganizes, and together with the Lewy body inclusions result in the PD clinical manifestations (Greenfield et al., 2008; Harris et al., 2009; Morris, 2000).

PD main impairments include bradykinesia, resting tremor, rigidity, and postural instability. Bradykinesia is defined as slowness of movement (National Collaborating Centre for Chronic Conditions, 2006). Resting tremor affects mainly the extremities; it usually initiates unilaterally and is always more prominent distally (Harris et al., 2009). Rigidity affects mostly the neck, wrists, shoulders and ankles, and contributes to the characteristic stooped posture. Postural instability is a consequence of the stooped posture and the lack of effective postural reflexes (Harris et al., 2009). The interaction between impairments and contextual factors in people living with PD translate into activity limitations and participation restrictions, eventually leading to disability.

Slowness of movement may present when performing certain activities, like walking. People living with PD may encounter difficulties in walking forward and backward, side stepping, turning, and control of the initiation and end of

walking. Slowness of movement can be complicated with rigidity and postural instability. Consequently, community ambulation and mobility around the home are often jeopardized, leading to a decrease in participation. Slowness of movement can also be present when carrying out non-mobility activities, like gross motor tasks involving the upper limbs, such as carrying or lifting things. As well, further complicated by other manifestations and the interaction of the contextual factors can lead to an undesired level of functioning. Communication ability can also be influenced by PD, and have an effect on the functioning state of the individual. People with PD may have difficulties maintaining their voice pitch and may lack facial expression, which affects communication and this may interfere with the relationships in social, family, and professional environments. In addition to the impact inherent to PD, the contextual factors of the person also have an effect on functioning. It is often difficult to differentiate if the primary cause of functioning limitations is PD related, contextual factors, or a combination of both. Some of the contextual factors that vary from person to person are factors like age, cognitive impairments, personality traits, economic and education level; or environmental factors like support from others, architectural barriers, and access to resources.

2.2.1 Importance of the measurement of functioning in people with PD

PD affects at various levels the life of people living with the disease. Consequently, the assessment and management of people living with PD has to go beyond impairments (Escorpizo et al., 2010). The use of the ICF as a guide to assess functioning allows shifting the attention from the body structures and functions, to activities and participation (Escorpizo et al., 2010). It has been suggested that the ICF should be utilized as a framework for the management of people living with PD, and that the assessment of functioning is pertinent in people living with PD (Keus et al., 2004; Nieuwboer, Rochester, & Jones, 2008). Such assessment of functioning could allow for a comprehensive description of the interactions of body functions and structures, and the contextual factors as reflected on the activities and participation component. PD is a chronic condition that varies from person to person, and the effect on functioning is different in every person regardless of the clinical manifestations and disease severity. Consequently, the assessment of functioning should be the starting point to improve well-being (Lollar & Simeonsson, 2005). Furthermore, multidisciplinary care is a common practice for the management of people with PD (Johnston & Chu, 2010), and the assessment of functioning allows for a better understanding of what each discipline could offer to the person without ignoring the patient's contextual factors.

2.2.2 Challenges for the measurement of functioning in people with PD

People living with PD present a decrease in the level of functioning at some point in the disease, and disability eventually sets in (Keus et al., 2009). However, the rate of the disease progression, the presentation of the clinical manifestations and the contextual factors are very different for every person. Therefore, as it happens with other chronic conditions, there is not a single assessment or management process that can capture appropriately the situation of every person. Consequently, there are challenges that come with the management and the assessment and people living with PD (Keus et al., 2009; Keus, Munneke, Nijkrake, Kwakkel, & Bloem, 2009; Nieuwboer Weerdt, Dom, & Bogaerts, 2002). For the assessment of functioning, the challenges may be those presented by the effects of age, cognitive state, personality, economic level, education level, support, and medications.

2.2.2.1 Age

The usual age at PD onset is 70 years (Harris et al., 2009). At that time, people with PD are likely to have comorbidities particularly those related to aging (Nanhoe-Mahabier et al., 2009). The effects of comorbidities and PD are often cumulative and have an overall effect in the person's life (Nanhoe-Mahabier et al., 2009). The measurement of functioning allows a comprehensive assessment

regardless of the comorbidities. However it is often difficult to discriminate the effects of PD from the effects of aging or other common chronic conditions (Nanhoe-Mahabier et al., 2009). For example, a woman with PD may complain about slowness of movement, memory loss, and present with balance impairment; all of these could be explained by PD but also by the natural aging process.

2.2.2.2 Medications

Currently, pharmacotherapy is the mainstay of the management of people living with PD. The efficacy and safety of medications vary across patients. The efficacy of levodopa, one of the most common drugs used in PD, decreases over time as well as induces fluctuations in the control of the motor functions. Another very important factor introduced by the medication is the presence of “on” and “off” states, particularly in people who have been taking levodopa for more than five years (Martin & Wieler, 2003). The On/Off state refers to the motor fluctuation that people living with PD experience in relation to pharmacokinetics of the levodopa. During the On state, the medication is working at the ideal level so it has a maximum effect and motor control is the least affected (Martin & Wieler, 2003). On the other hand, during the Off state the medication is starting to wear off or is already worn off so the motor control is very affected (Mattox, Port, Lin, & Bero, 2001). Adverse events include dizziness, edema, nausea, hypotension,

somnolence, and hallucinations. Many people have difficulties in getting the most effective dose and drug combinations. Usually, patients try different doses and medications until best response is achieved (Cubo, 2010; Hayes, Fung, Kimber, & O'Sullivan, 2010; Martin & Wieler, 2003; Mattox et al., 2001). The effectiveness of the medication, together with the adverse and long term use effects may present a layer of complexity to the functioning status. Therefore, the medication scheme should be considered when assessing functioning.

2.3.2.3 Cognitive State

People living with PD may present with cognitive impairments. Skills for visual construction, attention, concentration and verbal fluency have been associated with the decrease in functioning and poor quality of life (QoL) (Muslimovic, Post, Speelman, Schmand, & de Haan, 2008). Functioning is different for every person. Therefore, the way each person experiences functioning can only be understood when the person expresses actively his or her experiences. Unfortunately, cognitive impairments may be a barrier for the assessment of functioning, and at the same time they could be the cause for the decrease in functioning. Consequently, the assessment of people living with PD who have cognitive impairment poses a challenge for health providers, not only for assessing functioning but for communicating during the assessment as well.

2.2.2.4 Economic and Education Level

As a consequence of therapy, productivity and disability, PD may be a highly costly disease (Hayes et al., 2010). It has been reported that people with higher economic level and higher education present lower disease severity as measured by the UPDRS than people with lower economic and education level. This could be the result of different factors, which include differences in the prescription and use of medications, access to healthcare, and actual purchase power for environmental adaptations and health care (Hemming et al., 2011). Whatever the reason, disease severity can be affected by economic and education factors, which is parallel to functioning limitations. As functioning is not only affected by the disease but also by the contextual factors, economic and education levels play an important role in the decrease of functioning (Hemming et al., 2011). Therefore, contextual factors like economic and education level should be integrated in the assessment of functioning of a person living with PD.

2.2.3 Current measurement of functioning in people with PD

Functioning is a complex outcome to measure because it is not observable or tangible. Neither biomedical markers nor units to measure functioning exist. Functioning is an individual trait and varies from person to person regardless of the similarities in the clinical manifestations. Consequently, the measurement of

functioning in people living with PD, is done through questionnaires, physical assessment, and clinical history (Keus et al., 2004). A comprehensive patient-centred assessment of activities and participation is not available; instead measures commonly utilized target capacity and body function. As previously explained, the term body function is used in relation to body structures and their physiology. Capacity refers to the ability of an individual to carry out specific tasks in controlled environments and this could indicate the highest level of functioning possible. Performance describes what the individual experiences in his or her environment (World Health Organization, 2001).

It has been suggested that the measurement of functioning could be done by selecting outcome measures according to the ICF framework (Keus et al., 2004). An outcome measure for each component or a measure that integrates all of the components would be adequate. The questionnaires that aim to assess functioning through the assessment of activities and participation with a patient-centred focus may be comprehensive enough to understand functioning. Additionally, utilizing the ICF as a framework for guiding the physical assessment and obtaining the clinical history may provide further information about functioning.

2.2.3.1 Types of outcome measures

There are different measures that are currently in use for the assessment of people with PD. These measures can be generic or disease-specific, and could be rater based or patient reported. Generic measures are designed to assess traits that are common across different populations (Riazi, 2006). Generic measures contain items that cover a wide range of disorders that might be found across the umbrella population e.g., seniors, children, etc. The problem with this type of measure is that in order to cover a variety of populations, the measure may be long and the items are often very general. For instance, the Barthel Index is a generic measure of independence for carrying out Activities of Daily Living (ADLs) used across people with neurological and musculoskeletal conditions (Mahoney & Barthel, 1965).

Disease specific measures are designed to assess attributes in relation to what is relevant for a disease. The intent of these measures is to reflect relevant issues for a specific disease (Riazi, 2006). Disease specific measures are often created with the input of stakeholders. These measures target particular traits only found in people with the specified disease. For instance, items regarding freezing of gait, which is commonly found in people living with PD, may be included in a PD specific measure but would not be included in a measure for people with osteoarthritis. The use of these types of measures may pose a challenge when the respondents have concomitant diseases.

Generic and disease specific measures can be rater based or patient reported outcome measures. Rater based measures asses the outcome through observation, or questionnaire administration. Rater based outcome measures are believed to be more objective than patient reported outcome measures. An example of a rater based outcome measure is the Berg Balance Scale, in which the assessor observes how the person carries out specific tasks and registers the capacity of the individual (Berg, Wood-Dauphinee, Williams, & Maki, 1992). Patient reported outcome measures (PROMs) are designed to assess the outcome of interest according to the perspective of the respondent. An example of a patient reported outcome measure is the Australian/Canadian Hand Osteoarthritis Index; this measure assesses pain, disability and joint stiffness though 15 self-reported questions (Bellamy et al., 2002).

2.2.3.2 Measures commonly used for the assessment of people living with PD

The Movement Disorders Society Sponsored Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is the most widely used, disease-specific outcome measure in clinical trials and clinical settings (Goetz et al., 2008). It is a rater based outcome measure but some parts can also be used as patient-reported. The MDS-UPDRS is a clinical assessment tool that is divided into four parts; non-motor aspects of daily living, motor aspects of daily living, motor examination, and motor complications. The MDS-UPDRS assesses body functions and for

some items, it assesses how body functions affect their daily activities (Goetz et al., 2008). However, the MDS-UPDRS does not assess functioning in a consistent manner, and it does not cover environmental or personal factors, which can influence functioning. The psychometric analyses were done with a respondent sample of 877 subjects with PD with a full breadth of disease severity. Internal consistency was assessed for each part, Part I: α=0.79; Part II: α=0.90; Part III: α=0.93; and Part IV: α=0.79. Discriminant validity between the parts was assessed and only Part I and II showed a moderate correlation among them (r=0.67) and can be explained by the focus of both parts on assessment of daily living despite referring to motor and non-motor symptoms respectively. Factorial analysis was also performed and the results provide assurance that each of the parts should be scored independently and that each one of the four parts can be used independently (Goetz et al., 2008).

The Hoehn and Yahr (HY) scale is commonly used to classify the severity of PD. The HY has been found to be the most responsive measure for PD (Zhao et al., 2010). The HY scale is a rater based five point scale that is used to rate the severity of the disease from a motor perspective that includes postural instability and mobility (Goetz et al., 2004). Stage 1 comprises unilateral involvement and little or no disability, stage 2 comprises bilateral involvement without balance problems, stage 3 comprises bilateral affection with postural instability and balance impairment, stage 4 comprises severe disability while still being able to walk or stand without assistance, stage 5 comprises confinement to bed or

wheelchair bound without assistance (Goetz et al., 2004). There is very limited information on the psychometric properties if the HY. Intra rater reliability has been reported from 0.44 and 0.71. The face validity of the measure is difficult to establish because it confounds impairments and functioning. However, criterion validity has been tested and it is acceptable (Goetz et al, 2004).

The Parkinson Disease Questionnaire 39 (PDQ-39) is a disease specific patient reported questionnaire that assesses the health status of the clients through eight subscales or dimensions: activities of daily living (ADL), bodily discomfort (BOD), cognition (COG), communication (COM), emotional well-being (EMO), mobility (MOB), social support (SOC) and stigma (STI) (Peto, Jenkinson, Fitzpatrick, & Greenhall, 1995). Similar to the MDS-UPDRS, the PDQ-39 covers various components of functioning; however its multidimensionality makes it difficult to interpret the results in relation to the functioning level. Test retest reliability was examined within a 2 to 6 day period of stability and difference between tests was not calculated with an Intraclass Correlation Coefficient (ICC), but rather with a t-test analysis which yielded no significant differences between tests ($p=0.05$)(Peto, Jenkinson, & Fitzpatrick, 1998). The use of a t-test does not provide information about the error as an ICC would. Additionally the PDQ-39 shows a good level of agreement ($p<0.001$) with the Hoehn and Yahr (HY) scale throughout all the dimensions except for the social support dimension (Peto et al., 1998). In another study using the Swedish version, the test retest-reliability was assessed using an ICC with a 95%Confidence Interval (CI) and all the values

were acceptable except the CI of SOC includes a value lower than 0.70 (Hagell & Nilsson, 2009).

There are few disease specific measures that intend to assess functioning or components of it. Existing measures include the Self-Assessment Parkinson's Disease Disability Scale (SPDDS), the Parkinson's Disease Activities of Daily Living Scale (PADLS), and the Patient-Specific Index for Physiotherapy in PD (PSI-PD) (Martinez-Martin et al., 2008; Nijkrake et al., 2009). The SPDDS was created as a measure of disability and is formed by items that assess the performance of activities (daily living and instrumental) and ability to perform frequent tasks like getting up from a chair, climbing stairs and turning in bed (Biemans, Dekker, & van der Woude, 2001). The SPPDS is formed by items that assess different constructs so the interpretation of the total score is difficult due to multidimensionality. The PADLS provides a global rating of the respondent's perception about difficulty for daily living activities caused by PD. For the PADLS, respondents choose one out of five options that best describes their situation; the possible options range from "no difficulties with day-to-day activities" to "extreme difficulties with day-to-day activities" (Hobson, Edwards, & Meara, 2001). The Patient Specific Index (PSI) was originally created for the assessment of the impact that low back pain has on functioning. The PSI elicits the effort needed when doing motor tasks; respondents choose items that they relate to from a given list, then rank their selections and provide a rating of the level of difficulty to carry out the selected tasks. The selection list from the PSI was adapted to fit

common complaints from people living with PD by selecting items through a survey on frequent limitations among people with PD and resulted in the PSI-PD (Nijkrake et al., 2009). Items in measurement instruments like the PADLS, SPDDS, and the PSI-PD are obtained from a pool of items appropriate for the population for whom the instrument is intended. Those items become permanent once the most relevant ones have been identified through a process called item reduction (Streiner & Norman, 2008). It is possible that not all of the people from the target population will relate to every single item (Stratford et al., 1995). This is an issue when the trait measured is as complex as functioning in a heterogeneous population like people with PD, because everyone has different roles in life and expectations associated with those roles. In the case of the PSI-PD, the items are selected by the respondent from a predefined list of items that are distributed in a wide spectrum of mobility tasks and activities. There is the option for respondents to create their own items if none of the predefined items is relevant for the respondent; however, the fixed items on the list can introduce respondent bias by steering the respondents' focus to the specified items because respondents might interpret these as the "preferred" activities to be reported. This might be similar to the acquiescence bias where the respondent has a tendency to confirm what questionnaires state by responding to the items in a positive manner (yes, always, often, a lot) (Streiner & Norman, 2008). Additionally, the option to create their own items is at the very end of the predefined list, which introduces a risk for bias because respondents might have

filled in all the spaces despite not being the most relevant for them and it is easier to leave them than to start over again. While tools with fixed items may provide relevant information, it is important to complement them with an instrument that allows a thorough understanding of the way patients perceive that PD affects their functioning and participation in life. Utilizing an open item tool to elicit their functioning concerns could be an option.

2.3 The Patient Specific Functional Scale

The Patient-Specific Functional Scale (PSFS) is a patient-reported outcome measure without predefined items that was developed to complement generic tests and to provide a means to detect change in disability over time (Stratford et al., 1995). The psychometric properties of the PSFS have been assessed in individuals with low back pain, neck dysfunction, cervical radiculopathy, neck pain, and knee pain. For those conditions, the PSFS provides reliable scores and is a validated outcome measure (Chatman et al., 1997; Cleland, Fritz, Whitman, & Palmer, 2006; Jolles, Buchbinder, & Beaton, 2005; Sterling & Brentnall, 2007; Westaway, Stratford, & Binkley, 1998). Furthermore, the PSFS is a validated indicator of functioning for workers' compensation claimants (Gross, Battie, & Asante, 2008).

The PSFS has the potential to be used for a wide range of populations including people with chronic neurological conditions because the individual item generation allows the tool to adjust to different age groups and conditions (Costa

et al., 2008; Sterling & Brentnall, 2007; Westaway et al., 1998). The use of the PSFS in the Parkinson population could enhance health providers' understanding about the needs of the patients because the scale focuses on the creation and assessment of items that are relevant for the respondent (Cohen & Marino, 2000). The PSFS elicits functioning status in the present, so recall bias is avoided (Stratford et al., 1995). Additionally, the PSFS is easy to administer and free of charge (Sterling & Brentnall, 2007).

Considering the lack of an open item, and patient specific outcome measure for PD that allows the assessment of change over time in functioning from the patients' perspective, and the strengths of the PSFS, it is worthwhile to investigate the use of the PSFS in people with PD. Therefore, the purpose of this study was to assess the reliability, validity and ability to detect change over time of the PSFS when applied to people living with PD.

Conclusion of the chapter

The background of the thesis was presented in this chapter, which includes a description of functioning in people with Parkinson's Disease, and the current measurement of functioning in people with Parkinson's Disease. This chapter also contains the description of the Patient Specific Functional Scale. The chapter ends with the study purpose which is to validate the Patient Specific Functional Scale for the assessment of functioning in people living with Parkinson's Disease.

Chapter III: Methods and Materials

Introduction of this chapter

This chapter provides a review of the methods and materials that were utilized to answer the research question: To what extent is the Patient Specific Functional Scale reliable, valid, and responsive to change for the assessment of functioning in people living with Parkinson's Disease?

3.1 Study Design

A longitudinal single group repeated measures design (Figure 3.1) was used to answer the research question. The study was designed to enable the assessment of test retest reliability, convergent construct validity and longitudinal validity of the Patient Specific Functional Scale (PSFS). The chronology of the study was specified in accordance to the psychometric properties that would be evaluated. One of the objectives of the study was to assess longitudinal validity for distinguishing whether or not change over time could be detected with the PSFS. Therefore, a period of four months was set between Time 1 (T1) and Time 3 (T3), which was reported to be enough time to detect change in the functioning of people living with Parkinson's Disease (PD) (Peto et al., 1995). A period of three to five days between T1 and Time 2 (T2), and T3 and Time 4 (T4) was set because change was not expected to occur in that time. Another objective of the study was to assess the reliability of the scores yielded by the PSFS. Therefore, four repeated measures were included in the design in order to have two periods

of stability with enough time between them so that change in functioning would happen (T1-T2 and T3-T4). With the repeated measures set this way, it was possible to assess the reliability of the scores of the PSFS during a period of stability and once change had occurred.

The questionnaires were administered to the participants at the four different times. At T1, severity on the Hoehn and Yahr (HY) scale was determined and the subjects responded to the PSFS, part two of the Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) and the Parkinson Disease Questionnaire 39 (PDQ-39). At T2, three to five days after T1, participants responded to the PSFS. At T3, four months after T1, participants responded to the PSFS, PDQ-39 and the MDS-UPDRS. At T4, three to five days after T3, the HY level was determined, participants responded the PSFS, and rated their change on a 15 point scale.

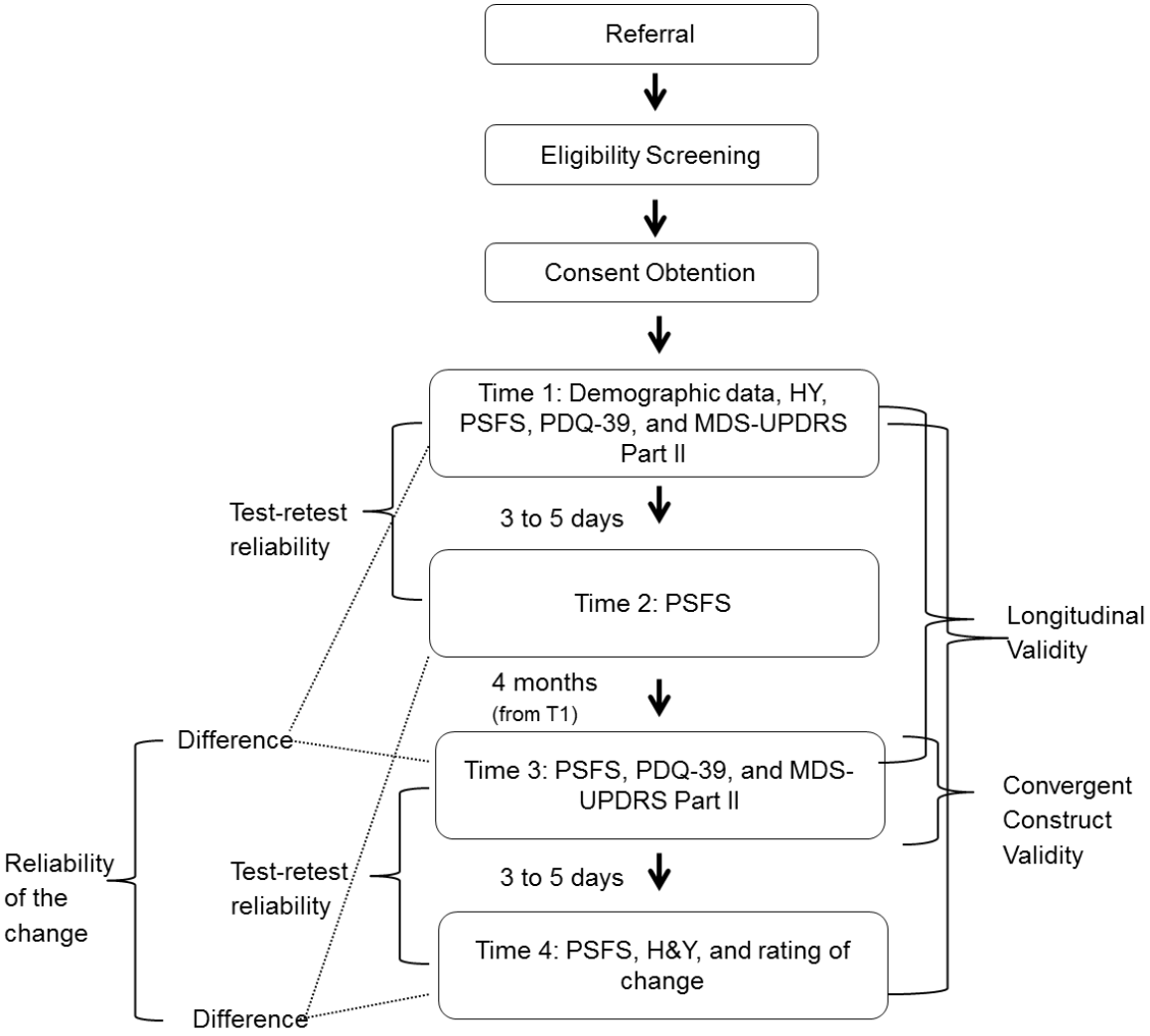

Figure 3.1 Study Design

For measures which purport to assess change over time such as the PSFS, it is particularly important to assess the reliability of the change scores. The scores should not only be stable during a period without change, but the scores should continue to be stable after change has occurred. Reliability of the scores obtained with the PSFS was assessed using two different approaches:

test-retest reliability and reliability of the change score. Test retest reliability was assessed to determine if the scores obtained with the PSFS can distinguish among persons at a point in time. The reliability of the change score assessed the ability of a measure to detect differences in change scores among participants (Streiner & Norman, 2008). Convergent construct validity was assessed in order to identify how the PSFS relates to other measures, the MDS-UPDRS and PDQ-39, which assess components of functioning in people living with PD. Longitudinal validity of the PSFS to measure change was assessed by comparing its change scores to change scores of the MDS-UPDRS, PDQ-39, HY scale, and the participants' global rating of change.

3.1.1 Participants and Recruitment

Study participants were men and women older than 45 years with a diagnosis by a neurologist of Idiopathic Parkinson Disease. Participants were excluded if they had any other disease that causes more impact on functioning than PD. For example if a person had PD but had had a stroke and the functioning was affected by the event, then that patient was excluded during the eligibility screening process before signing the consent form. The participants had to understand and provide consent; if his or her cognitive status did not allow for that to happen they were excluded from the study. Participants were also excluded if they were unable to commit to the assessment times, or were bed ridden.

After obtaining approval from the Hamilton Health Sciences/McMaster Research Ethics Board (Appendix 1), participants were recruited at St. Peter's Hospital from Hamilton Health Sciences and through the Parkinson Society of Canada. The principal investigator (PI) introduced the study to the referred potential participants in person or by telephone (Appendix 2). Those who agreed to participate and were eligible signed the consent and set an appointment for T1. Potential participants in the cities of Burlington and Hamilton were also contacted through letters mailed by the Parkinson Society Canada. The letters contained the information letter (Appendix 3) and an REB approved flyer (Appendix 4).

3.1.1.1 Sample Size Calculation

The statistical approach for the assessment of psychometric properties of measures can be conducted in two ways, by testing a hypothesis or estimating a parameter. The first option, testing a hypothesis, is used when there is the premise that the property assessed will surpass or be at least an expected single value. For the second option, estimating a parameter, there is no expectation about reaching a predetermined value, but rather to determine where the population value is likely to lie within a given confidence interval (CI). In the case of the parameter estimation only the alpha value is considered for the sample size calculation. The parameter estimation approach is more suitable when there is not sufficient information available to formulate a hypothesis. In the case of this study, parameter estimation was chosen because there was not previous

statistical information about the performance of the PSFS in people with PD that would allow formulating a hypothesis. The estimation of the sample size for the reliability parameter was based on a lower 1-sided 95% CI wide of 0.10 (0.70-0.80) and an anticipated reliability of 0.80. For the convergent construct validity and longitudinal validity parameters, the sample size was calculated based on an estimated correlation of 0.80 between the PSFS with the PDQ-39 and the MDS-UPDRS part II and a 95%CI wide of 0.10 (0.70-0.80). Applying these assumptions and an adaptation of the sample size formula of Stratford and Spadoni (beta was removed from the equation), 53 subjects were required. (Norman & Streiner, 2008; Stratford & Spadoni, 2003).

3.1.2 Instruments

For the collection of the demographic data, the interviewer followed the data form (Appendix V). The HY level was determined according to the status of the participant in the first assessment following the scale description by Goetz and colleagues (Goetz et al, 2004). The scale descriptors of the PSFS were adapted from its original version (Stratford et al., 1995) in order to comply the characteristics of the PD population (Appendix 6). The Canadian version of the PDQ-39 was utilized. As for the MDS-UPDRS, it was the second part which was administered. For the assessment of change, in addition of utilizing the measures already mentioned, a global rating of change (Appendix 6) was utilized as a potential criterion for change as it had been previously reported that if patients

reported a retrospective global rating of change it could provide a parameter for change (Stratford, Binkley, and Riddle, 1996). This type of rating was utilized because of the complexity of functioning. The use of a global rating of change as an anchor relates better to a clinical event as opposed to a statistical significance value because the second option is difficult to interpret particularly with outcomes that are complex (Lydick & Epstein, 1993). The global rating of change of change utilized in this study was a patient version with a 15-point-scale were the respondent would report the change from the first visit to the present day (Stratford et al, 1996).

3.1.3 Data Collection Procedures

Four appointments were scheduled with each participant. In the appointments, the participants answered questionnaires with the PI. People with PD often have difficulty writing (Greenfield et al., 2008), therefore the questionnaires were administrated in an interview format rather than having the person fill in the questionnaires (Appendix 5). At T1, after obtaining demographic data, the measures were administrated, starting with the PSFS, followed by the MDS-UPDRS and the PDQ-39. At T2 only the PSFS was administrated. At T3, the order was the same as T1 excluding the demographic data. At T4, the PSFS was administrated first and then the restrospective global rating of change. The order of instrument administration was the same for every participant with all measures administrated by the PI.

It was anticipated that the attendance at a specific location four times within four months would be difficult for the participants considering that transportation might be a barrier because of the characteristics of the target population. Consequently, participants were offered to have the interviews over the phone or in person. When the interviews were in person, the participants could choose to go to St. Peter's Hospital or McMaster University. Parking costs were reimbursed when applicable.

3.2 Analyses

3.2.1 Reliability

The assessment of the reliability of a measure provides information on the amount of error associated with the measures obtained. The error can be estimated for the different sources of error (i.e., error inherent to the measure or error related to the rater). Reliability is important because it sets an upper limit on validity (Finch, Brooke, Stratford, & Mayo, 2007).

3.2.1.1 Test-Retest Reliability

Test retest reliability was assessed for pre (T1 T2) and post (T3 T4) measurement pairs. The test-retest reliability coefficient was calculated using the following formula (Streiner & Norman, 2008): $ICC\ 2.1 = \frac{\sigma_s^2}{\sigma_s^2 + \sigma_e^2 + \sigma_o^2}$ The

number of this expression contains the variance due to participants and the denominator contains the total variance.

3.2.1.2 Reliability of the change scores

The PSFS was designed to assess change over time. Therefore the assessment of the error associated with the measures obtained should include the variance of the pre scores and the variance of the post scores. Consequently, the correlation of the variances of the pre-tests and the post-tests was performed for the assessment of the reliability of change scores. The reliability coefficient of the change scores was obtained with the formula

$$r\ (D) = \frac{\sigma_X^2 R_{XX} + \sigma_Y^2 R_{YY} - 2\sigma_X \sigma_Y r_{XY}}{\sigma_X^2 + \sigma_Y^2 - 2\sigma_X \sigma_Y r_{XY}}$$ (Streiner & Norman, 2008).

3.2.2 Convergent Construct Validity

For the assessment of convergent validity, the PSFS was compared to the MDS-UPDRS, and PDQ-39 by calculating the correlation among them. For the correlation with the PDQ-39, the correlation was calculated for the measure's total score, utilizing the SI, and also for each dimension. The formula utilized to obtain the correlation coefficient takes into account the covariance of both variables, and their standard deviations. Commonly known as the Pearson

correlation coefficient, it is expressed as follows $r=\frac{cov(X,Y)}{\sqrt{var(X)\cdot var(Y)}}$ (Norman & Streiner, 2008).

3.2.3 Longitudinal Validity

For the assessment of the ability of the PSFS to detect change, a comparison was performed using the Pearson correlation coefficient depicted in the previous paragraph. One set of comparisons included the correlation of the change detected between T1 and T3 with the PSFS and the change detected with the MDS-UPDRS, the PDQ-39 and each dimension of the PDQ-39 from T1 and T3. Another set of comparisons with the same correlation coefficient was done with the change detected between T1 and T4 by the PSFS, the HY scale, and the global rating of change.

Conclusion of the chapter

This was a longitudinal single group repeated measures study designed to evaluate the psychometric properties of the PSFS when administered to people living with PD. Hamilton Health Sciences/McMaster Research Ethics Board approved the protocol of the study. Participants were recruited at St. Peter's Hospital and through the PD Society, aiming to achieve 53 subjects. Participants met with the PI at four different points in time over a four-to-five-month period. At T1, demographic data and the severity on the HY scale were obtained and the

PSFS, MDS-UPDRS, and PDQ-39 were completed. In T2 the PSFS was administered. In T3 the participants responded to the PSFS, MDS-UPDRS, and the PDQ-39. In T4 participants responded the PSFS and global rating of change, and the severity on the HY scale was obtained. The analyses consist of comparison among measures and the approach varies according to the assumptions for each of the properties being assessed.

Chapter IV: Results

Introduction

This chapter provides the findings of the study. It summarizes the study development, including information about the recruitment, sample characteristics, and the results of the analyses of the reliability and validity of the Patient Specific Functional Scale when administered to people living with Parkinson's Disease.

4.1 Study Timeline

Upon approval from the Ethics Board, the study began in November of 2010. Recruitment was completed between November 2010 and March 2011. Data collection occurred between November 2010 and June 2011. Figure 4.1 depicts the study timeline.

Yr	Month	Ethics Procedures	Recruitment	T1 and T2	T3 and T4	Data analyses
2010	September	●				
	October	●				
	November		●	●		
	December		●	●		
2011	January		●	●		
	February		●	●		
	March		●	●		
	April				●	
	May				●	
	June				●	●

Figure 4.1 Study Timeline

4.2 Recruitment Flow

Of the 250 letters mailed through the Parkinson's Society, twelve letters were returned to sender because of incorrect address, three recipients had passed away, one refused to participate in the study and thirteen consented to participate. The other 221 letters resulted in no response. Twenty of the participants were referred from St. Peter's Hospital and three others heard about the study through word of mouth. In total, 37 participants signed consent. From those 37, one could not be reached due to missing contact information, one withdrew before T1, and one was lost to follow up. The data of the first 26 participants are included in this thesis.

4.3 Demographic Data

Of the 26 participants, 14 were women and 12 were men. Their mean age was 73 (SD=9.9) years, and the median time since diagnosis was six years (1st and 3rd quartile). The participants had a severity level from 1 to 4 as described by the Hoehn and Yahr (HY) scale. The level with the highest frequency was level 2 with 9 of the participants at that level. As reported by the participants, 15 had more than two concomitant chronic conditions in addition to PD, four people had one other condition and seven did not have any other chronic conditions. Regarding their medication scheme, 23 where on a stable scheme, two were

changing or adjusting medications and one did not take any medications (Figure 4.2).

Variable	Descriptive Statistics
Gender	Women n=14 Men=12
Age	X=73 (SD=9.9); Min=44, Max=88
Years Since Diagnosis	Median=6 Min=1 Max=35
Severity Level (Hoehn and Yahr scale)	I=4 II=9 III=6 IV=7 V=0
Medication Scheme	No medication=1 Stable=23 Changing medications=2
Concomitant chronic conditions	Nil=7 One=4 Two or more=15

Figure 4.2 Summary of the demographic data

4.4 Baseline Data

4.4.1 PSFS

Since the PSFS is a patient reported questionnaire in which the respondent creates his or her own items, the number of items was different from one person to another, with a range from one to seven items generated (Figure 4.3).

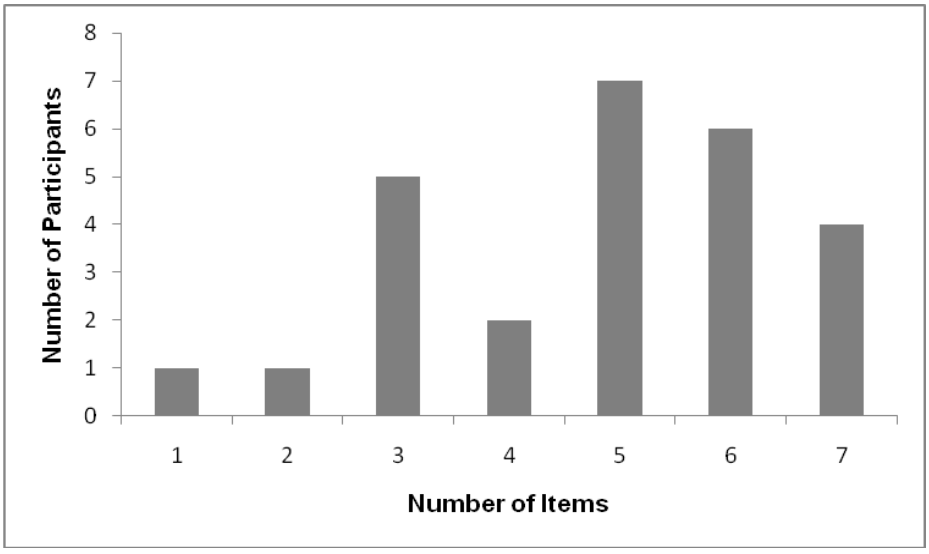

Figure 4.3 Number of items generated for the PSFS

Participants created items that referred to activities in which they were limited for carrying out or were restricted in regards to participation (Figure 4.4). The items included motor and cognitive activities and they covered mainly ADLs and leisure or recreation activities. The specificity of the items varied across participants, some reported something unspecific as “walking” and others

described in detail the activity, for example “taking out things from the right pocket of my pants with my right hand”. As for participation related items, a few examples are “going to the bingo”, “taking care of my grandchildren”, “driving”, “summarizing ideas into paper (for writing bulletins or letters)”. The items related to cognitive functions were related to memory, organizing time and thoughts, and management of stressful situations. Participants also reported items related to body functions, such as “going to the washroom (due to constipation)”, “controlling urination frequency”, and swallowing.

Beekeeping	Fishing	Multitasking	Swallowing (x3)
Bending over towards the floor	Gardening (x3)	Not feeling lonely and anxious	Sweeping (curling)
Biking	Getting in and out of the car	Organizing paperwork	Swimming (x2)
Bowling	Getting started with the day	Playing cards and Socializing (because she can’t sit too long)	Taking care of her grandchildren
Brushing teeth	Getting to the washroom	Playing the piano (x2)	Taking things out of his trousers’ pocket with the right hand
Buttoning (x2)	Going for a walk	Pouring water from a jug	Typing
Camping	Going for walks with my wife	Preparing food (cooking and slicing)	Typing in the computer
Carpet bowling	Going out	Preparing food (simple things)	Using cutlery
Carrying things with the right hand	Going out for dinner	Preparing meals	Using his tools (hammer, saws)

Figure 4.4 PSFS items (continues on next page)

Controlling urination frequency	Going out in the evening	Quilting	Using the mouse (x2)
Cleaning up the garage	Going shopping	Reaching with arms high above my head	Using the Elliptical
Cooking (x2)	Going to the bingo	Remembering (memory)(x3)	Using the washroom (due to constipation)
Cutting up food	Going up the stairs	Repairs around the house	Vacuuming
Dancing (x3)	Grocery Shopping (x2)	Riding a bicycle	Walk (x4)
Dealing with conflict situations	Handling stressful situations with people	She can't do anything on her own	Walking fast
Doing laundry	Hanging out with friends	Shopping	Walking on a golf course
Doing shoe laces	Household chores	Showering	Walking indoors
Doing things without help	Keeping my balance	Sitting for a long time	Walking long distances
Drawing	Keeping track of my schedule	Speaking	Walking long time (more than 30 min)
Dressing (x2)	Knitting (x4)	Speech	Walking two blocks
Dressing by myself	Lifting things	Square dancing	Walking w/walker (x2)
Driving	Looking after her home	Standing (x2)	Walking wo/ walker (x2)
Driving (feels risky at this point)	Maintaining voice tone while talking	Standing more than 10 minutes	Washing herself
Eating (in general, chewing too)	Making handcrafts	Standing while doing the dishes or cooking	Working out (lifting weights, running)
Finding motivation	Moving in general	Starting to walk	Writing (x5)

Figure 4.4 PSFS items (cont.)

4.4.2 MDS-UPDRS and PDQ-39

The baseline mean score for the MDS-UPDRS was 15.8 SD=7.4. The mean score for the PDQ-39 was 26.9 SD= 13.47 (Table 4.1)

Table 4.1 Baseline Data for the MDS-UPDRS and the PDQ-39

			Statistic	Std. Error
TOTAL_MDSUPDRS_T1	Mean		15.8077	1.45181
	95% Confidence Interval for Mean	Lower Bound	12.8176	
		Upper Bound	18.7978	
	Variance		54.802	
	Std. Deviation		7.40281	
PDQ39_SI_T1	Mean		26.9235	2.64330
	95% Confidence Interval for Mean	Lower Bound	21.4795	
		Upper Bound	32.3675	
	Variance		181.664	
	Std. Deviation		13.47826	

4.5. Reliability

4.5.1. Test Retest Reliability

Test retest reliability was assessed for pre (T1 T2) and post (T3 T4) measurement pairs. The pre scores of the PSFS had a mean of 4.4 (SD=1.3), the post scores had a mean of 4.1 (SD=1.65), and the change from pre to post had a mean of -2.17 (SD=1.30).

The test retest reliability of the pre measures (Table 4.1), T1 and T2, is 0.72 (95%CI=0.47-0.86). For the post pair (Table 4.2), T3 and T4, the test retest reliability is 0.83 (95%CI=0.66-0.92).

Table 4.2 ICC Pre change measurements

		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.723	.477	.865	6.227	25	26	.000
Average Measures	.839	.646	.928	6.227	25	26	.000

One-way random effects model where people effects are random.

Table 4.3 ICC Post change measurements

		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.834	.668	.922	11.071	25	26	.000
Average Measures	.910	.801	.959	11.071	25	26	.000

One-way random effects model where people effects are random.

4.5.2 Reliability of the change score

The reliability of change scores utilizing the formula in Streiner and Norman (Streiner & Norman, 2008) was 0.50.

4.6 Validity

4.6.1 Convergent Construct Validity

Before carrying out all the correlations, the assumptions of linearity and homoscedasticity were checked. For the assessment of the convergent validity, the PSFS T3 was compared to the MDS-UPDRS, and PDQ-39 from T3 by calculating the correlation among them (Table 4.4). In the case of the correlation with the PDQ-39, the correlation was done for the measure's total score. The correlations values yielded in the analyses (Table 4.5) did not fall within the parameters originally set for the assessments of the level of correlation except for the correlations between the Summary Index of the PDQ-39 and the MDS-UPDRS ($r=0.61$, $p=0.001$).

Table 4.4 Descriptive statistics PSFS, MDS-UPDRS, PDQ-39 at Time 3

			Statistic	Std. Error
TOTAL_PSFS_T3	Mean		4.3752	.33742
	95% Confidence Interval for Mean	Lower Bound	3.6802	
		Upper Bound	5.0701	
	Variance		2.960	
	Std. Deviation		1.72053	
	Minimum		.00	
	Maximum		7.00	
TOTAL_MDSUPDRS_T3	Mean		18.1923	1.38344
	95% Confidence Interval for Mean	Lower Bound	15.3431	
		Upper Bound	21.0416	
	Variance		49.762	
	Std. Deviation		7.05419	
	Minimum		7.00	
	Maximum		35.00	
PDQ39_SI_T3	Mean		30.6444	2.86788
	95% Confidence Interval for Mean	Lower Bound	24.7379	
		Upper Bound	36.5510	
	Variance		213.844	
	Std. Deviation		14.62339	
	Minimum		8.28	
	Maximum		63.07	

		TOTAL_PSFS_T3	TOTAL_MDSUPDRS_T3	PDQ39_SI_T3
TOTAL_PSFS_T3	Pearson Correlation	1	.001	.234
	Sig. (2-tailed)		.998	.261
	N	26	26	25
TOTAL_MDSUPDRS_T3	Pearson Correlation	.001	1	.615**
	Sig. (2-tailed)	.998		.001
	N	26	26	25
PDQ39_SI_T3	Pearson Correlation	.234	**.615****	1
	Sig. (2-tailed)	.261	**.001**	
	N	25	25	25

Table 4.5 Correlations for the convergent construct validity component.

**. Correlation is significant at the 0.01 level (2-tailed).

4.6.2 Longitudinal Validity

One set of comparisons included the correlation of the change detected between T1 and T3 with the PSFS and the change detected with the MDS-UPDRS, the PDQ-39SI and each dimension of the PDQ-39 from T1 and T3. No significant correlations were found. Another set of comparisons with the same correlation coefficient was done with the change detected between T1 and T4 by the PSFS, the HY scale, and the global rating of change. No significant correlations were found (Table 4.6).

	PSFS		Change rating		PDQ-39	MDS-UPDRS
	T3	T4	T3	T4		
PSFS	1	1	-0.54	0.10	-0.20	-0.02
PDQ-39	0.20	-	0.19	-	1	0.06
MDS-UPDRS	0.02	-	0.06	-	0.06	1
H and Y	-	0.348	-	-0.08	-	-

Table 4.6 Longitudinal validity correlations.

4.7. Additional analyses: assessment of change

4.7.1. Change reflected by the PDQ-39SI, MDS-UPDRS part II and the PSFS

A comparison of the pre and post scores was performed in order to assess whether there was actually change in functioning after a four month period. T-tests were performed to assess the change as measured by the PSFS, PDQ-39 and the MDS-UPDRS (Tables 4.5 and 4.6). The change from T1 to T3 is not significant as measured with the PSFS (t=0.01, p=0.99), however the change is significant when measured with the PDQ-39 (t=-2.39, p=0.003) and the MDS-UPDRS (t=-2.39, p=0.025)

Table 4.7 Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TOTAL_PSFS_T1	4.3788	26	1.48787	.29180
	TOTAL_PSFS_T3	4.3752	26	1.72053	.33742
Pair 2	TOTAL_MDSUPDRS_T1	15.8077	26	7.40281	1.45181
	TOTAL_MDSUPDRS_T3	18.1923	26	7.05419	1.38344
Pair 3	PDQ39_SI_T1	27.0104	25	13.74875	2.74975
	PDQ39_SI_T3	30.4354	25	14.88524	2.97705

Table 4.8 Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% CI of the Difference Lower	Upper			
PSFS_T1 - PSFS_T3	.00366	1.66345	.32623	-.66822	.67555	.011	25	.991
MDSUPDRS_T1 - MDSUPDRS_T3	-2.38462	3.73178	.73186	-3.89191	-.87732	-3.258	25	.003
PDQ39_SI_T1 - PDQ39_SI_T3	-3.42500	7.15488	1.43098	-6.37839	-.47161	-2.393	24	.025

4.7.1.2 Correlation of the change with each dimension of the PDQ-39

As depicted in table 4.7, the results yielded by the correlation analysis between the PSFS and the different dimensions of the PDQ-39 showed correlations that did not lie within the parameters originally proposed (95%CI 0.70-0.80).

Table 4.9 Correlations of the change among the PSFS, HY, change rating, and the dimensions of the PDQ-39													
		PDQ 39	MOB	ADL	EMO	STI	SUP	COG	COM	BOD	PSFS	Rating of change	HY
PDQ 39	R	1	.416	.309	.392	.532	.480	.464	.513	.489	-.183	.171	.182
	Sig		.034	.124	.048	.005	.013	.017	.007	.011	.372	.405	.372
MOB	R	.416	1	.205	.270	-.131	.260	.198	-.112	-.160	-.123	.095	-.229
	Sig	.034		.316	.181	.524	.199	.332	.585	.436	.550	.645	.260
ADL	R	.309	.205	1	-.029	-.196	-.074	.093	.204	-.024	.089	.188	-.131
	Sig	.124	.316		.888	.337	.720	.650	.317	.907	.666	.358	.524
EMO	R	.392	.270	-.029	1	.178	.372	.015	-.054	-.104	-.091	.291	.334
	Sig	.048	.181	.888		.383	.062	.941	.792	.614	.657	.150	.095
STI	R	.532	-.131	-.196	.178	1	.080	.146	.512	.291	-.132	-.052	.319
	Sig	.005	.524	.337	.383		.697	.476	.007	.150	.519	.801	.112
SUP	R	.480	.260	-.074	.372	.080	1	-.119	-.067	.268	-.243	.274	-.084
	Sig	.013	.199	.720	.062	.697		.564	.743	.186	.232	.175	.682
COG	R	.464	.198	.093	.015	.146	-.119	1	.221	.137	-.347	-.069	.010
	Sig	.017	.332	.650	.941	.476	.564		.278	.504	.082	.739	.962
COM	R	.513	-.112	.204	-.054	.512	-.067	.221	1	.138	-.091	-.196	.261
	Sig	.007	.585	.317	.792	.007	.743	.278		.502	.658	.338	.197
BOD	R	.489	-.160	-.024	-.104	.291	.268	.137	.138	1	.219	.128	.225
	Sig	.011	.436	.907	.614	.150	.186	.504	.502		.283	.534	.270
PSFS	R	-.183	-.123	.089	-.091	-.132	-.243	-.347	-.091	.219	1	-.164	.277
	Sig	.372	.550	.666	.657	.519	.232	.082	.658	.283		.422	.171
change	R	.171	.095	.188	.291	-.052	.274	-.069	-.196	.128	-.164	1	.081
	Sig	.405	.645	.358	.150	.801	.175	.739	.338	.534	.422		.696
HY	R	.182	-.229	-.131	.334	.319	-.084	.010	.261	.225	.277	.081	1
	Sig	.372	.260	.524	.095	.112	.682	.962	.197	.270	.171	.696	

PDQ-39: Parkinson's Disease Questionnaire 39**, HY:** Hoehn and Yahr Scale, , **ADL:** Activities of Daily Living, **BOD:** Bodily Discomfort, **COG:** Cognition, **COM:** Communication, **EMO:** Emotion, **MOB:** Mobility, **SOC:** Socia, **STI:** Stigma.

4.7.2 Change reflected by the Global Rating of Change

The scale distribution of the global rating of change is on a 15 point scale with the use qualifiers (better, worse) that indicate the direction of the change (Stratford, Binkley and Riddle, 1996). For the purpose of the analysis, the responses were transformed to a scale from 1 to 15. The values that indicated changes for the better were 1 to 7 (originally Better 1-Better 7), no change (originally 0) was given the value of 8, and the values that indicated change for the worse were from 9 to 15 (originally Worse 1- Worse 7). An additional analysis was run for the assessment of change regardless of the direction reflected by the global rating of change (Tables 4.10 and 4.11). A single sample t-test was performed to assess the presence of change. Since number 8 indicates no change, this was set as the test value for the comparison.

4.10 Rating of Change Descriptive Statistics

	N	Mean	Std. Deviation	Std. Error Mean
Rating of change	26	6.58	3.252	.638

4.11 Rating of Change: One-Sample Test

	Test Value = 8 (value given to no difference)					
					95% Confidence Interval of the Difference	
	T	Df	Sig. (2-tailed)	Mean Difference	Lower	Upper
Rating of change	-2.232	25	.035	-1.423	-2.74	-.11

Conclusion of the chapter

Upon approval of the Hamilton Health Sciences Board, recruitment and data collection was done between October 2010 and May 2011. Data from the first twenty six participants enrolled in the study are presented here. The data obtained were used to perform the analyses of reliability and validity of the PSFS when administered to people living with PD. The test retest reliability was 0.72 (95%CI=0.47-0.86) for the pre measures, and 0.83 (95%CI=0.66-0.92) for the post measures. For the assessment of validity, none of correlations found between the PSFS and the measures used for the comparison were within the parameter originally estimated. An additional analysis was performed to assess the existence of change and there was significant change as reported by the PDQ-39 and the MDS-UPDRS part II.

Chapter V: Discussion

Introduction

This chapter provides a comprehensive interpretation of the results obtained in the study. The recruitment and the questionnaire administration are discussed. In addition, the limitations of the study are acknowledged and implications of the results are described. Suggestions for building upon the work are presented.

5.1 Discussion of the results

5.1.1 Test Retest Reliability

The assessment of the test retest reliability of the scores yielded by the PSFS was acceptable for the pre and post measures (ICCpre= 0.7295%CI=0.47-0.86; ICCpost=0.83 95%CI=0.66-0.92), and were within or above the CI initially anticipated (95%CI=0.70-0.80). The observed CI however, was wider than anticipated for both the pre and the post measures. The test retest reliability coefficients were acceptable as observed in previous studies (Chatman et al., 1997; Cleland et al., 2006; Jolles et al., 2005).

The PSFS was first tested in people with low back pain (Stratford et al., 1995). The test retest reliability for that group was ICC=0.97. In a later study, Westaway and colleagues (Westaway et al., 1998) assessed the measure when

applied to people with neck dysfunction and they also found that the scores yielded by the PSFS were reliable with an ICC=0.92. Other studies have also reported findings of the scores being reliable (Chatman et al., 1997; Cleland et al., 2006; Jolles et al., 2005) and a study by Oliveira Pena-Costa and colleagues used the measure in a Brazilian population and found that the scores were reliable (ICC=0.85) (Costa et al., 2008).

The ICC coefficient in this study was lower than those reported in the literature. Before this study, there had not been a study that assessed the PSFS when applied to people with degenerative conditions like PD. The lower level of reliability might be an indicator of more error when applying the measure to people who have more complex conditions, more variability in the conditions, or various concomitant diseases. Still, the ICC was good enough to deem the scores of the PSFS reliable with this population. However, the observed CIs were wider than what had been anticipated. This is likely due to the fact that the originally calculated sample size (n=53) was not reached. Even with the obtained CI, the lower limit is still of acceptable reliability, particularly considering that it is a patient reported outcome measure and the number of items reported were as low as one item.

The approach that we took to assess reliability was that of the Classical Test Theory which states that the reliability of a measure increases with the number of items, therefore it would be likely that if the study was repeated with

the number of participants and all of them created seven items, the CI would have been narrower. Another factor that might have caused a wide CI is the score variation between persons. The score variation is related to the precision of the measurements (Sim & Reid, 1999; Streiner & Norman, 2008). The PSFS is a Patient Reported Outcome Measure (PROM) that allows for respondents to create their own items, so the amount of score variation might be unavoidable. but this is true of all uses of the PSFS. The score variation could have also been influenced by the stability periods that were chosen. People with PD may present variation across the day because of the effect of the medications and could have better days than others. Therefore, the stability periods should have been set based on each individual and narrowed to 1-2 days opposed to 3 to 5 days. The stability period could have probably been set even within the same day at the end of the session. This would allow for their emotional state to be the same as well as the perception of their functioning , especially considering that people with PD have “good” and “bad” days.

5.1.2. Convergent Construct Validity

Convergent Construct Validity examines how one measure correlates with another when both are thought to be measuring the same attribute (Finch et al., 2007). The PSFS had a low correlation with the MDS-UPDRS and the PDQ-39. The correlation coefficient suggests that the PSFS is not targeting the same outcome as the MDS-UPDRS and the PDQ-39.

The very low correlation with the MDS-UPDRS was not totally unexpected. The MDS-UPDRS is a clinical assessment tool that is used to assess the symptoms of people with PD. However the Part II, which was used for this study, includes the assessment of Activities of Daily Living so the comparison with the PSFS did not seem illogical when the study was designed. The MDS-UPDRS was created in the 1980s and is the most used measure for the assessment of PD. It was however, created with a biomedical perspective which is in accordance with the focus of the measure on symptoms and impairments. Since it is the most widely used measure, measurement studies often include it for the assessment of other tools, thus facilitating the translation of the findings. However, when there is the need to assess measures which have been created with new measurement techniques and with a biopsycosocial perspective, it becomes very difficult to validate these measures because the established ones are deeply cemented into the practice of health professionals.

The PDQ-39, was chosen because the investigator had doubts about the adequacy of the MDS-UPDRS for the assessment of functioning, and the PDQ-39 seemed like a better functioning measure. Despite the PDQ-39 having been created for the assessment of functioning, there was low correlation with the PSFS. The low correlation with the PSFS means that they do not target the same outcome and various hypotheses could be formulated. The possible hypotheses are that the PDQ-39 measures functioning and the PSFS does not, or that the

PSFS measures functioning while the PDQ-39 does not, or simply neither of them measure functioning. The PDQ-39 was created to assess functioning; however, it was tested for validity with the SF-36 as the comparison measure. The SF-36 is a health status measure for which there is often controversy about what outcome it targets (Peto et al., 1998). The fact that the PDQ-39 was validated with the SF-36 raises awareness about the use of the measure in relation to the target outcome. This controversy has led other researchers to study the PDQ-39 further. Hagel and colleagues carried out an analysis of the PDQ-39 using a technique to find if the items are repetitive, and belong to the same dimension. They found misfit between the items in the same dimensions. This means that the items are not placed in the correct dimension. Consequently the items with misfit are assessing something other than what it is though they measure (Hagell & Nilsson, 2009). In another study, it is reported that the PDQ-39 was compared to the PD QoL measure and they were moderately correlated (Hagell & Nygren, 2007). The similarity of the PDQ-39 with the PD QoL is reflected in the literature since the PDQ-39 is often regarded as a QoL measure (Martinez-Martin, Serrano-Duenas, Forjaz, & Serrano, 2007).

Considering the controversy on the construct of the PDQ-39, it makes it difficult to interpret the implications of the low correlation with the PSFS. Looking at the content of the PSFS from a different perspective may shed light on what

the PSFS actually is measuring and how that differs from the PDQ-39 and the MDS-UPDRS part II.

Mapping outcome measures onto the International Classification of Functioning, Disability and Health (ICF) could provide valuable information in regards to what outcomes the measures cover (Cieza et al., 2005). The findings of the study presented in this thesis generated interest about how the comparing measures would actually map onto the ICF. Therefore a secondary analysis using the items created for this study was performed. The content of the MDS-UPDRS, the PDQ-39 and the PSFS were mapped onto the ICF. The preliminary results (Appendix 7) showed that MDS-UPDRS and the PDQ-39 map mostly to the body functions category whereas the PSFS maps mostly onto activities and participation. These results confirm that the measures may target different outcomes. The three measures cover components of functioning however the PSFS might do it in a more comprehensive manner. To clarify, the PSFS targets Activities and Participation and most of the items created by the participants map onto the same component of the ICF. While all of the components of the ICF influence functioning, they converge in the component of Activities and Participation. Therefore targeting Activities and Participation could provide more information on the functioning of a person than the other components. For example rather than referring to the health condition alone, it is more informative to refer to a person with PD (Health Condition), who has freezing of gait (Body

Function), lives in a rural area (Environmental Factor), and has low socio-economic status (Personal Factor). These factors can be defined with the ICF, however the result of the interaction of these is reflected in Activities and Participation, so if the person has difficulties with ambulating in the community you know all the factors that play a part.

5.1.3 The target outcome of the Patient Specific Functional Scale

The PSFS does not appear to assess the same construct as the MDS-UPDRS part II, or the PDQ-39. However, the PSFS may target functioning better. The phrasing of the question and the patient centred approach allow the assessment of functioning. This is facilitated because the patients create their own items and within each item they are integrating their body functions and structures, as well as their contextual factors. Therefore, the PSFS integrates the interaction between body structures, body functions, and contextual factors, and how they reflect upon the activities and participation component. The MDS-UPDRS and the PDQ-39 do not integrate the interaction among the components as the PSFS because of the type of questions and biomedical perspective with which they were created.

5.1.4 Longitudinal validity

The ability to detect change, longitudinal validity, was assessed through the correlation of the change reflected by the PSFS and the change reflected by

the MDS-UPDRS, PDQ-39, Hoehn and Yahr (HY) scale, and the global rating of change. The correlations between the PSFS and the MDS-UPDRS, PDQ-39, HY and the global rating of change were not sufficient to say that the measures changed together. This low correlation may be caused by differences in the target outcome of the measures. The low correlation of the MDS-UPDRS and the PDQ-39 with the PSFS posed a challenge for the assessment of longitudinal validity. Both the MDS-UPDRS and the PDQ-39 seem sensitive to change over time in people with PD, and the ability to detect change of the PSFS was assessed by correlating the change scores of this measure to the change scores of the other two measures. Having demonstrated that they may not target the same outcomes facilitates the understanding of the results of the assessment of longitudinal validity.

In the assessment of longitudinal validity, it was found that the change scores from the MDS-UPDRS and the PDQ-39 did not correlate with those from the PSFS. Therefore it can be assumed that the measures did not change in the same way. Since the measures target different attributes, the change was not observed in the same way. It is possible that the measures target outcomes that change at different rates. Functioning is a result of various components so in order to observe a change in functioning, there have to be changes at a more basic level. For instance, if a person has a walking impairment, they might walk slower or less efficiently but they might still have the same functioning status. It is

only when impairments add up and combine with external factors that the functioning level is actually impacted. A concept related to this is preclinical disability; at some point due to aging or a disease, a person might change the way they do things because of impairment but that does not mean they have stopped doing them (Fried & Guralnik, 1997). As a result, it is possible that the method of functioning changes due to adaptation and adjustment but not the functioning status. When adjustments for maintaining the same level of functioning status are no longer possible, it may be then when functioning status changes.

5.1.5 Reliability of the change scores

One of the premises that Stratford et al. had for creating the PSFS was that it should be able to assess important change over time and to provide a comparison of the disability level at a specific point in time relative to the time before the lesion (Stratford et al., 1995). Therefore, it is important to assess how reliable the scores are once change has occurred. However, this had not been done in any of the other studies to validate the PSFS. For the interpretation of the reliability of the change scores, the detection of change with the measure in question is important because the coefficient is designed to discriminate individuals who change a great deal from those who barely changed. The failure to detect change with the PSFS may be due to the fact that four months is too little time to detect changes in functioning in people with PD. Consequently, the

lack of change in functioning and the short time lapse results in difficulty for the interpretation of the ICC of the change scores. The reliability of the change scores was ICC=0.50. The reliability of the change scores could be considered not acceptable but considering that the measure can be as short as a single item it could be too much to ask to have a higher reliability coefficient. The variation from pre measures to post measures could be related to the error observed within the stability periods. Such error was magnified by including the variation of both pre and post measures, into one coefficient. The variation between the pre and post measure could also be due to the stability period.Combined, these factors could have contributed to a lower test-retest ICC found in this study in comparison with previous studies. Describing a test's reliability as "acceptable" is not as straightforward as it may seem; there is no magic number. The reliability of the scores yielded by a measure depends on the ICC, the type of reliability being tested and the length of the test (Streiner & Norman, 2008). However, an ICC 0.60 is generally considered acceptable.

5.2 Reflection on the Questionnaire Administration

Participants in the study had to agree to meet four times to complete questionnaires. There were various strategies to decrease the burden for participants. The MDS-UPDRS part II and the PDQ-39 can be filled in by the respondent, however people with PD are often impaired for writing, therefore the questionnaires were all administered in an interview format and the interviewer,

who was the Principal Investigator (PI) wrote down the answers. In addition, participants were given the option to schedule the meetings over the phone, particularly the meetings at T2 and T4 which were anticipated to last a maximum of five minutes. This option was well received by the participants and every one had at least one telephone meeting.

Having the participants respond to questions verbally opposed to filling in the questionnaires themselves had advantages and disadvantages. One of the advantages was that every time a question was posed there was a chance for the respondent to discuss the question with the PI. This facilitated the understanding of the respondent and the insight of the PI. Another advantage was that no answers were missing since the PI was aware of the importance of having complete data. However, often this would lead to further conversation on the topic and would increase time of the meeting, something that should be considered for studies in the future. Another disadvantage was that sometimes respondents would elaborate on the answer without giving the direct answer as stated by the questionnaires. As a result, the PI had to redirect the participants to the possible answers in a sensitive manner. When participants felt strongly that the questions did not relate to them, the PI would make notes on the matter on the response sheet. In addition, participants would sometimes get emotional or the PI could sense that they were uncomfortable about the questions. For instance in the PDQ-39 in the emotional dimension, respondents have to say how

often they feel angry, depressed, worried about their future, and lonely to name a few. With this type of question, two participants who were at early stages of the disease commented “should I be worried?”. For participants who actually felt depressed or lonely, it seemed difficult for them to deal with that and there was an emotional reaction. Four of the participants cried during the questionnaire administration and expressed feelings of despair or hopelessness which was brought up by the questionnaires. The PI tried to give them comfort, which would not have been possible had they been filling in the questionnaire on their own.

The meetings over the phone also had advantages and disadvantages. One of the advantages was that offering an option to the participants that did not require them to be physically present helped with the recruitment because it reduced the burden of the study. Additionally, the data collection occurred primarily in the winter; the meetings over the phone made things easier in relation to community travel. A disadvantage was that for participants who had difficulty speaking, communication was further complicated by the lack of body language and face to face communication. Another disadvantage was that because it was a phone call, participants did not consider it a meeting so despite setting appointments it was often difficult to reach them.

5.3 Limitations

One of the limitations of research often encountered is the recruitment of participants. It might be difficult to recruit participants who are vulnerable and

dependent on others for mobilization within the community, as people with PD frequently are. This situation is further complicated by the time that each participant had to invest in the study. The recruitment was through the PD Society, a Movement Disorders clinic and a rehabilitation outpatient unit which serves people with PD. These were the right places to target people with PD. Despite significant efforts, the amount of time available for recruitment resulted in an inability to achieve the sample size.

Potential participants that were contacted by letter lived in the Hamilton and Burlington areas. Targeting a larger geographic area may have helped reach the sample size. For example, the letters could have been sent to people living in the Peel, Halton and Waterloo regions and not only to people in two cities. Similarly, the neurologist running the Movement Disorders Clinic was contacted, while he did refer participants, having contacted an additional neurologist may have been beneficial.

5.4 Implications

From a research perspective, there is still work to be done in order to be confident that the results from the PSFS could be used for the assessment of treatment effects. From a clinical perspective, participants seemed to appreciate the patient-centred focus of the tool. In addition, the PSFS might provide a better perspective on the functioning status of the patients than the MDS-UPDRS and the PDQ-39. The PSFS is a standardized way to inquire about functioning

difficulties that would not necessarily come up with such detail in the clinical assessment. Furthermore, the use of the PSFS facilitates a patient centred approach without the focus on impairment and provides an opportunity for physiotherapists to target interventions to areas of functioning important to their patients, not with the management of isolated impairments.

5.5 Future Directions

As previously mentioned, some participants had emotional reactions to question in the PDQ-39. This suggests that sometimes questionnaires might have an emotional impact which has yet to be studied. Therefore it would be important in the future to study the emotional effect that questionnaires might have on respondents, and how this might impact on the way they internalize the disease.

The study by Oliveira Pena Costa sets the ground to think that the PSFS can be applied in different cultural settings and still yield reliable scores (Costa et al., 2008). Therefore the PSFS warrants further studies relating to its use across different populations regarding health conditions but also cultural and geographical backgrounds.

The findings did not support the validity of the PSFS when compared to the instruments typically used with people with PD. The resulting uncertainty about the constructs being measured provides an example of a maze from which

there is no clear response when assessing instruments (old or newly developed) when there is no gold standard, nor are there other tools that assess the trait targeted by the questionnaire being investigated. This might happen more commonly with traits that are complex and cannot be measured directly; or even more due to their nature, are not unidimensional and change considerably from individual to individual. It seems adequate, that for these type of traits or outcomes, like functioning, quality of life, patient satisfaction and burden of a disease are measured in a patient-centred approach and utilizing PROMs might be the way to do so even when psychometric properties are difficult to assess.

A valuable part of the PSFS is the set up that allows the participants to create their own items. These may become more common as PROMs become more popular and the nature of care continues to shift more towards a patient-centred model. However, there has to be careful planning of the questions utilized to elicit the items in order to ascertain the outcome of interest and be sure what is actually being measured.

5.6 Concluding Remarks

The PSFS scores have a good test-retest realiability when administered within a three to five day period. The PSFS did not correlate in regards to content or assessment of change to the MDS-UPDRS nor to the PDQ-39. The PSFS does not detect change within a four-month period. Consequently it is difficult to interpret the results of the change scores reliability.

The PSFS provides a very unique opportunity for participants to create their own items, which is truly patient-centred; each individual is communicating what items are valid for him/her. In health, it is common to come across the need for trade offs, medication effects versus side effects, physiotherapy sessions versus time spent transporting to the rehabilitation unit, taking time for more leisure activities versus taking time for attending therapy. The same trade-offs occur with the application of assessments, more time for the assessment less time for therapy, going through the whole questionnaire versus just asking questions that are relevant for the patients, using outcome measures in compliance with the regulations of a site as opposed to being patient specific.

It cannot be confirmed that the PSFS is valid to use in people with PD at this point. Further assessment of the PSFS is necessary and a different way of assessing construct validity should be considered. From a clinical perspective, the PSFS is patient-centred. The PSFS is an easy tool to administer. The PSFS informs health providers on the level of functioning/disability of people living with PD. Additionally the PSFS seemed to have good acceptability among the participants of the study. Therefore, PSFS is a PROM that warrants further study when applied to people with PD.

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Appendix I: Ethics Board Approval

Hamilton Health Sciences McMaster University Health Sciences

HHS/FHS REB: Student Research Committee

Final Approval

Date:	Nov 3 2010
REB Number:	10-509-S
Title of Study:	Psychometric Properties of the patient Specific functional Scale for the assessment of Persons with Parkinson's Disease
Student PI:	Gabriela Burgos-Martinez
LPI:	Lori Letts
Version date:	Document:
Sept 22 2010	Application
Oct 22 2010	Protocol
Oct 22 2010	Consent Form
Nov 3 2010	Telephone Recruitment Script

Dear Gabriela:

We have completed our review of your study and are pleased to issue our final approval. You may now begin your study.

Any changes to this study must be submitted as an amendment before they can be implemented. Amendment forms are available on our website.

This approval is effective for 12 months from the date of this letter. If you require more time to complete your study you must request an extension in writing before this approval expires. Please submit an Annual review form with your request.

Please cite the REB number in any correspondence.

Good luck with your research,

Marie Townsend BA, MBA
Chair, HHS/FHS Student Research Committee
Health Research Services, HSC 1B7, McMaster University

The HHS/FHS SRC complies with the guidelines set by the Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* and with ICH Good Clinical Practice.

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Appendix II: Telephone Script

Telephone script for providing information about the study

1. Introduction of the call

Hello, my name is Gabriela and (Michelle Shilton or Dr. Paultseth) from St. Peter's Hospital informed me that you may be interested in participating in a study we are carrying out at McMaster University.

a. Would you like me to give you information at this time?

"Yes", proceed to number 2

"No", schedule a call for another time.

2. General information

The study is to determine if a questionnaire is adequate to assess people with Parkinson's about concerns they have about carrying out their regular activities. In order to do this we need participants who are willing to answer up to three questionnaires on four different occasions within the next 4 months, the first appointment would be either at St. Peter's or at McMaster University. The second, third and fourth appointments could be at the same locations, over the phone or at your home in case you cannot do it in any of the other manners.

a. Are you interested on participating?

"Yes", proceed to number 3

"No", thank for the time provided and end conversation.

3. Screen for eligibility

To make sure that you can be included in the study, I will ask you 4 questions:

a. Do you have a diagnosis of Parkinson's disease confirmed by a neurologist?

"Yes", proceed to b

"No", explain that it is important that the participants are diagnosed with Parkinson's for the study so you cannot include him/her; thank for the time provided and end conversation.

b. Are you at least 45 years old?

"Yes", proceed to c

"No", explain that it is important that the participants are at least 45 years old for the study so you cannot include him/her; thank for the time provided and end conversation.

c. Do you need an aid like a cane, walker or wheelchair, to move around?

"No", proceed to d

"Yes", If it is a wheelchair, can you move without the wheelchair, even if it is only around your house?

"Yes", proceed to d

"No", explain that it is important for the study to include people who are able to move without a wheelchair at least some of the time, so you cannot include him/her. Thank for the time provided and end conversation.

d. Do you have any physical restrictions that are not caused by Parkinson's disease? For example, limitations as a result of a stroke, amputation or other condition?

"No", proceed to part 4

"Yes", ask: What type of restriction?

If the person has a physical restriction that may confound the effect of Parkinson's of functioning, explain that it is important for the study to distinguish the effect of Parkinson and that in his/her case you would not be able to do so, thank for the time provided and end

conversation. If the physical restriction could not confound the effect of Parkinson's proceed to part 4.

4. Further information about the study procedure

The first appointment should be as soon as possible and will take approximately one hour. The second appointment will be over the phone or face to face within three to five days after the first and will take only about 20 minutes. Four months after your first appointment you will attend the third appointment to respond the same questionnaires as in the first appointment. Finally for the fourth appointment you will answer the same questionnaire as in the second appointment.

Do you have any doubts or questions about the study at this point?

"Yes", answer doubts

"No", proceed to number 5

5. Schedule first appointment

When would you like to come for the first appointment? Provide possible dates and register selection. Thank for the time and end conversation.

Appendix III: Information Letter

McMaster University
Inspiring Innovation and Discovery

Hamilton Health Sciences/McMaster
NOV 0 3 2010
Research Ethics Board

Information/Consent form (Participant)

Title of Study:

The Validity and Reliability of the Patient Specific Functional Scale for the assessment of Persons with Parkinson's Disease.

Local Principal Investigator:

Lori Letts, PhD, OT Reg. (Ont.) FCAOT
School of Rehabilitation Science
McMaster University
Institute for Applied Health Sciences
1400 Main Street West
Hamilton, Ontario L8S 1C7
tel: (905) 525-9140 ext. 27816
fax: (905) 524-0069
e-mail: lettsl@mcmaster.ca

Co-investigators:

Gabriela Burgos-Martínez, PT (Mexico);
Paul W. Stratford MSc, PT (Ont.);
Laurie R. Wishart PhD, PT (Ont.).
School of Rehabilitation Science, McMaster University

You are being invited to participate in a research study about the use of the Patient Specific Functional Scale in people with Parkinson's Disease. This letter gives you detailed information about the study. You should fully understand the study before you decide to participate. If you wish to take part of the study you will need to sign this letter on the last page. Your participation in the study is voluntary and if you choose not to participate your decision will have no negative impact on your health services. This project is part of the graduate studies of Gabriela Burgos-Martínez and Lori Letts is the supervisor.

Why is this study being done?

People with Parkinson's Disease sometimes experience difficulties with the performance of their daily activities. In order to provide adequate health management, it is important that the assessment of their daily difficulties is as accurate as possible. We believe that the use of the Patient Specific Functional Scale can enhance the understanding of the patient perspective of functional difficulties. Therefore the purpose of this study is to know if the Patient Specific Functional Scale is useful when completed by people with Parkinson's Disease.

How many participants will be in this study?

We expect to have 56 participants.

What will happen to participants in this study?

First we will ask you some questions about your disease and determine if you are eligible for entering the study. If you are eligible and decide to consent to participate in the study you will be asked to commit to four appointments within 4 months to fill in health related questionnaires. During the first appointment, you will be interviewed to answer three questionnaires; this appointment will take approximately one hour. Two weeks after the first appointment, you will have a second appointment to answer one questionnaire; this will take you approximately 10 minutes, and could be over the phone depending on your preference. Four months after your first appointment you will have a third appointment to answer three questionnaires and this will take approximately one hour. Finally a fourth appointment will be scheduled and you will be asked to answer the same questionnaire as in the second appointment. The place of the appointments will be determined according to your preference and the options will be at St. Peter's hospital or at McMaster University or for the second and last appointments the questionnaires can also be answered over the phone.

Are there any risks?

You may become tired during one of the assessment appointments. If you do, you will be offered an opportunity to rest or stop the assessment.

Are there any benefits?

There are no direct benefits for you but the results of the study may provide benefits for people with Parkinson Disease in the future.

Will I be paid to participate in this study?

You will not be paid to participate in this study.

Will there be any costs to me in this study?

The study will not generate any costs for you, parking at the interview site will be refunded.

What will happen to my personal information?

The personal information that you will be asked to provide includes gender, date of birth, time since diagnosis. All of your information, including contact information and questionnaires will be kept in a locked cabinet at McMaster University and the information obtained on paper will be shredded after being transferred to the database which will not contain your name or any information that could be traced back to you. Your anonymized data will be kept for ten years in an secure computer file.

Can participation end early?

While your full participation in the study will be appreciated, you may withdraw from the study at any time if you wish to do so. The information that was collected before you decide to withdraw will be kept together with the other participants' and go through the same security and discarding process. If you decide to withdraw you can call Lori Letts (905) 525-9140 ext. 27816 or Gabriela Burgos-Martínez (905) 525-9140 ext. 26410 or (905) 865-1550.

If I have questions about this study, who should I call?

If you have any questions about the study please feel free to call Gabriela Burgos-Martínez (905) 525-9140 ext. 26410 or (905) 865-1550.

Participant Consent

Participant: I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

Name	Signature	Date

Person obtaining consent: I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study	Signature	Date

This study has been reviewed by the Hamilton Health Sciences/McMaster Faculty of Health Sciences Research Ethics Board (HHS/FHS REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call The Office of the Chair, HHS/FHS REB at 905.521.2100 x 42013

Version date: November 6, 2009

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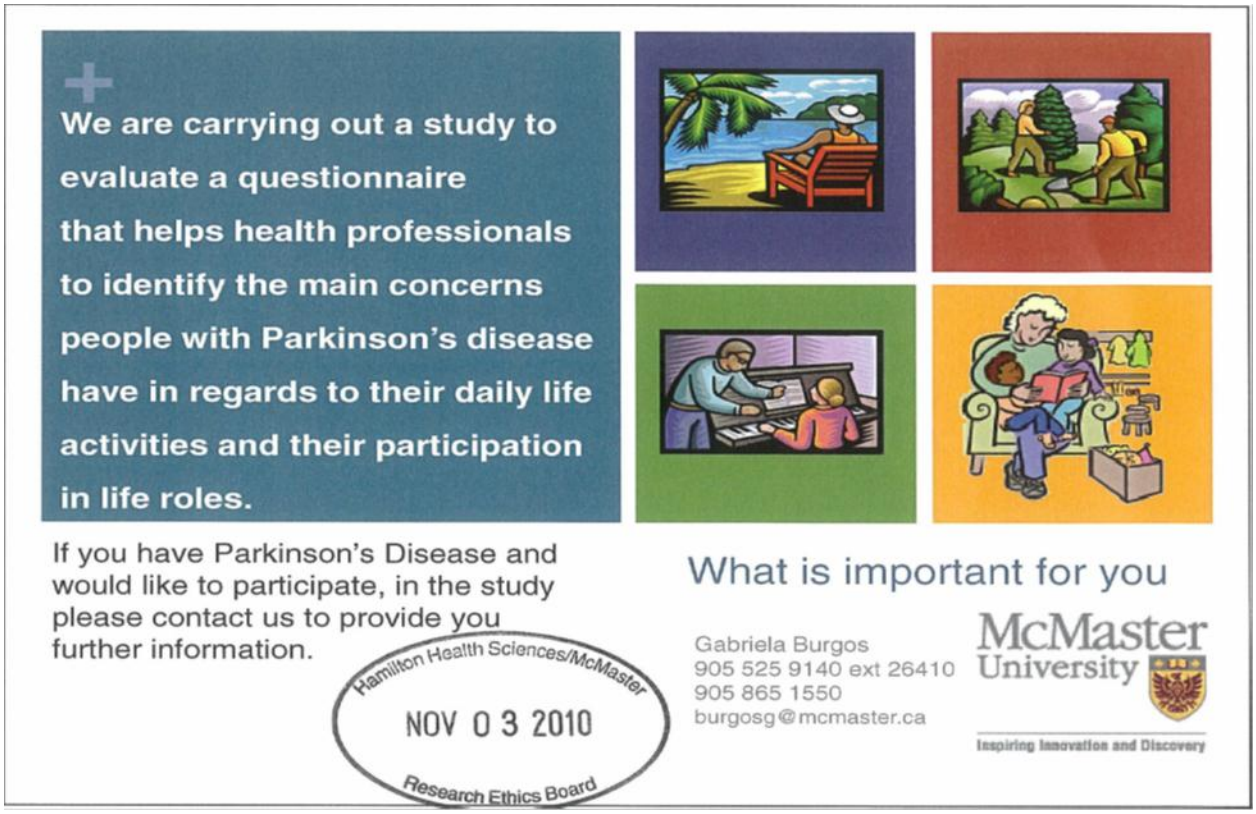
Appendix IV: Flyer



Appendix V: Data Collection Form

Study Id_____DOB_____

T1:_____ T2:_____T3:_____ T4:_____

Time since diagnosis:_____Hoehn and Yahr Stage 1 2 3 4 5

Medication scheme:_____

_____

Other chronic conditions:_____

_____

PSFS

Activity	T1	T2	T3	T4
1				
2				
3				
4				
5				
Additional				
Additional				

MDS-UPDRS: M-EDL

Item	Score T1	Score T2	Item	Score T1	Score T2
1			8		
2			9		
3			10		
4			11		
5			12		
6			13		
7					

Global rating of change:_____ Date:_____

T1 PDQ-39

1		9		17		25		33	
2		10		18		26		34	
3		11		19		27		35	
4		12		20		28		36	
5		13		21		29		37	
6		14		22		30		38	
7		15		23		31		39	
8		16		24		32			

T3 PDQ-39

1		9		17		25		33	
2		10		18		26		34	
3		11		19		27		35	
4		12		20		28		36	
5		13		21		29		37	
6		14		22		30		38	
7		15		23		31		39	
8		16		24		32			

Appendix 6: Outcome measures

Patient Specific Functional Scale

Initial Assessment

Clinician reads: I am going to ask you to identify up two 5 important activities that you are unable to do or have difficulty with as a result of Parkinson's Disease. Today, are there any activities that you are unable to do or have difficulty with because of Parkinson's Disease? (clinician writes the activities)

For each of the activities the clinician asks the participant to rate the ability to perform while showing the scoring scheme (Figure 1): Where do you situate your ability to (mention one activity at a time) on a scale from 0 to 10 where 0 means "unable to perform activity" and 10 means "able to perform similar to when you did not have Parkinson's Disease".

Follow up assessments

Clinician reads: When I assessed you on (mention previous assessment date) you told me that you have difficulty with (read each activity on the list from the previous assessment). Today do you still have difficulty with (mention the activities one at a time and elicit score showing the scoring scheme but do not mention previous score)?

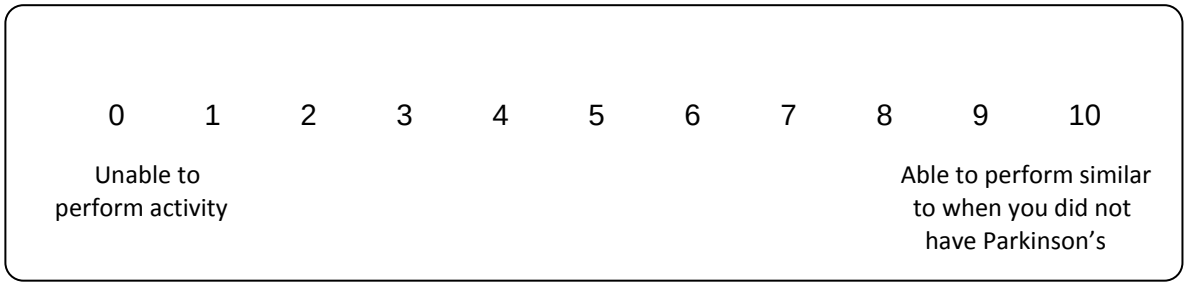


Figure 1: Scoring scheme to be shown at every assessment (Modified from: Stratford PW, Gill C, Westaway MD, Binkley JM. Assessing disability and change on individual patients: A report of a patient specific measure. Physiotherapy Canada. 1995;47(4):258-63.)

Isis Project Number:	3037

ISIS INNOVATION LIMITED
COPYRIGHT LICENCE AGREEMENT FOR HEALTH OUTCOMES QUESTIONNAIRE

PARTIES:

(1) Licensor:	Isis Innovation Limited with a principal place of business situated at Ewert House, Ewert Place, Summertown, Oxford, OX2 7SG
(2) Licensee:	McMaster University, School of Rehabilitation Science with a principal place of business situated at 1400 Main Street West, IAHS 403, Hamilton, ON L8S 1C7

The Licensor and Licensee are together referred to as "Parties" and individually as "Party"

AGREEMENT

Commercial Terms:

Commencement Date	1st August 2010
Contact details for Licensee	Name of contact: Ms Gabriela Burgos Job Title: Graduate Student Tel. No.: (011-1-905) 865 1550 Fax. No.: (905) 524 0069 E-Mail: burgosg@mcmaster.ca
Questionnaire	The health outcomes questionnaire titled: The Parkinson's Disease Questionnaire, the PDQ-39 and short-form, PDQ-8
Required Quantity	The number of copies of the Questionnaire that as at the date of this Licence Agreement Licensee expects to make in connection with the Permitted Use, being: 200 ("**Initial Quantity**") plus any additional copies subsequently purchased on payment of the Supplemental Fee
Signing Fee	Free of charge
Study	The Licensee's clinical trial study to be carried out in accordance with the study protocol titled: The Validity and Reliability of the Patient Specific Functional Scale for the assessment of Persons with Parkinson's Disease. A strictly non-commercial study at trial centers located in the Territory. The study to be completed by end of August 2011.
Supplemental Fee	Free of charge for each additional copy made above the Initial Quantity up to a maximum of 50 additional copies
Territory	School of Rehabilitation Science at McMaster University

This Licence Agreement comprises the Commercial Terms above and the General Conditions of Licence set out below.

Signed on behalf of Licensor:	Sign: LNaylor Print Name and Job Title: Linda Naylor Date: 30/7/10 Head of Technology Transfer Group Isis Innovation Ltd
Signed on behalf of Licensee:	Sign: Print Name and Job Title: LORI LOTTS, ASSISTANT DEAN, OT Date: July 23/2010 SS

PDQ-39 Canadian Version

DUE TO HAVING PARKINSON'S DISEASE, how often have you experienced the following, during the last month ?

Due to having Parkinson's disease, how often during the last month have you ….		*Please check one box for each question*				
		Never	Occasionally	Sometimes	Often	Always or cannot do at all
1.	Had difficulty doing the leisure activities which you would like to do?	☐	☐	☐	☐	☐
2.	Had difficulty looking after your home, e.g. repairs/ improvements, housework, cooking?	☐	☐	☐	☐	☐
3.	Had difficulty carrying shopping (or grocery) bags?	☐	☐	☐	☐	☐
4.	Had problems walking 1 km (half a mile)?	☐	☐	☐	☐	☐
5.	Had problems walking 100 m (100 yards)?	☐	☐	☐	☐	☐
6.	Had problems getting around the house as easily as you would like?	☐	☐	☐	☐	☐
7.	Had difficulty getting around in public places?	☐	☐	☐	☐	☐
8.	Needed someone else to accompany you when you went out?	☐	☐	☐	☐	☐
9.	Felt frightened or worried about falling in public?	☐	☐	☐	☐	☐

Due to having Parkinson's disease, how often <u>during the last month</u> have you ….	*Please check **one box** for each question*				
	Never	**Occasionally**	**Sometimes**	**Often**	**Always**
10. Been confined to the house more than you would like?	☐	☐	☐	☐	☐
11. Had difficulty washing yourself?	☐	☐	☐	☐	☐
12. Had difficulty dressing yourself?	☐	☐	☐	☐	☐
13. Had problems doing up buttons or shoe laces?	☐	☐	☐	☐	☐
14. Had problems writing clearly?	☐	☐	☐	☐	☐
15. Had difficulty cutting up your food?	☐	☐	☐	☐	☐
16. Had difficulty holding a drink without spilling it?	☐	☐	☐	☐	☐
17. Felt depressed?	☐	☐	☐	☐	☐
18. Felt isolated and lonely?	☐	☐	☐	☐	☐

19. Felt weepy or tearful? ☐ ☐ ☐ ☐ ☐

Due to having Parkinson's disease, how often <u>during the last month</u> have you ….	*Please check **one box** for each question*				
	Never	**Occasionally**	**Sometimes**	**Often**	**Always**
20. Felt angry or bitter?	☐	☐	☐	☐	☐
21. Felt anxious?	☐	☐	☐	☐	☐
22. Felt worried about your future?	☐	☐	☐	☐	☐
23. Felt you had to conceal your Parkinson's from people?	☐	☐	☐	☐	☐
24. Avoided situations which involve eating or drinking in public?	☐	☐	☐	☐	☐
25. Felt embarrassed in public due to having Parkinson's disease?	☐	☐	☐	☐	☐
26. Felt worried by other people's reaction to you?	☐	☐	☐	☐	☐
27. Had problems with your close personal relationships?	☐	☐	☐	☐	☐
28. Lacked support in the ways you need from your spouse or partner? ***If you do not have a spouse or partner, please tick here***	☐	☐	☐	☐	☐

29.	**Lacked support in the ways you need from your family or close friends?**	☐	☐	☐	☐	☐

Due to having Parkinson's disease, how often <u>during the last month</u> have you ….	*Please check **one box** for each question*				
	Never	**Occasionally**	**Sometimes**	**Often**	**Always**
30. Unexpectedly fallen asleep during the day?	☐	☐	☐	☐	☐
31. Had problems with your concentration, e.g. when reading or watching TV?	☐	☐	☐	☐	☐
32. Felt your memory was bad?	☐	☐	☐	☐	☐
33. Had distressing dreams or hallucinations?	☐	☐	☐	☐	☐
34. Had difficulty with your speech?	☐	☐	☐	☐	☐
35. Felt unable to communicate with people properly?	☐	☐	☐	☐	☐
36. Felt ignored by people?	☐	☐	☐	☐	☐
37. Had painful muscle cramps or spasms?	☐	☐	☐	☐	☐
38. Had aches and pains in your joints or other parts of your body?	☐	☐	☐	☐	☐
39. Felt cold or hot?	☐	☐	☐	☐	☐

On Mon, 19 Jul 2010 09:46:35 -0500
"Info \(MDS\)" <Info@movementdisorders.org> wrote:
> Dear Ms. Burgos Martinez,
>
> Thank you for your message. The Movement Disorder Society (MDS) grants you permission to use the MDS-UPDRS free of charge as a crosssectional validity component to the Patient Specific Functional Scale.
>
> Should you have any questions, please let me know.
>
> Kind regards,
>
> Andrea Wawrzyniak
> Administrative Coordinator
> The Movement Disorder Society (MDS)
> 555 East Wells Street, Suite 1100
> Milwaukee, WI 53202
> Phone: +1.414.276.2145 | Fax: +1.414.276.3349
> E-mail: info@movementdisorders.org
> Web: www.movementdisorders.org

MDS-UPDRS Part II

Instructions:

This questionnaire will ask you about your experiences of daily living.

There are 20 questions. We are trying to be thorough, and some of these questions may therefore not apply to you now or ever. If you do not have the problem, simply mark 0 for NO.

Please read each one carefully and read all answers before selecting the one that best applies to you.

We are interested in your average or usual function over the past week including today. Some patients can do things better at one time of the day than at others. However, only one answer is allowed for each question, so please mark the answer that best describes what you can do most of the time.

You may have other medical conditions besides Parkinson's disease. Do not worry about separating Parkinson's disease from other conditions. Just answer the question with your best response.

Use only 0, 1, 2, 3, 4 for answers, nothing else. Do not leave any blanks.

Your doctor or nurse can review the questions with you, but this questionnaire is for patients to complete, either alone or with their caregivers.

Part II: Motor Aspects of Experiences of Daily Living (M-EDL)

2.1 SPEECH

Over the past week, have you had problems with your speech?

0: Normal:	Not at all (no problems).	
1: Slight:	My speech is soft, slurred or uneven, but it does not cause others to ask me to repeat myself.	
2: Mild:	My speech causes people to ask me to occasionally repeat myself, but not everyday.	☐
3: Moderate:	My speech is unclear enough that others ask me to repeat myself every day even though most of my speech is understood.	
4: Severe:	Most or all of my speech cannot be understood	

	SCORE
2.4 EATING TASKS Over the past week, have you usually had troubles handling your food and using eating utensils? For example, do you have trouble handling finger foods or using forks, knifes, spoons, chopsticks? 0: Normal: Not at all (No problems). 1: Slight: I am slow, but I do not need any help handling my food and have not had food spills while eating. 2: Mild: I am slow with my eating and have occasional food spills. I may need help with a few tasks such as cutting meat. 3: Moderate: I need help with many eating tasks but can manage some alone. 4: Severe: I need help for most or all eating tasks.	☐
2.5 DRESSING Over the past week, have you usually had problems dressing? For example, are you slow or do you need help with buttoning, using zippers, putting on or taking off your clothes or jewelry? 0: Normal: Not at all (no problems). 1: Slight: I am slow but I do not need help. 2: Mild: I am slow and need help for a few dressing tasks (buttons, bracelets). 3: Moderate: I need help for many dressing tasks. 4: Severe: I need help for most or all dressing tasks.	☐

	SCORE
2.2 SALIVA & DROOLING Over the past week, have you usually had too much saliva during when you are awake or when you sleep? 0: Normal: Not at all (no problems). 1: Slight: I have too much saliva, but do not drool. 2: Mild: I have some drooling during sleep, but none when I am awake. 3: Moderate: I have some drooling when I am awake, but I usually do not need tissues or a handkerchief. 4: Severe: I have so much drooling that I regularly need to use tissues or a handkerchief to protect my clothes.	☐
2.3 CHEWING AND SWALLOWING Over the past week, have you usually had problems swallowing pills or eating meals? Do you need your pills cut or crushed or your meals to be made soft, chopped or blended to avoid choking? 0: Normal: No problems. 1: Slight: I am aware of slowness in my chewing or increased effort at swallowing, but I do not choke or need to have my food specially prepared. 2: Mild: I need to have my pills cut or my food specially prepared because of chewing or swallowing problems, but I have not choked over the past week. 3: Moderate. I choked at least once in the past week. 4: Severe: Because of chewing and swallowing problems, I need a feeding tube.	☐

	SCORE
2.6 HYGIENE Over the past week, have you usually been slow or do you need help with washing, bathing, shaving, brushing teeth, combing your hair or with other personal hygiene? 0: Normal: Not at all (no problems). 1: Slight: I am slow but I do not need any help. 2: Mild: I need someone else to help me with some hygiene tasks. 3: Moderate: I need help for many hygiene tasks. 4: Severe: I need help for most or all of my hygiene tasks.	☐
2.7 HANDWRITING Over the past week, have people usually had trouble reading your handwriting? 0: Normal: Not at all (no problems). 1: Slight: My writing is slow, clumsy or uneven, but all words are clear. 2: Mild: Some words are unclear and difficult to read. 3: Moderate: Many words are unclear and difficult to read. 4: Severe: Most or all words cannot be read.	☐
2.8 DOING HOBBIES AND OTHER ACTIVITIES Over the past week, have you usually had trouble doing your hobbies or other things that you like to do? 0: Normal: Not at all (no problems). 1: Slight: I am a bit slow but do these activities easily. 2: Mild: I have some difficulty doing these activities. 3: Moderate: I have major problems doing these activities, but still do most. 4: Severe: I am unable to do most or all of these activities.	☐

	SCORE
2.9 TURNING IN BED Over the past week, do you usually have trouble turning over in bed? 0: Normal: Not at all (no problems). 1: Slight: I have a bit of trouble turning, but I do not need any help. 2: Mild I have a lot of trouble turning and need occasional help from someone else. 3: Moderate: To turn over I often need help from someone else. 4: Severe: I am unable to turn over without help from someone else.	☐
2.10 TREMOR Over the past week, have you usually had shaking or tremor? 0: Normal: Not at all. I have no shaking or tremor. 1: Slight: Shaking or tremor occurs but does not cause problems with any activities. 2: Mild: Shaking or tremor causes problems with only a few activities. 3: Moderate: Shaking or tremor causes problems with many of my daily activities. 4: Severe: Shaking or tremor causes problems with most or all activities.	☐
2.11 GETTING OUT OF BED, A CAR, OR A DEEP CHAIR Over the past week, have you usually had trouble getting out of bed, a car seat, or a deep chair? 0: Normal: Not at all (no problems). 1: Slight: I am slow or awkward, but I usually can do it on my first try. 2: Mild: I need more than one try to get up or need occasional help. 3: Moderate: I sometimes need help to get up, but most times I can still do it on my own. 4: Severe: I need help most or all of the time.	☐

	SCORE
2.12 WALKING AND BALANCE Over the past week, have you usually had problems with balance and walking? 0: Normal: Not at all (no problems). 1: Slight: I am slightly slow or may drag a leg. I never use a walking aid. 2: Mild: I occasionally use a walking aid, but I do not need any help from another person. 3: Moderate: I usually use a walking aid (cane, walker) to walk safely without falling. However, I do not usually need the support of another person. 4: Severe: I usually use the support of another persons to walk safely without falling.	☐
2.13 FREEZING Over the past week, on your usual day when walking, do you suddenly stop or freeze as if your feet are stuck to the floor. 0: Normal: Not at all (no problems). 1: Slight: I briefly freeze but I can easily start walking again. I do not need help from someone else or a walking aid (cane or walker) because of freezing. 2: Mild: I freeze and have trouble starting to walk again, but I do not need someone's help or a walking aid (cane or walker) because of freezing. 3: Moderate: When I freeze I have a lot of trouble starting to walk again and, because of freezing, I sometimes need to use a walking aid or need someone else's help. 4: Severe: Because of freezing, most or all of the time, I need to use a walking aid or someone's help.	☐
This completes the questionnaire. We may have asked about problems you do not even have, and may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this questionnaire.	

Retrospective global rating of change

1. How would you say you are today compared to the visit when you first completed the questionnaire?
2. How important would you say this change is?

0 No change

Worse		Better
1	A tiny bit, almost the same	1
2	A little bit	2
3	Somewhat	3
4	Moderately	4
5	Quite a bit	5
6	A great deal	6
7	A very great deal	7

Modified from: Stratford, P.W., Binkley, J. M., Riddle, D. L. (1996). Health Status Measures: Strategies and Analytic Methods for Assessing Change Scores. *Physical Therapy*, 76, 1109-1123.

Appendix 7: Preliminary Results of the linking of the MDS-UPDRS, PDQ-39 and the PSFS to the ICF

Instrument	s	b	d	e	nd-qol	pf	nc
MDS-UPDRS	5	53	16	0			1
Section 1	—	22	0	—	—	—	—
Section 2	—	7	12	—	—	—	—
Section 3	5	17	2	—	—	—	—
Section 4	—	6	2	—	—	—	—
PDQ-39		22	18	9	1	—	—
MOB (1-10)	—	2	9	1	—	—	—
ADL (11-16)	—	0	6	0	—	—	—
EMO (17-22)	—	6	0	0	—	—	—
STI (23-26)	—	4	1	2	—	—	—
SUP (27-29)	—	0	1	5	—	—	—
COG (30-33)	—	5	0	0	—	—	—
COM (34-36)	—	1	1	1	—	—	—
BODIS (37-39)	—	4	0	0	—	—	—
PSFS	0	12	121	3	1	—	—

Overall results of measures' linking to the ICF codes. S= body structures, b= Body Functions, d=Activities and Participation, e-environmental factors, nd-qol=not defined quality of life, pf=Personal Factors, nc=Not Covered.