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EFFECTS OF TWO PARKINSON'S DISEASE PATIENT EDUCATION MODELS ON DISEASE SELF-MANAGEMENT AND QUALITY OF LIFE

by

Lorraine Pearl-Kraus

A Dissertation Submitted to the Faculty of The Graduate College in partial fulfillment of the requirements for the Degree of Doctor of Philosophy Department of Interdisciplinary Health Studies Dr. Nickola W. Nelson, Advisor

Western Michigan University Kalamazoo, Michigan June 2007

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This work is dedicated with the utmost love and gratitude to
my husband, Mark T. Kraus,
my parents, the late James and Irene Pearl,
my parents-in-law, Shirley and the late Eugene Virden Kraus,
my friend, Sister Mary Ann Gschwind, and to
my cat, Boops.
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Lorraine Pearl-Kraus
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CHAPTER I

INTRODUCTION

Parkinson's disease (PD) affects the lives of millions of people worldwide. It is the second most common chronic, neurodegenerative disease—second only to Alzheimer's dementia (Bertram & Tanzi, 2005; Nutt & Wooten, 2005). Parkinson's is a progressively debilitating disease that has an impact on the quality of life (QOL) of patients with this condition and their families (Jahanshahi & Marsden, 2000).

Efforts to address the impact of PD encompass not only basic research, but also applied research. As a chronic, progressive condition with no currently known cure, treatment is aimed at slowing the progression of the disease, managing symptoms, and lessening their impact on functional limitations. This investigation was designed to address questions about methods for educating patients about self-managing their disease. Specifically, it was designed to evaluate a collaborative care method that involves patient education and implementation of treatment regimens that have been established by the patients themselves with guidance and support from health care professionals. This is consistent with the observation by Marjama-Lyons and Shomon (2003) that "ultimately, living well with Parkinson's requires knowledge of how Parkinson's affects both mind and body" (p. xix).

Chapter I introduces the components and hypotheses of this intervention study. It also summarizes the magnitude of the problem of PD, as well as its scope in terms of impact on QOL. Treatment adherence issues in PD are described as well. The research
design and specific aims of the study, research questions and hypotheses are also introduced, as well as key constructs and their operational definitions.

The purpose of the study was to address the question of how to positively influence patient self-efficacy by comparing a new model of PD patient education and health care delivery to a traditional model of information transmission. The plan was to compare the effects of a PD collaborative care model of patient education to a traditional PD education model on patients' perceptions of their QOL and efficacy for managing their disease.

A pre-post design was used that involved asking participants with PD to complete measures of QOL and self-efficacy prior to training, immediately postintervention, and again 4 weeks later. The results were expected to have implications for health care professionals and health systems that provide care to PD patients, pharmaceutical companies, health insurance companies, policymakers, and PD patients and their families.

Magnitude of the Problem of Parkinson’s Disease

Epidemiological studies of Parkinson’s disease (PD) are scarce, but an estimated 4 million people worldwide are believed to experience this progressively disabling, neurodegenerative disease (Blake-Krebs & Herman, 2001; Huse, Schulman, et al., 2005; Marjama-Lyons, 2003). In the United States, approximately 1 to 1.5 million people have been diagnosed with PD (Bushnell & Martin, 1999; Marjama-Lyons, 2003) and about 60,000 new cases are diagnosed annually (Blake-Krebs & Herman, 2001). The average age of onset of PD is 55, but 15% of cases are diagnosed in individuals under the age of
50, and 10% are in individuals under the age of 40 (Blake-Krebs & Herman, 2001). The incidence of PD increases significantly with age (Huse et al., 2005), with its prevalence estimated to be as high as 1 in 100 persons over 60 years of age (Lang & Lozano, 1998; Marjama-Lyons & Shomon, 2003).

The latest morbidity and mortality trends data from 2003 from the Centers for Disease Control and Prevention (CDCP, 2006) have shown a significant increase in deaths attributable to PD. Parkinson’s disease now ranks as the 14th leading cause of death in the United States (CDCP, 2006). Given the aging population and its increasing longevity, the prevalence of PD and other chronic diseases is expected to rise (Global Parkinson’s Disease Survey Steering Committee [GPDSSC], 2002). Research studies have shown that 45% of the U. S. general population and 88% of individuals aged 65 years and older have at least one chronic disease (Wolff, Starfield, & Anderson, 2002).

Demographic trend projections estimate that by 2020, 157 million Americans (nearly 50% of the population) will have at least one chronic disease (Anderson, 2003; Wolff et al., 2002). Individuals with multiple chronic conditions, especially the frail elderly, are likely to experience a more rapid decline in functional health status and an increased likelihood of disability (Manton & Gu, 2001; Singer & Manton, 1998; Wolff et al., 2002).

People with chronic conditions accounted for more than 78% of the health care expenditures in 2000 (Anderson, 2003). Based on their analysis of health insurance claims data from January 1999 to December 2002, Huse et al. (2005) estimated that the annual direct health care costs per PD patient for care in the U. S. was $10,439 (in 2002 dollars) and $25,326 in indirect costs, such as uncompensated caregiving and
productivity loss. The cumulative effect is approximately $34 billion (in 2004 dollars) in annual health care expenditures for PD care (Noyes, Liu, Li, Holloway, & Dick, 2006). As the prevalence of PD increases, society can expect to see a substantial rise in the cost of PD care that will likely have a profound economic impact on health care systems (Blake-Krebs & Herman, 2001; Huse et al., 2005; Marjama-Lyons & Shomon, 2003). Thus, clinicians may be required to care for and support PD patients who are living longer with the disease. Although a cure is a legitimate long-range goal, an appropriate interim goal is to seek the most effective means for helping patients to maintain their quality of life (Welsh, 2004).

Scope of the Problem of QOL and Adherence Issues

The research that has been done in this area has shown that Parkinson’s disease has a substantial impact on patients’ health-related quality of life (HRQOL) (Karlsen, Larsen, Tandberg, & Maeland, 1999; Karlsen, Tandberg, Arslan, & Larsen, 2000; Martinez-Martin, 1998). Cardinal features of Parkinson’s disease are tremor, bradykinesia (slowness of movement), rigidity, and postural instability—with bradykinesia and tremor being the most commonly occurring symptoms (Lang & Lozano, 1998). These symptoms can make it difficult for PD patients to perform routine activities of daily living (ADLs), such as dressing, bathing, and grooming; getting out of bed or arising from a seated position; and walking or climbing stairs. Besides the motor impairment, many nonmotor symptoms also are associated with PD. These include dysfunction of the autonomic nervous system and cognitive changes, which have been
shown to have had a multifaceted impact on the QOL of these patients (GPDSSC, 2002; Welsh, 2004).

The symptoms that PD patients may experience and that influence their QOL are related in complex ways to their adherence (or nonadherence) to treatment regimens. Adherence can be a double-edged sword, with positive and negative consequences on symptom management and QOL. For example, some of the symptoms that affect QOL for patients with PD and their families include: impaired mobility, balance, and nutrition; emotional and sleep disturbances; fatigue, depression, cognitive changes, altered social roles, altered libido, sexual dysfunction, blurred vision, and other autonomic nervous system-related symptoms. Medication regimens are a mainstay in the treatment of such PD symptoms. Although drug regimens heavily focus on the control of PD-motor symptoms (Grosset & Grosset, 2005; Leopold, Polansky, & Hurka, 2004), pharmacological interventions are expensive, may have limited effects, and can also create side effects that have a negative impact on QOL (Welsh, 2004). Patients who take sufficient medication (dopamine) to control tremor, bradykinesia, and rigidity symptoms may over time develop involuntary motor movements (dyskinesia), which create an additional problem. When side effects become a source of social embarrassment or a person becomes dosage tolerant or other complications occur, patients may be influenced to become nonadherent to the prescribed treatment regimen in effort to achieve better symptom control.

Therefore, a major impediment to pharmacological management of PD is nonadherence to prescribed drug regimens (Leopold et al., 2004). Extant research on drug adherence to prescribed regimens and HRQOL in PD patients is limited (Leopold et
al., 2004; Welsh, 2004), but preliminary results suggest that adherence or nonadherence to prescribed medication regimens can significantly influence how well patients are able to control and manage their PD symptoms which, in turn, can directly affect their QOL.

Although pharmacological treatments have been the hallmark of PD therapy, there are several other beneficial treatment modalities available to aid in the management and control of PD symptoms that may improve the QOL and help to prevent injuries in this population (Chen, Zhang, Schwarzschild, Hernan, & Ascherio, 2005). Underutilized interventions include exercises, environmental design, and social support systems, all of which may be effective in improving QOL for these patients.

Significance of the Research

To maximize effective treatment of Parkinson’s disease patients, clinicians from multiple disciplines need a better understanding of the factors that contribute to adherence that may impact the QOL in this population. The current research constitutes an attempt to help bridge this knowledge gap.

Extant research is limited regarding the role of self-efficacy and patient education for disease self-management in Parkinson’s disease, and ultimately, the influence of such factors on self-reported HRQOL in PD (GPDSSC, 2002; Welsh, 2004). Further, this knowledge deficit has hindered the development and implementation of both conceptual models of health care delivery and clinical guidelines for the care management of patients with PD (GPDSSC, 2002; Welsh, 2004). Limited research has been reported regarding PD patients’ adherence to prescribed treatment regimens: self-report of perceived ability of PD patients to self-manage their disease, the impact of patient-centered educational
approaches on PD patients' self-reported adherence to treatment protocols, and patient-reported perceptions of impact on PD QOL indicators.

Insight gained from the results of this study may help to influence the implementation of patient education methods that will meet the needs of PD patients more appropriately, thereby enabling them to improve their self-management of PD and PD HRQOL. Further, information collected from this research study will provide background data for stakeholders, such as health care institutions, health care policymakers, and insurance and pharmaceutical companies that are responsible for developing and delivering health care services and products to treat PD and to enhance the care of Parkinson's patients and their families.

Research Design and Specific Aims

This research involved a small randomized clinical trial with pre-post assessment of desired outcomes of patient self-efficacy and QOL to investigate the effectiveness of an emerging paradigm in patient education and chronic disease self-management in comparison to the traditional patient education and disease management approach. The experimental patient education approach investigated was called the PD collaborative care (PDCC) model for purposes of this investigation. The conceptual model for this approach has been stimulated by the Chronic Disease Self-Management Program (CDSMP) developed by Stanford University researchers (Lorig, Stewart, et al., 1996), based on its purpose being to promote the PD patient's disease self-management skills, problem-solving capabilities, and knowledge. The PDCC model (also called the collaborative care model) enfolded components of the CDSMP (Lorig et al., 1996).
For contrast, some patients were randomly assigned to a comparison group that received a traditional standard of care model, which was referred to as the PD Informational Training (PDIT) model. The intent in selecting these two designators (PDCC and PDIT) was to have two terms that would not signal to the participants in the study which group was considered experimental and which was control (i.e., comparison group).

Both groups received information from interdisciplinary health care professionals regarding pertinent aspects of disease management specific to PD and were given information about technical skills specific to this disease. The experimental PDCC group participated in additional collaborative goal setting activities related to specific aspects of general recommendations they could select for immediate implementation. That is, in the PDCC model, peer mentors assisted these participants to create patient-identified, short-term “action plans,” which they worked on between sessions and updated at subsequent sessions.

The specific aims of this random control pre-/posttest intervention study (with one-month follow-up) were:

1. To compare the effectiveness of two health care delivery and patient education models (PDCC and PDIT) in enhancing PD patients’ perceived self-efficacy in PD disease self-management, and

2. To compare the effectiveness of the two health care delivery and patient education models (PDCC and PDIT) in enhancing PD patients’ self-reported perceived PD-HRQOL.
Research Questions, Hypotheses, and Definitions

The following research questions and hypotheses were generated to operationalize the intended aims of this study.

Research Questions and Hypotheses

1. Is there a difference between pre- and posttest scores (Time 1 – Time 2) on the Self-Efficacy for Managing Chronic Disease 6-Item Scale between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?

Hypotheses:

H₀₁: Pre-post scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale (Stanford University) will not differ between the two groups.

H₁₁: Pre-post scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale (Stanford University) will differ between the PDCC (experimental) group and the PDIT (control) group.

2. Is there a difference between pre- and posttest scores (Time 1 – Time 2) on the PDQ-39 Parkinson’s Disease Quality of Life Scale between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?

Hypotheses

H₀₂: Pre-post scores on the PDQ-39 Parkinson’s Disease Quality of Life Scale will not differ between the two groups.
10

H_{a2}: Pre-post scores on the *PDQ-39 Parkinson's Disease Quality of Life Scale* will differ between the PDCC (experimental) group and the PDIT (control) group.

3. Is there a difference between change scores from posttest (Time 2) to the 4-week follow-up (Time 3) on either of the dependent measures (*Self-Efficacy for Managing Chronic Disease 6-Item Scale* or *PDQ-39 Parkinson's Disease Quality of Life Scale*) between the PDCC and PDIT groups?

**Hypotheses**

H_{o3}: Time 2 – Time 3 change scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* will not differ between the two groups.

H_{a3}: Time 2 – Time 3 change scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* will differ between the two groups.

H_{o4}: Time 2 – Time 3 change scores on *PDQ-39 Parkinson's Disease Quality of Life Scale* will not differ between the two groups.

H_{a4}: Time 2 – Time 3 change scores on *PDQ-39 Parkinson's Disease Quality of Life Scale* will differ between the two groups.

4. Is there a difference between change scores from baseline (Time 1) to the 4-week follow-up (Time 3) on either of the dependent measures (*Self-Efficacy for Managing Chronic Disease 6-Item Scale* or *PDQ-39 Parkinson's Disease Quality of Life Scale*) between the PDCC and PDIT groups?

**Hypotheses**
$H_{05}$: Time 1 – Time 3 change scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* will not differ between the two groups.

$H_{A5}$: Time 1 – Time 3 change scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* will differ between the two groups.

$H_{06}$: Time 1 – Time 3 change scores on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* will not differ between the two groups.

$H_{A6}$: Time 1 – Time 3 change scores on *PDQ-39 Parkinson’s Disease Quality of Life Scale* will differ between the two groups.

*Constructs and Operational Definitions Relevant to Research Questions*

The key constructs (concepts) embedded within these research questions have been operationally defined as they relate to this study. These definitions are outlined in the sections below.

*Chronic Care Model:* This is a health care delivery model created by the Improving Chronic Illness Care National Program (Glasgow, Funnell, et al., 2002; Glasgow, Davis, Funnell, & Beck, 2003), which recommends evidence-based interventions within six areas known to improve processes of care and patient outcomes: delivery system design, self-management support, organization of the health system, decision support, information systems, and linkages to the community (Cretin, Shortell, & Keeler, 2004). The Chronic Care Model, along with Stanford University’s Chronic Disease Self-Management Program (Lorig et al., 1996), provided the conceptual frameworks for the PDCC model used to present a patient education and disease self-management program to PD patients who participated in this study.
Patient-Professional Partnership Paradigm: This is a new chronic disease self-management paradigm in which the expertise of the patient is regarded as important as the expertise of the health care professionals in making mutually-established health care goals and decisions for patient disease self-management (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Tattersall, 2002). For the purpose of this study, PD patients who were enrolled in the treatment (experimental) group received a structured PD disease self-management, interdisciplinary patient education intervention over a 3-week period.

Collaborative Patient Education Model: This is another term sometimes used in the literature (Bodenheimer et al., 2002; Lorig, 2003a, 2003b) to refer to a collaborative care model (CCM), in which patients act as equal participants in helping to formulate what type of information and skill-learning (technical and problem solving) that they require to manage their PD and its related sequelae to improve their QOL. For the purpose of this study, PD patients who were enrolled in the experimental PDCC group used their expertise and interacted with an interdisciplinary team of health care professionals to identify patient learning needs relevant to PD disease self-management, including but not limited to disease information, technical skills, and problem-solving skills.

Disease Self-Management Education: The disease self-management educational approach is related conceptually to the emerging paradigm of patient-centered care, which is context-based and emphasizes the teaching of problem-solving skills, such as patient empowerment and disease information, thereby complementing a traditional patient education (see next term). The goal of self-management education is to increase the patient’s perceived self-efficacy, thereby improving patient’s clinical outcomes.
In the current study, PD patients who were enrolled in the experimental group received this interventional educational approach as part of the PDCC model, whereas patients in the control group received the traditional patient education approach, but without the additional self-management components.

**Traditional Patient Education Model:** In the traditional patient education approach to disease treatment (called PDIT in this study—the control group), the healthcare professional team members are viewed as the experts, and the patients are the designated learners whose expertise is not actively engaged as part of the educational interaction and who offer very little to the educational process (Bodenheimer et al., 2002). The traditional patient educational model emphasizes the sharing of information and teaching of technical skills relevant to disease management as identified by the healthcare team, whereas the patient is the passive recipient of this education. Problem-solving skills, such as patient empowerment, are *not* taught in the traditional patient education model. The goal of the traditional patient education model is to increase patient adherence to the behavior changes that have been taught, thereby improving patients' clinical outcomes (Bodenheimer et al., 2002). In the current study, PD patients who were enrolled in the control group received this type of interventional educational approach. It was friendly and informational but lacked the peer-supported collaborative action planning components.

**Self-Efficacy:** This is a concept derived from social cognitive theory that relates to the human motivation and confidence that one has the ability to produce the desired changes by one's actions (Bandura, 2004). As it is difficult to measure self-efficacy directly, for the purpose of this study it was measured as the self-reported perceived self-
efficacy that PD patients had in their ability to self-manage their PD and other comorbid illnesses, if they existed. The self-reported perceived self-efficacy for PD disease self-management by patients enrolled in this study was measured serially by using the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* (Lorig et al., 1996) developed by the Chronic Disease Self-Management Program researchers at Stanford University.

*Parkinson's Disease*: A progressive, neurodegenerative disease with hallmark features of tremor, bradykinesia (slowness of movement), rigidity, and postural instability; other symptoms include autonomic nervous system dysfunction, mood and cognitive changes, hallucinations, psychoses, masked facies, sleep disorder, sexual dysfunction, dysphonia, and micrographia (Nutt & Wooten, 2005). Incidence increases with age, affects all races and ethnicities, and has a slightly greater prevalence in males than females.

*Parkinson's Disease Patient*: For purposes of this study, the PD patient was either male or female; ≥ 30 years of age, but not greater than 80 years old; with middle stage (Modified Hoehn & Yahr stages 2 and 3) PD, who did not have a known diagnosis of Dementia with Lewy Bodies (DLB) or other dementiae.

*Parkinson's Disease Self-Management Skills*: Skills in PD self-management generally encompass the degree to which a person can demonstrate knowledge and application of disease information, technical skills, and problem-solving skills relevant to the disease. Self-management skills comprise areas related to a variety of professional domains, including skills for managing one's medications (as recommended by physicians and supported by pharmacists); physical exercise (as recommended by physical therapists), functional activities and home modification/environmental design (as
recommended by occupational therapists); speech intelligibility and social communication functions (as recommended by speech-language pathologists); and identification and access of appropriate social support systems (as recommended by social workers). In this study, pertinent information that met the standard of care for PD patients was offered by specialists in each of these key content areas to patients in both groups, but the delivery method of patient education, instructional materials, and skills development differed between the two groups. Patients in both groups were given information about the relevant technical skills for PD disease self-management. The difference was that the experimental PDCC group was engaged in peer-supported active learning of problem-solving skills to enhance their self-efficacy in PD disease self-management. The control group PDIT members received the information and technical skills, but did not receive the additional peer-supported collaborative planning and problem-solving skills practice.

*Self-Reported Perceived Parkinson’s Disease Self-Management Skills:* For purposes of this study, this was the PD patients' self-reported assessment of their self-efficacy of PD disease self-management skills as noted above and measured on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* developed by the Stanford University Chronic Disease Self-Management Program.

*Prescribed Treatment Regimen:* For purposes of this study, pharmacological and nonpharmacological interventions prescribed by the PD interdisciplinary health care team for treatment of PD and other comorbid conditions for patients enrolled in this research project.

*Quality of Life:* The adequacy of one’s physical and psychosocial functioning as based on key QOL indicators valued by the individual. For purposes of this study, this...
was measured by the self-reported perceived PD QOL as expressed by both patient groups on serial measures of the \textit{PDQ-39} over a 7-week period. The \textit{PDQ-39} measures several parameters of each of the QOL indicators identified by PD patients, i.e.: mobility, activities of daily living, emotional well being, stigma, social support, cognition, communication, and bodily discomfort (Peto, Jenkinson, & Fitzpatrick, 1998). The \textit{PDQ-39} measure was self-administered to both groups at baseline, after completion of the intervention, and at one month after completing the intervention.

\textbf{Chapter Summary}

In summary, Chapter I has provided an introduction and overview of this research project including its significance, aims, research questions, and hypotheses. Key concepts and operational definitions related to the research questions and outcome measures have also been discussed. Results of this study may provide information that health care institutions and clinicians can use to enhance the care they provide to PD patients and their families, can serve as the impetus for realignment of reimbursement systems to support evidence-based practices, and can stimulate development of health policies that support healthcare innovation and safe, effective, patient-centered quality care.
CHAPTER II

LITERATURE REVIEW

The efforts of research scientists to unveil the mysteries of PD have led to valuable insights into its myriad complexities, disease models, and symptoms. These research endeavors have resulted in a new understanding of the organization of the brain’s neural circuitry, especially within the basal ganglia (deep brain structures) (Olanow, 2004), and its associated effects on the body. Research also has illuminated how symptoms of PD impact the quality of life for patients (Global Parkinson’s Disease Survey Steering Committee [GPDSSC], 2002). Further, this knowledge has helped scientists to reaffirm the use of standard treatments (for example, levodopa) as well as developing new treatments (Olanow, 2004), such as pharmaceuticals, neural tissue implants, physical rehabilitation modalities (DeGoede, Keus, Kwakkel, & Wagenaar, 2001; Ferry, Johnson, & Wallis, 2002; Ramig et al., 2001; Schenkman, 2002), and such medical devices as Deep Brain Stimulators. Such treatments are specifically targeted to abate the onset of PD, treat its constellation of symptoms, or delay disease progression (Quality Standards Subcommittee of the American Academy of Neurology [QSSAAN], 2006a, 2006b, 2006c, 2006d; Rascol, Goetz, Koller, Poewe, & Sampaio, 2002).

Health care professionals caring for patients with PD have translated this research into the clinical setting in an effort to improve both the quality of care and lives of PD patients and their families. Given the chronic nature of PD, these clinicians are also seeking to develop and implement new models of health care delivery that will better
address the needs of PD patients and their families (McRae, Sherry, & Roper, 1999). Health care delivery models, such as the Patient-Professional Partnership Collaborative Care Model (PPPCCM), engage Parkinson’s patients as active partners in the care process (Bodenheimer et al., 2002). Through self-management patient education, the PPPCCM and other similar models, collaboratively empower patients to be efficacious in the daily management of their PD and to manage any comorbidities (Bandura, 2004; Barr et al., 2003; Clark, 2003; Epping-Jordan, Pruitt, Bengoa, & Wagner, 2004; Fries, Lorig, & Holman, 2003; Holman & Lorig, 2000, 2004; Lorig, 2001, 2002, 2003a, 2003b; Marks, Allegrante, & Lorig, 2005a, 2005b).

The purpose of this chapter is to present a scholarly review of the literature relevant to the: (a) overview of PD: including its epidemiology, symptomatology, treatment options and their ramifications, and the financial impact of PD; (b) PD patient health-related quality of life issues: including PD HRQOL indicators, impact of PD treatment options on the physical and social functioning of Parkinson’s patients, impact of patients’ adherence or nonadherence to treatment options and the role of patient education in promoting patient adherence; (c) PD and health care patient education and delivery paradigms: including the traditional care-patient education model and the new collaborative care model, PPPCCM; and, lastly, (d) the impact of PD and chronic disease self-management, patient education programs on self-reported patient outcomes and systems outcomes.
Parkinson’s Disease

Overview of Parkinson’s Disease

Description of PD and Its Symptomatology

The first description of the “shaking palsy” was written by James Parkinson in 1817 as an observational case review of 6 patients who had motor symptoms of tremor, bradykinesia (slowness of movement), and rigidity (Slaughter, Slaughter, Nichols, Holmes, & Martens, 2001). Since then, a fourth cardinal symptom, postural instability with gait disturbance, has been added to the classic triad of symptoms that typify the PD syndrome. Nonmotor symptoms of PD affect three domains: (a) autonomic dysfunction (impaired functioning of the autonomic nervous system), such as visual disturbances, bowel and bladder dysfunction, and erectile dysfunction; (b) neuropsychological dysfunction, such as depression, emotional lability, hallucinations, sleep disturbances, psychoses, cognitive impairment, and dementia; and (c) sensory dysfunction, including pain (Olanow, 2004; QSSAAN, 2006a, 2006b, 2006c, 2006d). Effective control of the major and minor symptoms of PD impacts the health-related QOL (HRQOL) experienced by Parkinson’s patients and their families.

The presentation of PD motor and nonmotor symptoms is due to the loss and imbalance of neurochemical transmitter substances in the brain, particularly dopamine, but also norepinephrine, acetylcholine, serotonin, and glutamate which are thought to play a role in the manifestation of PD symptoms (Bergman & Deuschl, 2002; Olanow, 2004; Schrag, Ben-Shlomo, & Quinn, 2002). Pathologically, a loss of melanized...
dopaminergic neurons is seen in the deep structures of the brain, specifically the substantia nigra pars compacta (SNc), which is accompanied with abnormal protein inclusions, called Lewy bodies (Olanow, 2004). It is estimated that 70-80% of dopaminergic cell loss has already occurred by the time the clinical diagnosis of PD is made (DeGoede et al., 2001; QSSAAN, 2006c). Basic neuroscience research has shown that neurodegeneration may also affect other deep brain structures resulting in loss of norepinephrine from the locus ceruleus, serotonin from the cerebral cortex, brainstem, spinal cord, dorsal raphe nucleus, and peripheral autonomic nervous system, and cholinergic neurons from the nucleus basalis of Meynert (Bergman & Deuschl, 2002; Olanow, 2004). It is thought that the neurochemical imbalances caused by the neurodegeneration seen in PD disrupts the neural circuitry of the basal ganglia (deep brain structures) resulting in the motor (including the involuntary movements called dyskinesia) and nonmotor symptoms of PD (Bergman & Deuschl, 2002; Betarbet, Sherer, DiMonte, & Greenamyre, 2002; Olanow, 2004; Schrag & Quinn, 2000). The basal ganglia are part of the neural circuitry that arises from the cortex of the brain, passes through the striatum, pallidum, and thalamus, and then project back to the cerebral frontal cortex (Bergman & Deuschl, 2002).

**Epidemiology of PD**

Epidemiological studies of PD are relatively scarce; however, approximately 1.5 million Americans have been diagnosed as having PD, and PD is estimated to affect about 4 million people worldwide (Bertram & Tanzi, 2005; Bushnell & Martin, 1999; Lang & Lozano, 1998). As previously noted, about 60,000 new cases of PD are
diagnosed annually in the United States (Blake-Krebs & Herman, 2001). The incidence rate is expected to increase significantly as the population continues to age (Nutt & Wooten, 2005; Olanow, 2004; Welsh, 2004). The likelihood of developing PD increases with age; its prevalence is estimated to be as high as 1 in 100 persons over 60 years of age (Lang & Lozano, 1998; Nutt & Wooten, 2005). Payami, Larsen, Bernard, and Nutt’s (1994) study (as cited in Nutt & Wooten, 2005) noted that genetics play a role in approximately 10-15% of PD cases with 10 autosomal dominant and recessive genes being linked to PD. Bertram and Tanzi (2005) noted, however, that Mendelian inheritance appears to be associated with an early or even juvenile onset of PD. The role genetics plays in the onset of PD in persons greater than 50 years of age remains debatable. All racial and ethnic groups are affected, with a slightly higher preponderance among Caucasians (Lang & Lozano, 1998; VanDenEeden et al., 2003). Males have a slightly greater preponderance for developing PD than do women (Bertram & Tanzi, 2005).

Some studies have indicated that a rural environment (Lang & Lozano, 1998) and geographical distribution of pesticide usage (Bertarbet et al., 2002; Gorell, Johnson, Rybicki, Peterson, & Richardson, 1998) are associated with an increased risk for developing PD. Further, many other factors have been implicated as plausible etiological agents of PD, including exposure to radiation, viruses, oxidative stress, and drug abuse (Bergman & Deuschl, 2002; Betarbet et al., 2002; Lang & Lozano, 1998). Marras and Tanner (2004) noted (as cited in Nutt and Wooten, 2005), however, that there have been no clear environmental determinants of PD identified. Yet, Vaughan and Hardie (2002) contended that the “absence of any specific and sensitive diagnostic test or bioassay for
PD has always meant that epidemiological studies underestimate PD in any given population exposed to environmental triggers" (p. 47). Regardless of its etiology, PD is a slowly, progressively debilitating disease that exacts a heavy toll on PD patients, spouses, and families. The latest morbidity and mortality data (2003) from the Centers for Disease Control and Prevention (CDCP) has shown a significant increase in deaths attributable to PD. Parkinson’s disease now ranks as the 14th leading cause of death in the United States (CDCP, 2006).

**Financial Burden of PD**

As previously noted, PD exacts a significant economic burden on PD patients, their families, and society. Noyes et al. (2006) compared the utilization of health services, health care expenditures, and economic burden of self-reported PD among 35,217 Medicare beneficiaries with and without PD, using data obtained from the 1992-2000 Medicare Current Beneficiaries Survey. Noyes et al. found that total annual health expenditures of PD patients were over two times greater than in their non-PD counterparts. PD patients also paid more out-of-pocket costs for prescription medications than non-PD beneficiaries and for long-term insurance (Noyes et al., 2006). Further, an increased use of all health care services by community-dwelling PD versus non-PD beneficiaries was noted, but this difference was not evident among institutionalized PD versus non-PD beneficiaries (Noyes et al., 2006). PD patients used 3.0 times more home health services and had 1.3 times more outpatient visits, 1.7 times more hospice events, 2.8 more short-term care stays, and 1.8 times more long-term care stays, than did their non-PD counterparts (Noyes et al., 2006).
Adjusted annual expenditures for PD patients in the 1990s exceeded $20,000 yearly in direct medical costs (Noyes et al., 2006). Medicare PD-beneficiaries' total annual health care costs were 70% higher than non-PD beneficiaries even after adjusting for socioeconomic status, ADLs, and comorbidities, i.e., $18,528 versus $10,818 ($p = <0.001), respectively (Noyes et al., 2006). Noyes et al. found that PD patients had higher levels of costly comorbidities, including depression, dementia, falls, diabetes, and cardiovascular disease, whereas cerebrovascular disease and cancer were determinants of higher medical costs among non-PD beneficiaries.

Guttman, Slaughter, Theriault, DeBoer, and Naylor (2003) conducted a 6-year inception cohort study of $N = 45,912$ patients in Ontario, Canada ($n = 15,304$ with PD; $n = 30,608$ without PD) which revealed findings similar to those of Noyes and colleagues (2006) with regard to increased utilization of health care services and increased health care expenditures. Among members of this inception cohort, PD patients had 1.45 times more acute care hospitalizations with 1.19 times longer length of stay (LOS); they also incurred 1.4 times more cost for physician services and 3.0 times more drug costs than did their non-PD control group members (Guttman et al., 2003).

Few studies exist that analyze the cost of illness of PD and only one published cost effectiveness study addressed the value of PD interventions (Siderowf, Holloway, & Stern 2000). Hoerger, Bala, Rowland, et al.'s (1998) study assessed the effectiveness of the use of pramipexole (a dopamine agonist) in comparison to baseline levodopa therapy in early and late-stage PD based on changes in the patients' scores on the Unified Parkinson's Disease Rating Scale (UPDRS). Siderowf et al. (2000) reported that results from this study revealed that pramipexole was both more effective and more costly than
baseline levodopa therapy for early and late-stage PD patients. Based on change in UPDRS scores, the cost-effectiveness ratio per QALY (quality-adjusted life years) for treatment of early PD with pramipexole versus baseline levodopa was $9,139 (in 1998 dollars) and $12,714 per QALY for treatment of late-stage PD with pramipexole versus levodopa (Siderowf et al., 2000). QALY is life expectancy adjusted based on the patient's subjective preference for the value of a given health state in which one's remaining life expectancy is spent (Siderowf et al., 2000). Siderowf et al. noted that an incremental cost-effectiveness ratio of less than $20,000 per QALY is strong evidence in support of interventions that are both more costly and more effective than standard care.

The economic burden of PD and rising national health care expenditures, mandate the need for conducting more cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) studies to determine the value of existing resource-intensive and emerging PD therapies, including surgical, pharmacological, and nonpharmacological interventions.

**PD Symptoms and Related Patient Health Issues**

**Motor Symptoms**

_Tremor._ The asymmetrical occurrence of a resting tremor (rhythmic shaking of a body part) that disappears with voluntary movement is the most common symptom of PD. It usually affects the arm, leg, or chin (Nutt & Wooten, 2005; Vaughan & Hardie, 2002). Postural instability generally occurs later in PD and is not particularly helpful in diagnosing early PD; however, it aids in differentiating incipient PD from other forms of
parkinsonism, such as multiple system atrophy (MSA), progressive supranuclear palsy (PSP), or drug-induced parkinsonism (QSSAAN, 2006a). Nutt and Wooten (2005) have noted four common presentations of PD, including (a) tremor, (b) a weak and clumsy limb, (c) a stiff and aching limb, and (d) a gait disorder.

The resting tremor of PD, which may be present in early PD, is often confused with the symmetrical tremor seen in patients with essential tremor. Essential tremor usually affects the hands and may be accompanied by voice and head tremor, whereas PD tremor may involve the cranial musculature, but usually does not cause head tremor (Nutt & Wooten, 2005; Vaughan & Hardie, 2002). Resting tremor can be further distinguished from essential tremor based on the patient’s handwriting. Micrographia (small, irregular handwriting) is typically seen in PD patients, but the handwriting of patients with essential tremor is usually large and tremulous (Nutt & Wooten, 2005).

**Bradykinesia.** About 75% of PD patients initially experience asymmetrical bradykinesia (Nutt & Wooten, 2005) resulting in impaired mobility and balance. Bradykinesia may present itself in a variety of ways. PD patients may complain of having a weak and uncoordinated limb. Clinical examination of the patient’s rapid, alternating movements, such as finger tapping or toe tapping, however, reveals slowness of dexterity, decreased amplitude of movement, and irregular, rhythmic movement; yet muscle strength is normal (Nutt & Wooten, 2005). Bradykinesia usually results in fine motor and repetitive movements being impaired more than gross motor movements, which may interfere with the patient’s ability to perform activities of daily living (ADLs) such as dressing, fastening buttons, and brushing one’s teeth (Nutt & Wooten, 2005; Wade, Gage, Owen, Trend, Grossmith, & Kaye, 2003). The presence of any of the
following symptoms are suggestive of bradykinesia: difficulty with fine motor tasks, difficulty initiating movement, dysphagia, hypophonia, micrographia, change in gait or walking, masked facies, and freeze attacks (the "off" phenomenon due to wearing off of antiparkinson's medications, such as dopamine) (Marjama-Lyons & Shomon, 2003).

Rigidity. Rigidity resulting from increased muscle tone or stiffness limits mobility and affects the balance of PD patients. Initially, rigidity symptoms may occur on one side of the body and affect only one limb. Early symptoms of rigidity may include complaints of vague stiffness and aching in a limb which may be difficult to differentiate from musculoskeletal conditions, such as bursitis or arthritis (Marjama-Lyons & Shomon, 2003; Nutt & Wooten, 2005). The rigidity gradually worsens and the patient may exhibit signs of dragging a foot, slowing of gait, and decreasing arm swing on the affected side, which may mimic a mild hemiparesis (unilateral paralysis) (Nutt & Wooten, 2005). Research studies have shown that gait disturbances resulting in reduced velocity, reduced stride and step length, increased duration of double-limb support phase of stance, decreased arm swing, and increased trunk flexion are common in PD patients (Krystowiak et al., 2003). Patients may experience difficulty in ambulation, climbing stairs, rising from a sitting position, and difficulty rolling over in bed (Ashburn, Stack, Pickering, & Ward, 2001; DeGoede et al., 2001; Schenkman, 2002). Some PD patients also experience visual disturbances, most notably spatial contrast sensitivity and blurring, which complicates their ability to walk safely and predisposes them to falls (Uc, Rizzo, Anderson, Qian, Rodnitzky, & Dawson, 2005).

Shuffling gait, falls, and freezing are not commonly seen in early PD, however, and should prompt the astute clinician to consider other diagnoses such as one of the
other parkinsonism disorders, such as MSA or PSP (Nutt & Wooten, 2005; Olanow, 2004; Vaughan & Hardie, 2002). MSA or PSP should be suspected if the patient’s parkinsonian symptoms are symmetrical, tremor is absent, and there is rapid disease progression (QSSAAN, 2006a). Wenning, Ebersbach, Verny, et al.’s (1999) case control study of 77 PD patients (as cited in QSSAAN, 2006a) revealed that falling within one year of diagnosis was the strongest predictor of other forms of parkinsonism. The QSSAAN’s (2006a) recent evidence-based review practice parameter pertaining to the diagnosis and prognosis of new onset Parkinson’s disease concluded that the following are useful signs in identifying forms of parkinsonism other than PD in patients: (a) falls at presentation or early in disease course, (b) poor response to levodopa, (c) rapid progression to Hoehn and Yahr stage 3, (d) symmetry of motor signs, (e) lack of tremor, and (f) early dysautonomia. Tests useful in distinguishing PD from other forms of parkinsonism are: (a) levodopa and apomorphine challenge tests, (b) olfaction testing, and (c) magnetic resonance imaging (MRI) scans. The QSSAAN also concluded that growth hormone stimulation with clonidine, electrooculography, and SPECT imaging scans were not useful test in differentiating PD from other forms of parkinsonism.

*Postural instability and gait difficulty.* Jankovic and Kapadia’s (2001) retrospective cohort study of 297 PD patients (as cited in QSSAAN, 2006a) used the UPDRS to measure the rate of disease progression among patients categorized as having either tremor-dominant or postural instability-gait difficulty (PIGD) PD. They found that older age (> 57 years) at onset of PD and PIGD-dominant PD patients experienced a more rapid rate of disease progression than did patients with middle-age onset and tremor-dominant PD (QSSAAN, 2006a). Roos, Jongen, and van der Velde’s (1996)
single-blind, retrospective cohort study of PD patients (as cited in QSSAAN, 2006a) revealed the importance of the first presenting symptom of PD in predicting rate of disease progression, with tremor patients progressing more slowly to Hoehn and Yahr stage 3 than rigidity/hypokinetic patients. The evidence-based review of seven qualifying studies (out of 59) conducted by the QSSAAN (2006a) revealed more rapid rate of disease progression and greater intellectual, motor, and occupational impairment among PIGD-dominant PD patients than among tremor-dominant PD patients.

Speech and communications disorders in PD. Hypophonia and other voice changes occur in 80-90% of PD patients; 45-50% have articulation changes (Miller, Noble, Jones, & Burn, 2006). Based on diagnostic speech testing, the underlying mechanisms involved in producing the speech changes evidenced in PD patients are due to reduction in vocal muscle movement strength, endurance, peak velocity, and amplitude (Miller et al., 2006). Miller et al. conducted a qualitative study to investigate the impact of communication changes in 37 PD patients ($n = 23$ men; $n = 14$ women) and noted four impact themes: (a) interaction with others, (b) problems with conversations, (c) feelings about intelligibility, and (d) voice. PD patients’ perceptions regarding their voices conveyed concern about the decreased strength of voice; deterioration in its quality, rate, and clarity; and difficulty with initiating speech movements. Patients had expressed concern regarding the physiological and mental burden and limitations that PD had imposed on their ability to communicate with others, how they were perceived by others, and how they were able to cope with these changes. Patients also were cognizant of their distractibility and difficulty with word-finding and thought processing while engaging in conversation, which influenced their decision to
participate or not in conversation. As a consequence of their speech and communication difficulties, PD participants reported that they experienced loss of self-esteem, loss of dignity, humiliation, and altered socialization processes ranging from apprehension, disengagement, to complete withdrawal. In the study by Miller et al. (2006), PD patients reported managing their speech difficulties by using coping strategies that were context-based, dynamic, and dependent on their cognitive appraisal of the importance of the situation. Coping strategies used included: (a) monitoring their strength and fatigue levels before engaging in conversation; (b) using alternative forms of communicating, including writing notes, sending e-mails, or gesturing; and (c) gauging the reactions of others. Miller et al. (2006) reported that written communication is further affected in PD due to tremor resulting in the typical micrographic handwriting seen in PD.

The Lee Silverman Voice Training (LSVT) method has been shown to be efficacious for improving vocal function in PD patients (Ramig et al., 2001). Ramig et al. conducted a randomized trial involving 33 PD patients who were randomized either to receive the LSVT treatment or respiratory therapy (RET) (high respiratory effort only). The researchers reported that the LSVT group maintained improved vocal loudness and inflection in voice fundamental frequency when sound level pressure (SLP) and semitone standard deviation (STSD) were measured at 2-year follow-up.

Nonmotor Symptoms of PD

Depression. Depression is a major nonmotor symptom of PD (Global Parkinson's Disease Steering Committee [GPDSC], 2002; Leentjens, 2004; QSSAAN, 2006b). With the availability of better therapeutics to treat the motor symptoms of PD,
nonmotor symptoms such as depression, psychosis, cognitive impairment, and dementia may be responsible for significant disability in PD patients (QSSAAN, 2006b). The pathological mechanisms for many of the nonmotor symptoms in PD remain poorly understood (QSSAAN, 2006b). The prevalence of depression in PD and its impact on QOL for PD patients and their families is significant (GPDSSC, 2002). Based on their meta-analysis of 45 PD depression studies (total $N = 5,911$ PD patients; of whom 1,835 were depressed), Slaughter et al. (2001) calculated the prevalence of depression in PD to be 31%. Prevalence of minor depression in PD was noted to be 36.6% ($n = 155$) in three studies of PD patients ($N = 423$) (Slaughter et al., 2001). Dysthymia was diagnosed in 22.5% ($n = 48$) of 213 PD patients evaluated in four studies (Slaughter et al., 2001). As Slaughter and colleagues noted in the meta-analysis, the consensus opinion across researchers is that depression is one of the most common neuropsychiatric disorders in PD.

Santamaria, Tolosa, and Valles (1986) noted that depression may actually be a prodromal symptom in a subgroup of PD patients who have onset of PD at a younger age, decreased disease severity, and a stronger family history of depression. Cummings (1992) noted that the most reliable indicators of depression in PD are dysphoria, pessimism, irritability, sadness, and suicidal ideation, but the incidence of suicidal behavior in PD patients does not differ from that seen in the general population. Starkstein, Mayberg, Leiguarda, et al. (1992) also noted that duration of PD and prior history of depression preceding onset of PD was significantly correlated with major depression. They further noted that greater risk of depression was associated with a unilateral left hemispheric versus right hemispheric presentation of PD. Converging
evidence reviewed by the QSSAAN (2006b) suggests that the behavioral symptoms in PD may be pathophysiologically different from behavioral symptoms observed in the general population. The meta-analysis of PD depression studies by Slaughter et al. (2001) indicated that “PD personality” features may be due to the insidious neurochemical abnormalities, such as depleted serotonin levels associated with PD, and the resulting cognitive and behavioral changes may be manifestations of progressive neurochemical deficits. Rogers, Lees, Smith, et al. (1987) noted that progressive frontal lobe dysfunction may be present in PD patients with major depression due to decreased dopaminergic neuronal input or secondary pathological changes to the frontal cortex. Slaughter et al. (2001) conjectured that lack of improvement in depression despite physical improvement in PD may be due to the severity of the underlying neurochemical abnormalities versus depressive reaction to the physical limitations imposed by PD.

The Global Parkinson’s Disease Survey Steering Committee’s (GPDSSC) (2002) multi-center international (six countries) survey of patients (N = 1,020) with PD, caregivers, and clinicians (N = 203) to assess the HRQOL of people with PD revealed that Hoehn and Yahr stage of disease severity and medication use explained only 17.3% of the variability in the HRQOL of PD patients. Further, the GPDSSC (2002) reported that multiple regression data analysis results indicated that depression was the most significant predictor PD-HRQOL (adjusted $R^2 = 0.597$) and explained 59.7% of the variability in HRQOL. The Global Parkinson’s Disease Survey (GPDS) study was a cross-sectional, randomized selection clinical trial conducted in the United Kingdom, Italy, Spain, the United States, Canada, and Japan (GPDSSC, 2002). PD participants in the GPDS study were screened for depression with the Beck Depression Inventory.
(BDI) measurement instrument (GPDSSC, 2002). Despite the fact that depression is considered to be highly prevalent in PD patients, it is underreported and should be screened for routinely at PD patients' office visits (GPDSSC, 2002; Slaughter et al., 2001). In the GPDS study (2002), only 1% of the PD patients ($N=1,020$) reported depression as being a problem for them, but BDI screening results revealed that 50% of these patients were considered depressed. Although the QSSAAN (2006b) has recently endorsed the use of the BDI, Hamilton Depression Rating Scale, and the Montgomery-Asberg Depression Rating Scales to screen for depression in PD patients, it also concluded that clinically relevant, PD-specific screening and diagnostic tools need to be developed to better assess for depression, psychosis, and cognitive decline in PD patients (Weintraub, Oehlberg, Katz, & Stern, 2006). The GPDSSC (2002) also concluded that better screening for and treatment of depression in PD patients was essential to improving the QOL for PD patients and their families.

Four classes of antidepressant medications have been used in treating depression in PD patients, including tricyclic antidepressants (TCAs), serotonin reuptake inhibitors (SSRIs), norepinephrine reuptake inhibitors, and combined reuptake inhibitors (Slaughter et al., 2001). Slaughter and colleagues (2001) noted that efficacy is lacking for many of these medications. Only TCAs have been studied in randomized, placebo-controlled, double-blind clinical trials. The potential ameliorative anticholinergic effects of TCAs on other PD symptoms still make them a drug of choice for treating depression in PD by some neurologists (Slaughter et al., 2001); however, many clinicians prescribe SSRIs instead to treat depleted serotonin levels, due to their improved safety and better side effects profile versus that of TCAs. Side effects commonly seen with use of TCAs
include, but are not limited to, orthostatic hypotension due to alpha-adrenergic blockade (which increases risk of falls and injuries), delirium, and memory impairment. In contrast, SSRIs may increase the likelihood of hepatotoxicity and interfere with hepatic metabolism of other drugs, but they do not have the cardiac conduction and alpha-adrenergic blockade effects seen in TCAs (Slaughter et al., 2001).

Nonpharmacological treatments of depression of PD have shown that psychotherapy can be of particular benefit in the younger PD population, which also have been shown to improve the motor symptoms of PD (QSSAAN, 2006b; Slaughter et al., 2001; Wint, Okun, & Fernandez, 2004). Electroconvulsive Therapy (ECT) has been shown to be of short-term benefit in treating depression in PD and its use is recommended only for emergencies in treating suicidal PD patients due to its risk of inducing delirium (Slaughter et al., 2001; Wint et al., 2004).

*Psychosis, hallucinations, and delusions in PD.* The prevalence of drug-induced psychosis in PD patients, particularly in advanced PD, has been reported to be as high as 22% (Rascol, Goetz, et al., 2002; Rascol, Payoux, Ory, Ferriera, Brefel-Courbon, & Montrastruc, 2003). Whether or not they are drug-induced, psychoses, hallucinations, and delusions contribute significantly to the disability in PD and present another treatment challenge for the clinician (Holroyd, Currie, & Wooten, 2001; QSSAAN, 2006b; Thanvi, Munshi, Vijaykumar, & Lo, 2003; Wint et al., 2004). Cummings (1991) reported that the prevalence of hallucinations and delusions in PD ranges from 6-40%. Naimark, Jackson, Rockwell, et al. (1996) have noted that psychosis, hallucinations, delusions (as well as dementia) are major risk factors for nursing home placement. Effective agents for treatment of psychosis include clozapine and quetiapine. Clozapine
also appears to improve the motor symptoms seen in PD, but this has not been noted with quetiapine (QSSAAN, 2006b). However, quetiapine has a better safety profile than clozapine, which needs to be closely monitored for the life-threatening side effect of agranulocytosis (QSSAAN, 2006b).

The most common types of hallucinations that occur in PD are visual (30%), auditory (10%), and tactile (8%) (Wint et al., 2004). Bioussé, Skibell, Watts, Loupe, Drews-Botsch, and Newman (2004) studied the ocular symptoms in 61 patients (n = 30 PD patients; 31 non-PD patients) to assess the ophthalmologic features of PD. They found that 25% of the PD patients had visual hallucinations that were attributable to decreased visual acuity, cognitive impairment, medications such as dopamine or anticholinergics, or a combination of these factors. Visual hallucinations in early, untreated PD implies that they may be a direct result from underlying PD pathology rather than side effects of PD medications. This is an ominous prognostic finding in early PD and may indicate the potential evolution of this process into dementia with Lewy bodies (DLB). At 2-year follow-up, Bioussé et al. (2004) reported that none of their PD patients who had hallucinations had progressed to developing dementia. Blepharospasm and eyelid apraxia, which often occur in PD, were noted only in a few PD participants; however, decreased tear-film breakup time (TFBUT) leading to increased incidence of dry eye did occur in two thirds of PD patients. Their research points to the need for clinicians to be aware of the potential effect that prescribed medications may have on the vision of PD patients. Other significant findings included: decreased blink rate likely due to hypokinesia related to decreased dopamine activity, and complaint of ocular irritation (Bioussé et al., 2004).
Uc et al. (2005) studied visual dysfunction in 237 (n = 76 PD patients; n = 161 non-PD patients) community-dwelling adults. They used a battery of visual and neuropsychological cognitive testing to assess participants’ visual acuity (VA), contrast sensitivity (CS), visual speed of processing and attention, spatial and motion perception, visual and verbal memory, visuoconstructional abilities, executive functions, depression, and motor function (Uc et al., 2005). PD patients were also assessed using Hoehn and Yahr Scale for stage of PD and the UPDRS Motor Scale. Salient research findings reported by Uc et al. (2005) indicated that PD participants performed significantly worse than controls on (a) near and far visual acuity, and contrast sensitivity; (b) tests of speed of processing, attention, and usual field of vision; (c) tests of visual cognition and construction and memory; (d) tests of executive functions; and (e) visual motion perception testing. Further, Hoehn and Yahr stage correlated with impairment in visual attention, memory, and constructional abilities, whereas the UPDRS motor scores did not correlate with any of the vision or cognitive tests (Uc et al., 2005). A disturbing finding among PD participants that the researchers noted, yet consistent with other research, was the presence of mild, widespread cognitive deficits across multiple domains (Uc et al., 2005). This finding does not prognosticate well for those with early PD since it indicates increased risk of developing dementia in later stages of PD (Rascol, Goetz, et al., 2002; Uc et al., 2005; Vaughan & Hardie, 2002; Wint et al., 2004).

Dementia in PD. Prevalence of dementia is estimated to occur in one third of PD patients, particularly in late stage PD (Rascol, Goetz, et al., 2002). The Mini-Mental State Examination (MMSE) and the Cambridge Cognitive Examination (CAMCog) may be considered for use in screening PD patients for possible cognitive impairment or
dementia (Hobson & Meara, 1999; QSSAAN, 2006b), but the MMSE is recommended as being the more easily administered tool. MacPhee and Steward (2001) identified the following risk factors for developing dementia in PD: older age at onset of PD, severity of initial motor deficit, longer duration of illness, and psychotic reactions to levodopa. Lewy body dementia, the second most common type of neurodegenerative dementia, is seen in both PD and Alzheimer’s disease (Bertram & Tanzi, 2005). Dementia, like the presence of hallucinations and psychosis, is a major risk factor for nursing home placement (Wint et al., 2004). The evidence-based review conducted by the QSSAAN (2006b) has determined that rivastigmine is effective in improving cognitive functioning in patients with PD dementia or DLB, but it may exacerbate PD tremor; alternatively, PD dementia may be treated with donepezil (Aricept).

Dysautonomia. PD’s impairment of autonomic nervous system functioning may be manifested by symptoms such as orthostatic hypotension; neurogenic bladder, including urgency, frequency, and incontinence; constipation; drooling; and sexual dysfunction, including erectile dysfunction (Rascol, Goetz, et al., 2002). Minimal research exists regarding PD’s role in dysautonomia. One study was conducted to evaluate treatment of erectile dysfunction in PD. Hussain, Brady, Swinn, Mathias, and Fowler (2001) conducted a randomized trial of 24 men (n = 12 PD patients; 6 MSA patients) with erectile dysfunction (ED) to evaluate the treatment effectiveness of sildenafil (Viagra) 50 milligrams on ED and its impact on orthostatic hypotension. Sildenafil was efficacious in treating ED in the PD patients and caused only a minimal change (5mm to 9 mmHg) in blood pressure, whereas it improved the ED in MSA
patients, but caused a severe drop (approximately 50%) in blood pressure that resulted in closure of this arm of the study (Hussain et al., 2001).

**Medical Treatments for Motor Symptoms of PD**

Pharmacotherapeutics are a mainstay in the treatment and control of Parkinson's disease-related symptoms. For initial PD therapy, effective agents include dopamine agonists such as ropinirole or pramipexole, carbidopa plus levodopa, anticholinergics, amantadine, and certain monoamine oxidase B (MAO-B) inhibitors (Huse, Castelli-Haley, Orsini, Lenhart, & Abdalla, 2006; Nutt & Wooten, 2005). Although drug therapy is the major treatment modality for PD, it may have its own attendant consequences and side effects that can also impact the HRQOL for PD patients causing symptoms such as dyskinesiae, hedonistic dopamine dysregulation syndrome (Giovannoni, O'Sullivan, Turner, Manson, & Lees, 2000; Marras et al., 2004), freezing orthostatic hypotension, hallucinations, psychoses, (Nutt & Wooten, 2005; Wint et al., 2004), and visual disturbances (Uc et al., 2005). Such consequences are generally seen in patients that consume increased and more frequent doses of dopamine to control their PD symptoms or are on combination therapy.

Levodopa was introduced more than 30 years ago for the treatment of PD (Lang & Lozano, 1998). Levodopa's success in treating the motor symptoms of PD resulted in less interest in using surgical treatments for PD (Olanow, 2004). Despite its success in treating PD symptoms, theoretical concerns have been raised regarding the possibility that levodopa increases the rate of progression of PD because of toxic free radical generation (QSSAAN, 2006c; Wasielewski & Koller, 1998). Murer, Raisman-Vozari,
and Gershnik’s (1999) research indicated that there is no clinical evidence to support that such toxicity occurs. Thus, levodopa remains the most effective treatment for PD even today, but it is not without its attendant complications and consequences.

Levodopa-induced dyskinesias (LID), involuntary jerking movements, often become very problematic for PD patients. Most PD patients require increasingly higher doses over the course of their disease to control their PD symptoms which can lead to the development of LID. These motor complications usually are seen in patients who have been treated with levodopa for more than 5 years (Nutt & Wooten, 2005; Olanow, 2004). As patients become refractory to increasing doses and frequencies of levodopa administration, other medications are added to their medical treatment regimen.

A new class of drugs called catechol-O-methyltransferase inhibitors (COMT), for example tasmar and comtan, may be used to supplement the levodopa and help decrease the PD patient’s “off” time. “Off” states potentially occur when PD medications wear off and are no longer available to control the symptoms. During an “off” state, patients can literally “freeze” in position and are unable to move until more medication is given and reaches an adequate blood level to control patient’s symptoms. The difficulty with COMT inhibitors is that they can increase the levodopa dyskinesias, whereas amantadine may lessen them (Marjama-Lyons & Shomon, 2003).

Anticholinergic drugs such as cogentin and artane do help to control the PD tremor, excessive drooling, and muscle rigidity, but they are not very effective in lessening the bradykinesia. Like the COMT inhibitors, anticholinergic drugs also create troublesome side effects manifested as hallucinations, urinary retention, constipation, dry mouth, blurred vision, and orthostatic hypotension (Marjama-Lyons & Shomon, 2003).
Orthostatic hypotension further increases the incidence of falls in the PD patient population.

The MAO inhibitor selegiline was once thought to help slow the progression of PD, but more recent research studies have not supported this claim, and it now has a limited role in treatment of PD (Weiner, Shulman, & Lang, 2001). Several neuroprotective agents such as Vitamin E, Coenzyme Q10, and bromocriptine have been studied in clinical trials, but no conclusive evidence exists to support their efficacy (Rascol, Goetz, et al., 2002; Nutt & Wooten, 2005; QSSAAN, 2006c).

Surgical Treatments for PD

Renewed interest in surgical treatment of PD symptoms has occurred due to limitations of drug therapy, improved surgical techniques and instrumentation, use of microelectrode monitoring to more precisely define surgical targets, and better understanding of neuroanatomy and neurophysiology (Gray et al., 2002; McRae, Cherin, et al., 2003; Olanow, 2004; Pollak et al., 2002). Ablative lesioning of the globus pallidus interna (GPi) has yielded beneficial results from pallidotomy as evidenced by a marked reduction in contralateral dyskinesia (Olanow, 2004). Attendant side effects may occur from pallidotomy, however, including hemorrhage and damage to surrounding structures (Olanow, 2004). Dysarthria, dysphagia, and cognitive impairment can occur in bilateral pallidotomy (Olanow, 2004).

Ablative procedures have largely been replaced by deep brain stimulation (DBS) procedures, which involve implanting a permanent electrode in the selected brain target and connecting it to an external radiofrequency stimulating device at 100-180 Hz (Lang
Pollak et al. (2002) compared and contrasted the benefits and risks of Vim, GPI, and STN DBS procedures to each other as well as to pharmacological management of PD symptoms. Vim DBS' effectiveness is limited to controlling tremor symptoms only and has fallen into disfavor as a viable treatment for PD. Bilateral STN DBS seems to be more effective than GPI DBS in controlling PD symptoms, but a large longitudinal randomized clinical trials need to be conducted to garner further support for this as the treatment of choice for PD patients (Krack et al., 1998; Lang, 2000; Obeso et al., 2001; Pollak et al., 2002).

While noting that DBS procedures carry adverse effects resulting in patient morbidity and mortality, Pollak et al. (2002) concluded that most researchers agreed that the benefit-risk ratio for DBS as an effective treatment for PD patients is favorable. Their systematic review of 117 research studies resulted in support of three findings:
1. The benefit-to-risk ratio of DBS to treat movement disorders, particularly PD, was favorable.

2. STN DBS is the most efficacious DBS procedure in treating the cardinal symptoms of PD.

3. Young-onset PD patients with levodopa-induced motor dyskinesias, who still respond well to levodopa and who exhibit no cognitive, behavioral, or mood impairment, benefit the most from STN DBS (Pollack et al., 2002).

Moro, Scerrati, Romito, Roselli, Tonali, and Albanese (1999) conducted a descriptive, nonrandomized, investigational research study in which they recruited 7 patients ($n = 6$ females; $n = 1$ male) who had severe PD. Their research attempted to determine whether or not the use of chronic stereotactic neurostimulation to inactivate the STN would result in effective treatment of off-state related signs of motor fluctuations, i.e., tremor, rigidity, and bradykinesia. They did determine that chronic, bilateral high-frequency stimulation of the STN was an effective treatment modality to inactivate hyperactive STNS, thereby reducing parkinsonian signs and off-drug related phenomena in their sample of 7 patients. Given the small numbers of participants in many of these research trials, there is a need for further research trials to determine the efficacy of DBS, the best surgical location for controlling PD symptoms, and the most appropriate patient selection for DBS implantation (Lang, 2000; Sheriff & Chenoweth, 2003; Siderowf, Jaggi, et al., 2006).
Quality of Life in Parkinson’s Disease

The Global Parkinson’s Disease Survey Steering Committee (2002) has noted that current PD disease-management guidelines are limited due to lack of knowledge of the factors that influence the HRQOL in PD. Quality of life (QOL) is a multidimensional concept, which means different things to people depending on their perspective at any given point in time. Health is another domain that contributes to QOL (Cheng, Siderowf, Swartruber, Eisa, Lee, & Vickrey, 2004; Marinus, Ramaker, vanHilten, & Stiggelbout, 2002). For people living with chronic diseases such as PD, QOL may change daily and even frequently within the course of a day, as they struggle to adapt to and manage the challenges which the disease thrusts upon them (Baker & Graham, 2004; Cote, Sprinzeles, Elliott, & Kutscher, 2000; Damiano, Snyder, Strausser, & Willian, 1999; Harrison, Preston, & Blunt, 2000; Hobson, Holden, & Meara, 1999). In a general sense, QOL refers to a person’s sense of well-being, autonomy, and purpose in life, which encompasses the person’s physical, mental, and social functioning (Fleming, Cook, Nelson, & Lai, 2005; Jahanshahi & Marsden, 2000; Siderowf, Ravina, & Glick, 2002; Welsh, 2004).

Health-related quality of life (HRQOL) comprises the total effect that illness and wellness has on a person’s biopsychosocial well-being and the effect that illness has on his or her actual and desired life (Jahanshahi & Marsden, 2000; Shindler, Brown, Welburn, & Parkes, 1987; Walsh & Bennett, 2001). Health-related QOL has become a central issue in health care delivery because of its impact on measuring the effectiveness of patient-centered clinical interventions with respect to patient and system outcomes, as
well as determining resource allocation and policies (Damiano et al., 2000; Gage, Hendricks, Zhang, & Kazis, 2003; Guyatt, Feeney, & Patrick, 1993; Hays et al., 1994).

Measuring Quality of Life in PD

Peto, Jenkinson, and Fitzpatrick (1998) endeavored to assess the impact of PD on QOL by developing an instrument, the Parkinson’s Disease Questionnaire-39 (PDQ-39), that would measure disease-specific quality of life indicators for Parkinson’s disease. They surveyed PD patients \(N = 359\) from eight branches of the PD Society in the United Kingdom on 65 items pertaining to aspects of PD. A factor analysis was performed on the data, which led to elimination of redundant items and resulted in a 39-item questionnaire comprised of eight factors denoting quality of life indicators (mobility, activities of daily living, emotional well-being, stigma, social support, cognitions, communication, and bodily discomfort) (Peto et al., 1998). Repeat testing has shown that the \(PDQ-39\) is sensitive to change \((p < 0.01)\) as well as having good reliability, validity, and reproducibility.

Determinants of Quality of Life in PD

Schrag, Jahanshahi, and Quinn (2000) used the self-administered \(PDQ-39\), ED-5D, and SF-36 to assess the QOL of 124 probable PD patients from 15 general practices in the United Kingdom. Participants also completed the Beck Depression Inventory (BDI). Clinicians assessed participants’ status on the Hoehn and Yahr disease severity scale, motor portion of the UPDRS, and the MMSE. Response rate for completed questionnaires was 78%. Research findings revealed that depression was the
strongest indicator of QOL in PD patients. Schrag and colleagues (2000) noted that other key contributors to QOL of life were disability, postural instability, and cognitive impairment. Significant correlations with QOL included disease severity ($r = 0.6$, $p < 0.001$), UPDRS motor score ($r = 0.41$, $p < 0.001$), and UPDRS motor score of axial features ($r = 0.57$, $p < 0.001$), but duration of disease ($r = 0.18$, $p = 0.19$) and age ($r = 0.14$, $p = 0.25$) were not significantly correlated with QOL.

The cross-sectional, randomized Global Parkinson’s Disease Survey study (2002) conducted in six countries with PD patients ($N = 1,020$), caregivers ($N = 687$), and clinicians ($N = 203$) to identify the determinants of HRQOL in PD yielded similar results to those noted by Schrag and colleagues (2000). The aim of the GPDS was to identify key management issues that have the greatest effect on HRQOL in PD and utilize that information to develop universal interdisciplinary guidelines for the effective management of PD. Several medication regimens were assessed for their impact on QOL, but only one was shown to be a significant predictor of QOL in PD—levodopa. Using stepwise multiple regression analysis, disease severity as measured by Hoehn and Yahr stage and levodopa treatment explained 17.3% of the variance in HRQOL in Step one regression. Step two regression analyses identified three other significant determinants of HRQOL in PD—depression (adjusted $R^2 = 0.582$, $p < 0.001$) (GPDSSC, 2002), satisfaction with explanation of condition at diagnosis, and current feelings of optimism. PD patients, however, underreported their depression (1%), which conflicted with the 50% rate detected by BDI results.

Satisfaction with the explanation of condition at diagnosis and current feelings of optimism were also significant ($p < .05$) contributors to HRQOL in PD (GPDSSC,
2002). The significance of the explanation of one's condition at time of diagnosis acknowledges the important role that accurate information giving and patient education plays in contributing to the QOL of PD patients and their families (GPDSSC, 2002). Further, it supports the need for quality patient educational materials and psychological interventions to better meet the needs of PD patients when giving them their diagnosis (GPDSSC, 2002; Nutt & Wooten, 2005).

Adherence and Nonadherence to Treatment Regimen and QOL

Patient adherence not only to prescribed drug treatments, but also adherence to treatment schedules is essential to achieve effective symptom control, enhance QOL, and improve outcomes for PD patients (Grosset, Bone, & Grosset, 2005; Peterson, Takiya, & Finley, 2003). Dunbar-Jacob et al. (2000) noted that approximately 50% of patients with chronic diseases have medication adherence problems that limit their obtaining the optimal benefit from their prescribed treatment regimens (Cameron, 1996; MacStravic, 2005; Schaffer & Yoon, 2001; Vermeire, Hearnshaw, VanRoyer, & Denekens, 2001). Leopold et al. (2004) reported that although drug adherence to prescribed treatment regimens has been well studied in several other chronic diseases such as asthma, hypertension, and diabetes, it has not been studied in PD patients prior to their research (Sherbourne, Hays, Ordway, DiMatteo, & Kravitz, 1992). To date, there is limited extant research regarding drug adherence to prescribed treatment regimens in PD patients, which further supports the importance of the current study. Nonadherence to prescribed drug and other treatment regimens can result in poor symptom control that could result in serious consequences to PD patients, such as increased frequency of
“on-off” states, falls, injuries, etc. Research that may provide insight to perceived barriers and facilitators of PD patients’ adherence to prescribed treatment regimens may lead to improvement in patient safety and quality of care, patient outcomes, and systems outcomes.

Parkinson’s Disease and Health Care Delivery Models

Confronting the life-changing diagnosis of Parkinson’s disease and its complex biopsychosocial ramifications is, undoubtedly, one of the most daunting tasks for PD patients and their families. As Clark (2003) noted, clinicians have a central role in establishing the partnership between patients and clinicians that is essential to effective chronic disease management. PD patients have complex health-related and social issues that impact their QOL as well as their ability to self-manage the PD. Clinicians across disciplines need to expand their conceptual approach to PD care and other chronic diseases to more effectively and holistically address the multiple issues facing patients and their families (Clark, 2003; Koch, Jenkin, & Kralik, 2004; Kralik, Koch, Price, & Howard, 2004; Lorig, Stewart, et al., 1996; Sanson-Fisher, Campbell, Redman, & Hennrikus, 1989; Welsh, 2004; Yarcheski, Mahon, Yarcheski, & Cannella, 2004).

Welsh (2004) reported on a QOL conceptual model for delivering health care to PD patients that she and her colleagues have developed. Further, Welsh and her colleagues have advocated adopting their QOL conceptual model for delivering health care to PD patients and discarding the traditional medical model with its limited scope. The Parkinson’s disease QOL model espoused by Welsh and colleagues addresses 12 PD QOL domains, including physical function, mental health/emotional well-being, self-
image, social functioning, health-related distress, cognitive function, communication, sleep and rest, eating, role function, energy/fatigue, and sexual function (Welsh, 2004).

Holman and Lorig (2004) contended that there must be a “complementary sharing of knowledge and authority in the health care process between patient and health care professionals” (p. 239) in order to achieve effective and efficient chronic disease management. This philosophical approach has been the underpinning of the patient education, collaborative Chronic Disease Self-Management Program that was developed at Stanford University by Lorig and Holman (see Model 1 in Appendix A) (Lorig, 2003a, 2003b; Lorig, Homan, et al., 2006; Lorig et al., 1996). Lorig et al.’s (1996) Chronic Disease Self-Management Program integrated within a PD quality of life context provides the conceptual framework for the PDCC patient education model developed for implementation in this research study (represented as Model 2 in Appendix A).

*Traditional Health Care*

The traditional health care delivery model, which is often referred to as the medical model, places constraints on the role of the patient as the recipient of health care and patient education (see Model 3 in Appendix A). The traditional health care model focuses on disease markers for establishing diagnoses and assessing outcomes of care (Welsh, 2004), yet many complex diseases such as PD may be better managed if a more holistic, QOL approach is used to address the multidimensional aspects of the illness.

In the traditional patient education approach, health care professionals define the patients’ problem(s) and identify the learning needs that they think patients may have for effective management of their disease. Patients are not active participants in the
education process, but rather the passive recipients of knowledge being conveyed by
health care professionals (Lorig et al., 1996).

Collaborative Patient-Professional Health Care

Bodenheimer et al. (2002) have noted that emerging chronic disease paradigms
focus on the patient-professional partnership that includes collaborative care and disease
self-management education (see Model 2, Appendix A). PD patients, like patients with
other chronic diseases, have to learn how to live with and self-manage their symptoms
and disease-related issues on a daily basis. Central to the ability of self-managing their
disease is having the confidence that they have the knowledge, skills, and ability, i.e.,
self-efficacy, to carry out the required behaviors and tasks to achieve the desired goals
(Bodenheimer et al., 2002). The concept of self-efficacy is derived from social-cognitive
theory (Bandura, 1977, 1986, 2004; Bandura, Reese, & Adams, 1982; Lorig et al.,
1996).
CHAPTER III

METHODS

The purpose of this project was to investigate the effectiveness of an emerging paradigm in patient education and disease self-management in a population of patients diagnosed with middle-stage Parkinson's disease in comparison to the traditional patient education and disease management approach. This paradigm is illustrated with Model 1 (see Appendix A), which conceptually depicts the interaction between disease self-management education and patient's self-efficacy for PD self-management. Resulting from their interactions with health care professionals, patients established and wrote action plans based on problems, goals, and short-term objectives identified by the patients that might impact PD-QOL. The investigator used the concepts shown in Model 1 (see Appendix A) to develop a collaborative, interdisciplinary care approach, Collaborative Care and Patient Education for PD Self-Management Model (see Model 2, Appendix A), to teach PD self-care management strategies to Parkinson's patients.

Secondly, the study was designed to compare the effectiveness of the new model of health care delivery and patient education with the traditional model (see Model 3, Appendix A) in enhancing PD patients' self-reported perceived PD-HRQOL one month after completion of the treatment intervention. Based on their conceptual consistency to the variables being studied and their psychometric properties, the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* and the *PDQ-39 Parkinson's Disease Quality*
of Life Questionnaire were the data collection instruments selected to measure these outcomes.

Design and Setting

A single-center, randomly assigned intervention study was conducted with Parkinson’s disease patients to compare the two paradigms of patient education for disease management and their impact on patient self-reported self-efficacy and PD QOL outcomes—the Parkinson’s Disease Collaborative Care (PDCC) and Parkinson’s Disease Informational Training (PDIT) models. The PDCC and PDIT participants were recruited from patients who attended the outpatient Hauenstein Parkinson’s Center (HPC) in Grand Rapids, Michigan. Formal Human Subjects Institutional Review Board (HSIRB) applications for approval to conduct research on human subjects were submitted to the institutional review boards at Western Michigan University and St. Mary’s Health Care in Grand Rapids, Michigan, with which the HPC is affiliated. The investigator was granted formal approval to conduct the study by Western Michigan University’s HSIRB in July 2007 and by the HSIRB at St. Mary’s Health Care in August 2007 (see Appendix B). Having received HSIRB approval from both institutions, the process for recruiting study participants was initiated. Subsequent expedited HSIRB approval was received for additional patient education materials and for the revised postintervention follow-up letter to study participants (see Appendix B).
Participants

Sample

The current patient population at the Hauenstein Parkinson’s Center (HPC) was estimated to be approximately 300 patients. The entire patient population at the HPC was screened by the nurse clinical manager for possible enrollment based on the inclusion and exclusion criteria for the study (Table 1). She deemed that a total of 202 PD patients were potentially eligible for the study. Given the nurse clinical manager’s workload demands, she obtained permission (in compliance with the Health Insurance Portability and Accountability Act [HIPAA] regulations) for the investigator to help with mailing letters about the study to potential participants (see Appendix C).

For this study’s sample population, the investigator had planned to enroll up to 48 participants (N = 48) and then randomly assign them to two equal groups (24 per group), that is, either the treatment group (PDCC) or the control group (PDIT). For a Phase II clinical trial, such as this pilot study, a maximum enrollment of 20 patients per intervention group is recommended (Friedman, Furberg, & DeMets, 1998; Hulley et al., 2001). Thus, allowing for 10% rate of attrition, a maximum enrollment of 48 patients was desirable.

Recruitment

The nurse clinical manager of the HPC provided the investigator with the list of the 202 potential participants over a period of several weeks. Over a period of 9 weeks, the investigator mailed a letter of invitation (see Appendix C) to all potential
### Table 1

*Study Inclusion and Exclusion Criteria*

<table>
<thead>
<tr>
<th>Item</th>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Hoehn &amp; Yahr Parkinson’s Disease Stage</td>
<td>Equal to Modified Hoehn &amp; Yahr Stages 2 through 3</td>
<td>Less than Modified Hoehn &amp; Yahr Stage 2 or greater than 3</td>
</tr>
<tr>
<td>Age</td>
<td>( \geq 30 \text{ years of age, but have not had their } 80^{\text{th}} \text{ birthday} )</td>
<td>Less than 30 years or greater than or equal to 80 y. o.</td>
</tr>
<tr>
<td>Language</td>
<td>Speak, read, &amp; write English</td>
<td>Unable to speak, read, or write English</td>
</tr>
<tr>
<td>Hearing</td>
<td>Hearing or aided-hearing sufficient to support normal conversation and direction following</td>
<td>Deafness or hearing loss (aided or not) insufficient to support normal conversation and direction following</td>
</tr>
<tr>
<td>Mini-Mental State Exam (MMSE)</td>
<td>Score of 23 or greater</td>
<td>Score of 22 or less</td>
</tr>
<tr>
<td>Dementia</td>
<td>No established diagnosis of dementia or other cognitive impairments</td>
<td>Known diagnosis of Dementia with Lewy Bodies (DLB) or other dementiae</td>
</tr>
<tr>
<td>Education</td>
<td>9(^{\text{th}}) grade or higher</td>
<td>Less than 9(^{\text{th}}) grade</td>
</tr>
<tr>
<td>Telephone Access</td>
<td>Has access to telephone in home (either land line or cellular phone)</td>
<td>Does not have access to telephone in home (either land line or cellular phone)</td>
</tr>
<tr>
<td>Transportation</td>
<td>Has access to reliable transportation to and from clinic site to attend the 3 educational sessions</td>
<td>Does not have access to reliable transportation to and from clinic site to attend the 3 educational sessions</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>Signed</td>
<td>Not signed</td>
</tr>
<tr>
<td>HIPAA Consent</td>
<td>Signed form</td>
<td>Not signed</td>
</tr>
</tbody>
</table>
participants informing them about the study and inviting them to participate in it. A study brochure (see Appendix C), which explained the study in greater detail, was enclosed with the letter. Patients were asked if they were interested in participating in the study and, if so, were requested to complete the enclosed response form (see Appendix C). On the patient response form, potential participants were asked to answer two demographic questions that pertained to the patient’s date of birth and the number of years since diagnosed as having Parkinson’s disease. They were also asked if they had access to reliable transportation and telephone. If participants were willing to have the investigator contact them, they were asked to include their telephone number on the response form.

A stamped, self-addressed envelope was included for patients to submit their responses to the investigator. Returned response forms were mailed directly to the investigator at the Graduate Center of Western Michigan University in Grand Rapids, Michigan. Thirty-one percent (62/202) of the potential participants mailed their response forms to the investigator. The investigator screened all returned patient response forms and called the HPC patients who had indicated an interest in the study (N = 62). The investigator did not contact participants who indicated that they were not interested in the study (N = 140) by their lack of response. The investigator also attended PD patient support group meetings to disseminate information about the study in effort to stimulate recruitment of study participants.

The investigator or a trained research associate arranged to meet with the potential participants in their home or at the Parkinson’s Association of West Michigan, to explain the study and do the pretesting related to the study’s eligibility criteria. Research associates were hired to assist with the recruitment and enrollment of study
participants. Two of the three research associates were experienced clinical research associates and one was an upper division undergraduate college student. Prior to recruiting study participants, all three took and passed a research integrity course offered either by Citiprogram.org or the National Institutes of Health and obtained certification. Subsequently, the investigator trained all three research associates how to administer and score the Mini-Mental State Exam. The investigator also reviewed the study and HIPAA consents, informed consent process, and demographic information sheet with the research associates.

Each research associate completed two prospective participant home visits with the investigator. During the first joint home visit, each research associate observed how the investigator conducted the informed consent process and administered the required screening tests to determine the client's eligibility, and if client wanted to be enrolled in the study. At the second joint home visit, roles were reversed so that the investigator observed and supervised the research associate's conduct of the informed consent process and administration of the screening tests to the potential study participant. At this point, each research associate had met the researcher's expectations and then was permitted to independently screen and enroll potential study participants. Because letters were sent out to potential participants over a period of several weeks (rather than as a mass mailing as had been originally planned), only one research associate and the investigator were needed to recruit and enroll all eligible participants over a period of approximately 12 weeks.
Informed Consent and HIPAA

At the patient’s clinic or home visit, the investigator or research associate conducted the informed consent process for the study with the patient. During the informed consent process, potential participants had the following explained to them: (a) the purpose and indications of the study; (b) study procedures; (c) risks, benefits, and alternatives of study; (d) assurances of anonymity and confidentiality; (e) authorized entities that would have access to their information; (f) that participation in the study was voluntary and they should not feel coerced to participate; (g) that they had the freedom to withdraw from the study at any time without incurring any risk of penalty or prejudice or suffering diminution of care; (h) how to contact the investigators and chair of the Human Subjects Institutional Review Board (HSIRB) at Western Michigan University and at St. Mary’s Health Care if they had any concerns; and (i) when study results would become available to them (see Appendix D).

Both HSIRBs concurred with the investigator that the study posed minimal potential risks to the participants and that potential benefits might be significant. Identified potential risks to participants included: (a) fatigue, (b) emotional distress due to confronting health concerns, (c) participating in a group process, and (d) concerns regarding confidentiality of personal data. The recruiters informed potential participants about the measures that were to be implemented to assure confidentiality and protection of any of their personal data that were collected during the study. Further, participants were informed that it was impossible to assure them of complete anonymity due to participation in a group process in either the treatment or control group. To minimize
other identified risks, a break period was scheduled during each interventional session to assure that participants had time to relax, interact with others in their group, and take nourishment. Several of the participants in both groups, however, preferred to have access to refreshments throughout the session rather than just during a formal break time.

Recruiters also informed participants of any potential benefits that they may experience by being in the study which included (a) increased knowledge of and self-confidence (self-efficacy) regarding management of PD care and other health issues, (b) increased problem-solving skills to deal with health-related and social support issues, (c) opportunities for increased social interaction, (d) increased QOL, and (e) an opportunity to participate in research that may benefit other PD patients and families. To provide participants with further assurances of confidentiality of collected data, collected data would be stored in a locked file in the investigator’s office in Grand Rapids, Michigan. To further protect participants’ personal health information, participants were given a study-specific identification number assigned by the investigator. The participant numbering system (ranging from 1 to 41) was determined by the investigator and did not use any personal identifiers unique to individual participants, such as social security or medical record numbers. A master list and code book for all study participants was developed and used by the investigator. This was destroyed by the investigator once all data had been analyzed. Only the principal investigator, co-principal investigator, and biostatistician had access to the data. Participants were informed that, after data analysis was completed, the data would be stored and secured in locked cabinets housed in the doctoral program data storage unit at Western Michigan University. Dr. Nickola W.
Nelson, director of the doctoral program in Interdisciplinary Health Studies at Western Michigan University, will be responsible for the secured data and maintaining confidentiality until such time that it is deemed that the data can legally be destroyed.

The Health Insurance Portability and Accountability Act (HIPAA) and its role in the protection of research participants also was explained to study participants. The HIPAA consent for the study was then reviewed and discussed with the participant (see Appendix D). Copies of the participant's signed research study consent and HIPAA consent were placed in the participant's medical record at the Hauenstein Parkinson Center. Copies of both consents also were given to the participant to retain for their personal record.

After the patient had signed the informed consent for the study and the HIPAA consent, the investigator or research associate then proceeded to determine the participant's eligibility status based on inclusion and exclusion criteria which included administering screening tests (Table 1) (see Appendix E) and obtaining demographic information (see Appendix F). Participants who were deemed ineligible for the study were not enrolled, but their interest in the study was acknowledged and they were informed as to when study results would become available.

All 62 respondents were screened (see Appendix G), but only 41 were enrolled in the study. Of the 21 respondents who were not enrolled, 13 declined to participate due to disinterest or the possibility of inclement weather, two had a possible diagnosis of dementia, three were older than the upper age limit for eligibility, one had early-stage PD rather than required criterion of middle-stage PD, and the spouses of two potential participants informed the investigator that the person had died. After all participants
were enrolled, Excel's random number operators program was used to assign participants randomly to condition. This procedure was used to decrease systematic bias in group assignment and to increase the likelihood of equivalent groups. Indeed, this procedure resulted in groups that were approximately of equal size in that the experimental group (PDCC) had 21 participants, and the control group (PDIT) had 20. As will be seen subsequently, the groups were similar in other ways as well. The investigator developed a code book (using an Excel spreadsheet) for registering participants. This codebook also served as a tracking system denoting each participant's randomly assigned group. The system also recorded later: participants' study identification number, gender, age, birth date, Modified Hoehn and Yahr stage of PD, MMSE score, years of education, monitored their attendance at intervention sessions, date and reason(s) for attrition, and completion of PDQ-39 and Self-Efficacy measures at baseline, completion of intervention, and at 1-month follow-up.

Measurement Instruments

Screening Instruments

After initially screening interested patients for research eligibility, the investigator or research associate administered screening measures (Table 1) to potentially eligible participants to assess their cognitive status (Mini-Mental Status Exam [MMSE]) (see Appendix E) and stage of Parkinson's disease using the Modified Hoehn and Yahr (MH & Y) scale (see Appendix E).
**Mini-Mental State Examination (MMSE)**

The MMSE is a clinical assessment tool that includes 11 items and has a maximum score of 30 points. It can be used to assess a participant’s cognitive status based on their orientation to time and place, registration (repeating three objects), recall ability, naming objects, calculation or attention (Serial 7s or spelling “world” backwards), short-term memory, following verbal and written commands, and constructional ability (drawing an object) (McDowell, 2006). The MMSE can be used to assess change in the cognitive status of an individual, but it cannot be used to diagnose dementia (McDowell, 2006).

Several research studies (Butler, Ashford, & Snowdon, 1996; Launer, Dinkgreve, Jonker, Hooijer, & Lindeboom, 1993) have shown that the respondent’s age and educational level impact the validity of the MMSE and recommend that lower cut-off scores, i.e., 17/18, instead of the 23/24 cut-off score used with respondents who have less than a ninth-grade education level (McDowell, 2006). The MMSE has been shown to have good sensitivity and specificity, but its reliability has been shown to decrease as the time lapse between repeat testing increases (Table 2; McDowell, 2006).

Folstein et al. (2001) have noted that the MMSE is a very useful measurement tool for assessing cognitive function in PD patients as the disease progresses (middle and late stages), but it is not an adequate screening tool to use in early stage PD. Severity of depression also has been shown to correlate with MMSE scores (Mayeux, Stern, Rosen, & Leventhal, 1981). Tandberg, Larsen, Aarsland, and Cummings (1996) also reported that PD patients who were depressed scored lower on the MMSE. Further, some PD
patients develop subcortical dementia, and these patients are likely to experience impaired calculation ability early in their disease process (Folstein, Folstein, & Fanjiang, 2001). Churchyard and Lees (1997) have noted that severity of dementia in PD patients \((N = 38; 27 \text{ with PD and 11 controls})\) was positively correlated with MMSE scores and increased density of Lewy bodies in the anterior cingulate gyrus and Lewy neurites in the amygdala. Lower MMSE scores were noted in PD patients as stage of dementia worsened (Churchyard & Lees, 1997). When administering the MMSE to PD patients, Folstein et al. (2001) recommend that the Serial 7s task be used to check for calculation and attention rather than spelling the word “world” backwards. Thus, the investigator and research associate used the Serial 7s task on the MMSE to assess calculation and attention for all 41 participants enrolled in this study. Potential participants had to achieve a score of 23 or greater on the MMSE to meet the inclusion eligibility criterion for this parameter.

**Hoehn and Yahr Scale**

The Hoehn and Yahr Scale (see Appendix E) is a widely used instrument for staging the severity of Parkinson’s disease symptomatology. The original Hoehn and Yahr Scale described five stages of progressive PD severity based on presenting symptoms (Hoehn & Yahr, 1967). The scale was criticized as lacking sensitivity to less than major changes in the patient’s condition (Diamond & Markham, 1983). Thus, to increase its sensitivity to the gradual deterioration of the PD patient’s condition, the scale was further divided into eight stages, ranging from 0 to 5, with half-point gradations between stages 1 and 2 and stages 2 and 3. The Modified Hoehn and Yahr Scale is used
widely for evaluating disease severity in PD and is considered to be the gold standard for staging severity of PD symptomatology. Further, it has been added to the Unified Parkinson’s Disease Rating Scale (UPDRS), which has become the gold standard for measuring PD disability.

**Measurements of Dependent Variables**

If their Modified Hoehn and Yahr Stage of PD (equal to stages 2 through 3) and MMSE score (≥ 23 out of 30) qualified them for participation, individuals were enrolled in the study. At that point, two validated questionnaires were completed by the participants (later repeated at two additional points across the study) to assess their self-reported perceived self-efficacy (Stanford Chronic Disease Self-Management Program’s *Self-Efficacy for Managing Chronic Disease 6-Item Scale*) (see Appendix E) and self-reported perceived Parkinson’s disease HRQOL (*Parkinson’s Disease Questionnaire [PDQ-39] version 1.1*) (see Appendix E). The features of these tools are outlined in Table 2.

*Self-Efficacy for Managing Chronic Disease 6-Item Scale*

The *Self-Efficacy for Managing Chronic Disease 6-Item Scale* is one of several scales that are included in the *Chronic Disease Self-Measurement Program Study Measures* developed by researchers at Stanford University. As noted by Lorig et al. (1996), self-efficacy involves having self-confidence in one’s ability and the motivation to produce the desired changes by one’s actions (Bandura, 2004). Enhanced self-efficacy is the primary target of the interventions in the Chronic Disease Self-Management Program
Table 2

Measurement Instruments

<table>
<thead>
<tr>
<th>Instrument &amp; Purpose</th>
<th>Number of Items</th>
<th>Administration Method</th>
<th>Completion Time</th>
<th>Scoring Method</th>
<th>Psychometric Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Hoehn &amp; Yahr Scale for Staging of Parkinson’s Disease (screening test)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Considered to be the gold standard for staging of Parkinson’s disease. Specific psychometric properties not reported.</td>
</tr>
<tr>
<td>*Mini-Mental State Examination (screening test)</td>
<td>11 items for a total of 30 points</td>
<td>Clinician or trained interviewer (nurse)</td>
<td>5-15 minutes to complete</td>
<td>Questions are summed; cutoff score of 23/24 or less indicative of dementia</td>
<td>**Sensitivity = 81-93% Specificity = 75-100% Test-retest Reliability = not less than 0.89 Interrater reliability = not less than 0.82 Concurrent Validity = 0.66 to 0.83 (Wechsler adult intelligence test; Lawson’s dementia rating scale)</td>
</tr>
<tr>
<td>PDQ-39 Quality of Life (PD-QOL)</td>
<td>39 items (eight subscales)</td>
<td>Self-administered or interviewer administered</td>
<td>10-15 minutes or less to complete</td>
<td>Lower scores indicate better self-reported perceived health status. Scored on a scale of 0-100; All eight subscales can be summed to create a PD Summary Index Score (PDSI) or reported in a profile format. (This is a dependent variable.)</td>
<td>Good internal consistency (range of 0.69 to 0.94 for all eight subscales) Test-retest reliability (range of 0.68 to 0.94 for all eight subscales) and good face &amp; construct validity (Jenkinson, Fitzpatrick, Peto, et al., 1998). Note: PDQ-39SI has a Cronbach’s alpha of 0.84-0.89</td>
</tr>
</tbody>
</table>
Table 2—Continued

<table>
<thead>
<tr>
<th>Instrument &amp; Purpose</th>
<th>Number of Items</th>
<th>Administration Method</th>
<th>Completion Time</th>
<th>Scoring Method</th>
<th>Psychometric Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>***Chronic Disease Self-Measurement Program Study Measures (self-management behaviors, self-efficacy, exercise scale, health distress, mental health stress, fatigue, pain, health outcomes, and communication with physician/interdisciplinary team members) (Lorig, Stewart, et al.)</td>
<td></td>
<td>Consists of multiple short scales (only the Self-Efficacy for Managing Chronic Disease was used in this study)</td>
<td>15-40 minutes to complete depending on degree of assistance needed</td>
<td>See separate scales</td>
<td>See separate scales</td>
</tr>
<tr>
<td>- Self-Efficacy for Managing Chronic Disease 6-Item Scale</td>
<td>6 items</td>
<td>Self-administered or interviewer-administered</td>
<td>5 minutes or less</td>
<td>Number circled is the score for each item (This is a dependent variable.)</td>
<td>Internal consistency reliability = 0.91</td>
</tr>
</tbody>
</table>

*MMSE has recently been copyrighted by the American Psychological Association; permission and payment are required to use it.

**Sensitivity and specificity of the MMSE is significantly affected by level of one’s education (McDowell, 2006). Available at: http://www.parinc.com

*** Stanford Scales and related psychometric information obtained from Stanford School of Medicine Patient Education website at: http://patienteducation.stanford.edu/materials/
Lorig et al. (1996) noted that the three tenets of Bandura’s (1986) Self-Efficacy Theory that underpin the theoretical framework for the CDSMP are:

1. Strength of belief in one’s capability to do a specific task or achieve a certain result is a good predictor of motivation and behavior.

2. One’s self-efficacy belief can be enhanced through performance mastery, modeling, reinterpretation of symptoms, and social persuasion.

3. Enhanced self-efficacy leads to improved behavior, motivation, linking patterns, and emotional well-being. (pp. 5-6)

These three tenets also were used by Lorig et al. (1996) to identify key elements descriptive of how well persons were managing their chronic disease(s). Lorig et al. sorted these key elements into three categories: behaviors, beliefs about self-efficacy, and outcomes. The three categories were later divided into the following subcategories:

(a) behaviors (self-management); (b) beliefs about self-efficacy (to perform specific behaviors, manage disease generally, and achieve outcomes); and (c) outcomes (health status and health care utilization). Then, Lorig and her colleagues constructed a series of short scales to measure the outcomes of self-management behaviors and self-efficacy of participants in the CDSMP.

Lorig et al. (1996) reported that the Chronic Disease Self-Measurement Program Study Measures were either modified from existing measures that had been shown to have good reliability, validity, and responsiveness to change or developed de novo. The researchers noted that the earlier versions of their self-efficacy scales, which had been designed to use a 1 to 5 Likert scale, had sensitivity problems detecting change (Lorig et al., 1996). Hoping to circumvent the potential problem of lack of scale
sensitivity, they modified the format of their self-efficacy scales to a 1 to 10 scale with labeled end points, which appears to have improved the scales’ sensitivity to change (Lorig et al., 1996).

The *Self-Efficacy for Managing Chronic Disease 6-Item Scale* was the short scale selected from the CDSMP to measure the self-efficacy outcome in this study. Lorig et al. (1996) reported that testing of the self-efficacy measures in the CDSMP revealed that most of them had means slightly above the midpoint (± 1 to 2 points) of the 10-point scale. Floor and ceiling effects of the self-efficacy scales were not evident. Further, reliability of all the self-efficacy scales appeared to be good, with test-retest reliability coefficients ranging from .82 to .89 and internal consistency coefficients ranging from .77 to .92. The researchers reported an internal consistency coefficient for the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* of .91.

*Parkinson’s Disease Questionnaire (PDQ-39)*

The *PDQ-39* (see Appendix E) is a Parkinson’s disease-specific QOL questionnaire that was developed by researchers in the United Kingdom (Health Services Research Unit at Oxford University) on the basis of interviews with Parkinson’s patients who identified key QOL indicators that were important to the patients (Fitzpatrick, Peto, Jenkinson, Greenhall, & Hyman, 1997; Peto, Jenkinson, & Fitzpatrick, 2000, 2001). The items on the *PDQ-39* measure eight dimensions identified by PD patients as being important to their health and quality of life: (a) mobility, (b) activities of daily living (ADLs), (c) emotional well-being, (d) stigma, (e) social support, (f) cognition, (g) communication, and (h) bodily discomfort (Peto et al., 2001).
The PDQ-39 is a measure of PD-QOL widely used in several countries, and its psychometric properties have been evaluated cross-culturally (Jenkinson, Fitzpatrick, Norquist, Findley, & Hughes, 2003). Jenkinson et al. (2003) reported that results of cross-cultural evaluation of the PDQ-39 have shown it to be a valid and reliable measure of PD-QOL across all eight of its dimensions (subscales), with the exception of the social support subscale (range of \( r = 0.13 \) [Japan] to 0.68 [United States]). Cross-cultural evaluation of floor and ceiling effects of the PDQ-39 yielded limited evidence of such effects (extent to which respondents score at the bottom or top of a scale) of this measure except on the social support dimension (Jenkinson et al., 2003). Jenkinson et al. reported that over 50% of respondents in the United States, Japan, Canada, and Spain scored at the floor (i.e., scored zero) on the social support subscale.

The PDQ-39 also has been shown to be a valid and reliable instrument that is responsive to change and able to detect minimally important differences on serial measures (Jenkinson & McGee, 1998; Jenkinson, Peto, Fitzpatrick, Greenhall, & Hyman 1995; Peto et al., 1998, 2001; Peto, Jenkinson, Fitzpatrick, & Greenhall, 1995). Minimally important differences reflect the smallest change in scores on repeated measures that are subjectively meaningful to patients (Peto et al., 2001).

The scoring methodology of the PDQ-39 is presented in Appendix E. PDQ-39 scores can be reported in either a profile format, thereby delineating the scores on each of the eight dimensions or as a summary index score (i.e., global score) which also has been determined to be an internally reliable and valid measure of PD-QOL (Jenkinson, Fitzpatrick, Peto, Greenhall, & Hyman, 1997a, 1997b). PDQ-39 profile scores on the eight dimensions have value in determining the merit of various treatment regimens.
targeting the functioning and well-being of PD patients, whereas the summary index score has value for determining the overall impact on QOL of such treatment regimens (Jenkinson et al., 1997a).

Procedure

*Parkinson's Disease Collaborative Care (Experimental Educational Method)*

The components of the PDCC intervention are illustrated in Model 2 (see Appendix A). The PDCC intervention was developed as the experimental patient education method for teaching middle-stage Parkinson's patients who were enrolled in this study. It was taught by an interdisciplinary team of health care professionals who had expertise in caring for PD patients and by Parkinson's patients who were trained as peer mentors/leaders to work in collaboration with the participants. The health care professional(s) and four Parkinson's patients who were trained by the investigator to be patient peer-mentors(s) also acted as cofacilitators at each of the training sessions for the Parkinson's patients enrolled in this study.

The investigator based the PDCC experimental educational approach on two related approaches that have been discussed in the literature on patient self-management education for chronic disease. First, the PDCC treatment was modeled after the Chronic Disease Self-Management Program (CDSMP) developed at Stanford University (Lorig et al., 1996). The Parkinson's Disease-CDSMP was designed to help Parkinson's patients gain requisite knowledge and skills, and enhance self-efficacy to self-manage their PD and, if present, other comorbid chronic diseases such as heart disease, diabetes,
arthritis, and lung diseases. Prior to initiating the intervention, the investigator had completed training offered by the Area Agency on Aging in Grand Rapids, Michigan, to become certified as a facilitator for Stanford University’s Chronic Disease Self-Management Program (CDSMP).

Secondly, the conceptual framework for the CDSMP was used in conjunction with the National Parkinson Foundation’s (NPF) Allied Health Team Training (ATTP) in Parkinson’s disease care model. In June 2006, the investigator participated in a 5-day workshop that was offered by the National Parkinson’s Foundation at the Oregon Health Sciences University for training interdisciplinary allied health professional teams in the care of PD patients. The NPF’s allied health team training linked the interdisciplinary health professionals’ perspectives to the care interventions required at each stage (i.e., early, middle, and late) of PD.

After completing the NPF Allied Health Team Training workshop, the investigator ordered the NPF’s Rainbow Series of PD patient education booklets. These informative patient education booklets contained essential material for PD patients and their families to learn about PD, including general overview of PD and related conditions, PD medications, nutrition, physical fitness, mental health, speech and swallowing disorders in PD, and available social support resources. The PD Rainbow Series booklets were included in toolkits given to each participant at each educational session in the study. Participant toolkits contained information specific to the educational content that was offered at each particular session of the intervention.
Parkinson's Disease Information Transfer (Comparison Educational Method)

The components of the PDIT intervention are illustrated in Model 3 (see Appendix A). The PDIT (control) group received patient education about PD and other comorbid illnesses from the same team of interdisciplinary health care professionals who provided information to the PDCC group, but they used the traditional approach to patient education for the PDIT (control) group (Table 3). The traditional patient education approach emphasized the expert role of the health professional who shared information with and taught technical skills to the patient based on patient problems identified by the health care professionals rather than by the patient, but patients were not taught explicitly how to develop the necessary problem-solving skills to self-manage their disease. Nor was the expertise that the patient brought to this situation recognized as an integral component of the patient-education interaction; whereas it was recognized as an essential component in the patient-professional collaborative care model. Thus, the patient in the traditional care, patient education model was a passive learner and was acted upon rather than being an active partner engaged in the patient education process, as in the collaborative care model (CCM) used with the PDCC group.

Training and Scheduling Procedures

Recruitment of Interdisciplinary Health Team Professionals

Meetings also were held with the administrative representatives from RehabPros Physical Rehabilitation and the Hauenstein Parkinson Center to determine their willingness to provide the expert allied health professionals needed to deliver the PD
Table 3

Schema for Intervention Sessions

<table>
<thead>
<tr>
<th>Session &amp; Content Area</th>
<th>Collaborative Care Model (CCM)</th>
<th>Informational Care Model (ICM)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parkinson’s Disease Overview &amp; PD Medications</td>
<td>Led by Nurse Facilitator &amp; 4 Patient Peers Welcome Remarks (5 min) &amp; Pretest (15 min) Introduction &amp; Overview of Parkinson’s Disease (Facilitator) (25 min) Break (20 min) Parkinson’s Drugs (Pharmacist) (25 min) Review PD Toolkits and develop Action Plans (participants divide into 4 groups of 4-6 participants each for individualized mentoring with peer &amp; floating facilitator) and Evaluation (30 minutes)</td>
<td>Led by Nurse Facilitator Welcome Remarks (5 min.) &amp; Pretest (15 min) Introduction &amp; Overview of Parkinson’s Disease (Facilitator) (25 min) Q &amp; A (10 min) Distribute PD Toolkits &amp; handout materials (Session 1-Parts I &amp; II) (10 min) Break (20 min) Parkinson’s Drugs (Pharmacist) (25 min) Q &amp; A and Evaluation (10 min)</td>
</tr>
<tr>
<td><strong>Session 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>Led by Nurse Facilitator &amp; 4 Patient Peers Physical Functioning/Mobility/Exercise Physical Therapist (35 min) Break (20 min) Environmental Design Occupational Therapist (35 min) Develop Action Plan (Participants divided into 4 groups of 4-6 participants each for individual mentoring with peer &amp; floating facilitator) and Evaluation (30 minutes)</td>
<td>Led by Nurse Facilitator Physical Functioning/Mobility/Exercise Physical Therapist (35 min) Review of Toolkit materials (35 min) Break (30 min) Environmental Design Occupational Therapist (35 min) Review of Toolkit materials and Evaluation (10 min)</td>
</tr>
<tr>
<td><strong>Session 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Functioning</td>
<td>Led by Nurse Facilitator &amp; 4 Patient Peers Communication &amp; Social Functioning Speech-Language Therapist (35 min) Break (20 min) Social Worker (35 min) Develop Action Plan (Participants divided into 4 groups of 4-6 participants each for individualized mentoring with peer &amp; floating facilitator) (30 min) Posttest and Evaluation (15 min)</td>
<td>Led by Nurse Facilitator Communication &amp; Social Functioning Speech-Language Therapist (35 min) Review of Toolkit materials (10 min) Break (30 min) Social Worker (35 min) Review of Toolkit materials (10 min) Posttest and Evaluation (15 min)</td>
</tr>
<tr>
<td><strong>Follow-Up Mailing</strong></td>
<td>Mail participants a packet containing: Letter requesting them to complete PDQ-39 &amp; Self-Efficacy Questionnaires within 1 week and return to investigator in the enclosed self-addressed, postage-paid envelope.</td>
<td>Mail participants a packet containing: Letter requesting them to complete PDQ-39 &amp; Self-Efficacy Questionnaires within 1 week and return to investigator in the enclosed self-addressed, postage-paid envelope.</td>
</tr>
</tbody>
</table>

(4 weeks after completion of education sessions)
educational content to the PDCC and PDIT groups. RehabPros endorsed the study and agreed to solicit for volunteers within its organization who were willing to assist in delivering the PD educational intervention to both groups. As an in-kind budgetary contribution, RehabPros provided the support of a physical therapist, occupational therapist, and speech therapist. The Hauenstein Parkinson's Center provided the in-kind contribution of their pharmacist and social worker who had both volunteered to assist with the intervention. St. Mary's Health Care also agreed to provide the meeting rooms where the education sessions were held. The investigator contacted the facilities manager at St. Mary's Health Care approximately 3 months prior to implementation of the intervention and room reservations were made for 4 consecutive weeks. Room reservations were made for 4 weeks to allow for a make-up session due to the possibility of inclement weather. However, no make-up session was required.

Once the allied health professionals were recruited, the investigator conducted a separate early planning session with each one to discuss the nature of the study, the differences between the two patient education methods, expectations of their role; and to provide them with related materials, such as journal article, schema for intervention sessions, and NPF educational materials related to their content area. The same professionals were involved in both educational approaches; therefore, it was important for them to have explicit instruction in the elements that were similar and different across the two models. To minimize bias and increase interrater reliability, the investigator created handouts that provided separate descriptions of standard operating procedures regarding the distinctions between the two educational programs. The professional presenters were given these materials to help guide their activities during their session.
with each group. The materials were derived from the primary journal article (Bodenheimer et al., 2002) that depicted the distinctions between the two patient education methods, along with materials from the CDSMP training program in which the investigator had participated. Lastly, the investigator asked professionals to provide any additional materials or handouts that they wanted to give participants at the sessions so these could be submitted for expedited HSIRB approval prior to launching the intervention. All additional handouts developed by the presenters were submitted for expedited HSIRB approval which was obtained in early January 2007.

Approximately 4 weeks prior to the inception of the intervention, the investigator contacted all of the allied health professionals again via e-mail to (a) review the expectations for their particular sessions, (b) provide them with the journal article (which also had been given to them earlier) that detailed the differences between the two patient educational approaches, (c) provide them with additional handouts created by the investigator for use with the PDCC group which had been given expedited approval by the HSIRB, (d) provide schedule and room assignments for intervention sessions, and (e) ascertain if they had any questions or concerns about their role with the two groups or expectations of the investigator.

*Patient Peer Mentors*

One week prior to the inception of the intervention, a training session was held by the investigator with the selected PD patient peer mentors at the Parkinson's Association of West Michigan. One of the peer mentor trainees was unable to attend this session, so the investigator conducted a separate training session for that particular peer
mentor. According to Bodenheimer et al. (2002), the role of patient peer mentors has been an important element in the success of the patient-professional collaborative health care delivery model. Patients recommended for the peer mentor role should be individuals who have demonstrated strengths in self-management of their disease and who have social skills that suggest they would be good at working with others (Bodenheimer et al., 2002).

PD patient peer mentors selected to participate in the study had been identified for recruitment based on the recommendation of the medical director and nurse clinical manager of the HPC or from the pool of ineligible PD patients identified by the investigator (see Appendix H). Two of the age-ineligible PD patients were experienced, retired college or primary school teachers who were in middle-stage PD with a history of good management of their PD symptoms. Both were very interested in being a patient peer mentor and willing to participate in the study. After either the medical director or the nurse clinical manager had discussed this volunteer opportunity with the other PD patients, their name and contact information were given to the investigator if the patient had expressed an interest and willingness to possibly participate as a peer mentor in the study. A very active businessman and a retired gentleman were selected to also be PD patient peer mentors. Four (3 men, 1 female) peer mentors were recruited and trained. The age of the peer mentors ranged from mid-50s to 83. All peer mentors were given a $40 gift card to help defray their transportation expenses related to attending and performing their volunteer roles at the educational sessions.

Materials provided to the PD patient peer mentors were similar to those given to the health care presenters and emphasized their interactive role in mentoring patients in
the PDCC group. The investigator informed and discussed the role expectations of peer mentors with the volunteers. Further, the investigator discussed the distinctions between the two patient education approaches with the patient peer mentors. They were also given the journal article (Bodenheimer et al., 2002) that delineated the two patient education methods and discussed the important support that the patient peer mentor role made in contributing to the success of the collaborative care model. Patient peer mentors received training and materials to assist them in working with the PDCC participants and helping them to develop the requisite knowledge and problem-solving skills to aid them in developing their patient-identified action plans.

**PD Education Intervention Groups**

Both experimental and control group training programs comprised three 2-hour weekly training sessions conducted one afternoon per week, over a period of 3 consecutive weeks (Table 3). Care was taken to communicate with the participants in such a way that they were not aware whether they had been randomized into the "experimental" (hence, potentially better, worse, or no difference) or "control" (i.e., traditional) condition. Participants were instructed that they would be informed as to which group they had been randomized to once the study had been completed and results were analyzed. Participants had been informed, in advance of starting the intervention, that Sessions 1 and 3 would run an additional 15 minutes longer to allow time for them to complete the *PDQ-39* and *Self-Efficacy*, and session evaluation measures. Participants were asked to complete the *PDQ-39* and *Self-Efficacy* measures at the beginning of Session 1 and at the end of Session 3. Recognizing the potential for fatigue...
and the importance of the socialization process for study participants, a 20-minute (Table 3) period for group socialization and relaxation was included in each 2-hour weekly training session. As previously noted, some participants, however, preferred to have access to refreshments and restroom facilities at random versus just at the designated break period.

At each session, participants received a free toolkit which comprised materials specific to the educational content of the session and included (a) NPF patient education books; (b) handouts prepared by the presenters; (c) reference materials related to PD websites, PD research resources, and community resources; (d) NPF PD identification card; (e) a 5'' × 7'' notepad; and (f) an ink pen. Participants in the PDCC group received additional educational materials that were to be used to assist them in developing the knowledge and problem-solving skills that they needed to self-manage their PD and any comorbid illnesses. At each session, participants in the PDCC group conducted the additional step of developing short-term action plans based on the problems that they had identified that they wanted to work on during the coming week. For each of the patient-identified problems, the patient partnered with patient peer mentors and members of the interdisciplinary health care team to establish personal goals and objectives for which the patient had the confidence, (i.e., sense of self-efficacy) of reasonable attainment during the coming week. Peer mentors and participants also contacted each other in between sessions to offer support and discuss problems. Patients reviewed these action plans at the following session with their health care professional and peer-leader mentors to evaluate how well the participant had been able to achieve or not achieve the mutually established goals and objectives they had written in their action plans at the
prior week’s session. The participants identified the facilitators and/or impediments to adherence to the action plans that they had developed. Then the participants and mentors engaged in active problem-solving skill building strategies to facilitate adherence to their action plan, to reduce or remove any impediments, and to establish new goals and objectives for the following weeks. Some of the PDCC participants and their peer mentors elected to maintain contact with each other after the intervention sessions ended.

One month after completion of the program, participants in both groups were sent a letter (see Appendix I) from the investigator asking them to complete the PDQ-39 and Self-Efficacy questionnaires. Participants were asked to complete and return these questionnaires to the investigator within 1 week after receiving them by using the enclosed addressed, postage-paid envelope.

To summarize, participants were requested to complete study questionnaires at baseline, upon completion of the 3-week program, and at 1 month later. Participants were also requested to complete a brief evaluation questionnaire at the end of each session to evaluate each intervention session (see Appendix J). One week and 2 weeks (if necessary) after final questionnaires had been mailed to participants, a follow-up letter (see Appendix K) was sent to participants who had not returned their questionnaires informing them that their surveys had not been received and providing replacement surveys in case the earlier set had been misplaced.

To reduce the possibility of leakage of information between the two groups, participants, peer leaders, facilitators, and interdisciplinary health care team members participating in the intervention sessions were asked not to discuss their participation in
or any other aspects of the research study with anyone outside their group. Participants were informed that upon completion of the intervention and all posttests, they were at liberty to discuss the study with whomever they wished.

**PDIT Education Group**

The traditional care patient education program comprised 2-hour weekly training sessions for 3 weeks which covered the same content areas as in the collaborative care PDCC group. Like the PDCC participants, the PDIT participants had been informed, in advance of starting the intervention, that Sessions 1 and 3 would run an additional 15 minutes longer to allow time for them to complete the *PDQ-39* and *Self-Efficacy*, and session evaluation measures. PDIT participants were asked to complete the *PDQ-39* and *Self-Efficacy* measures at the beginning of Session 1 and at the end of Session 3.

A 30-minute period for group socialization was included in each 2-hour training session. Like PDCC participants, at each session PDIT participants received a free toolkit which comprised materials specific to the educational content of the session and included (a) NPF patient education books; (b) handouts prepared by the presenters; (c) reference materials related to PD websites, PD research resources, and community resources; (d) NPF PD identification card; (e) a 5” x 7” notepad; and (f) an ink pen. PDIT group members were also taught the technical skills that would be helpful to them to self-manage their PD and any comorbid illnesses, but they did not receive the extra instruction in problem-solving skills to resolve their health care issues. PDIT group members neither were asked to develop goals, objectives, or action plans to address their
health care problems, nor did they receive the patient peer and health care professional mentoring that was offered to PDCC members.

One month after completion of the program, participants were sent a letter (see Appendix I) from the investigator asking them to complete the PDQ-39 and Self-Efficacy questionnaires one more time as a follow-up measure. On this occasion, participants were asked to complete and return these questionnaires to the investigator within 1 week after receiving them by using the enclosed addressed, postage-paid envelope. PDIT group participants were requested to complete study questionnaires at baseline, upon completion of the 3-week program, and 1 month later. Participants also were requested to complete a brief evaluation questionnaire (see Appendix J) at the end of each session to evaluate each intervention session. Two weeks and 4 weeks (if necessary) after final questionnaires had been mailed to participants, a follow-up letter (see Appendix K) was sent to participants who had not returned their questionnaires informing them that their questionnaires had not been received and providing replacement questionnaires in case the earlier set had been misplaced.

Analysis

The respondents' data were entered into an SPSS version 15 database for analysis. Excel spreadsheet programs were also used and data imported into SPSS. Descriptive statistics such as percentages, frequencies, means, and standard deviations, were used to describe the sample population, e.g., demographic data, and responses to questionnaires. These distributional characteristics, along with tests of skewness and kurtosis, were used to determine whether the sample met the assumptions for conducting
parametric analyses of data. If the distributional requirements for using parametric analyses were met, \( t \) tests were used to analyze single-time between-groups data. When parametric distributional assumptions were not met, the nonparametric Mann-Whitney U test was used. Between-groups repeated measures analyses were performed using repeated measures of analysis of variance (ANOVA). Data quality assurance and cleaning procedures were used to ensure that all data entry was accurate prior to analysis.

The four hypotheses proposed in this study were assessed by using inferential statistics to analyze data obtained to assess the association between independent variables, i.e., patient education method/group and elapsed time (see Appendix M) and the dependent (outcome) variables (see Appendix M), i.e., self-reported perceived self-efficacy in PD self-management, self-reported perceived PD-HRQOL, and change scores. The first research question and hypotheses addressed the relationship between the independent variable, PD educational method/group, and the outcome variable, self-efficacy (dependent variable). The Mann-Whitney U test was used to assess the difference in means between groups on the independent variable, PD educational method, and self-efficacy (dependent variable). ANOVA repeated measures were also used to assess for statistically significant differences in means between groups on the independent variable, PD educational method in terms of self-efficacy (dependent variable) measured over time.

The second research question and its related hypotheses addressed the relationship between groups on the independent variable, PD educational method/group, and the outcome variable, PD-QOL (dependent variable). The Mann-Whitney U test was
used to assess the difference in means between the two groups on the outcome (dependent) variable, PD-QOL. ANOVA repeated measures tests were also used to assess for statistically significant differences between the two PD educational groups (independent variable) as measured by the PD-QOL (dependent variable) over time. ANOVA repeated measures tests were also used to answer the third and fourth research questions to assess for any change in scores on both dependent measures (self-efficacy and PD-QOL) postintervention, or from baseline to the point of follow-up testing.

Effect sizes were also calculated to determine the magnitude of any observed effect of the PD education intervention between the two groups over time. Streiner and Norman (2003) defined effect size as “the difference between the two means expressed in standard deviation (SD) units (mean difference/SD at baseline)” (p. 117). Cohen (1988) proposed the following conventions for assessing the magnitude of observed effect sizes: 0.2 represents a small effect (i.e., a difference between the means equal to one fifth of the $SD$), 0.5 is a medium effect, and 0.8 is a large effect.
CHAPTER IV

RESULTS

Original data obtained from middle-stage PD participants \( N = 41 \) on the Self-Efficacy for Managing Chronic Disease 6-Item Scale and the PDQ-39 Parkinson’s Disease Quality of Life Scale were used to examine the effects of two patient education models (independent variable, two levels: PDCC and PDIT) on the outcome (dependent) variables: (a) self-reported perceived self-efficacy for PD disease self-management, and (b) self-reported perceived PD-HRQOL. The sample for this study was obtained from a fixed population of middle-stage PD patients who received their care at the Hauenstein Parkinson Clinic (HPC) and who met the eligibility criteria for enrollment (Table 1). The specific aims of this single-blind randomized control study were to: (a) compare the effectiveness of two health care delivery and patient education models (PDCC and PDIT) in enhancing PD patients’ perceived self-efficacy in PD disease self-management, and (b) compare the effectiveness of the two health care delivery and patient education models (PDCC and PDIT) in enhancing PD patients’ self-reported perceived quality of life (PD-HRQOL). The baseline measures were re-administered immediately postintervention and at 4 weeks postintervention.

This chapter presents the results of the data analyses of the outcome measures. It is divided into two sections: (a) descriptive analysis of demographic characteristics of the
sample, and (2) inferential statistical analysis of the research questions addressed by this study and their associated hypotheses.

Research Questions and Hypotheses

The following research questions and null hypotheses were addressed in this study:

1. Is there a difference in pre-post test scores (Time 1 – Time 2) on the Self-Efficacy for Managing Chronic Disease 6-Item Scale between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?
   
   Hypothesis:
   
   $H_{01}$: Pre-post scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale (Stanford University) will not differ between the two groups.

2. Is there a difference in pre-post test scores (Time 1 – Time 2) on the PDQ-39 Parkinson’s Disease Quality of Life Scale between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?
   
   Hypothesis:
   
   $H_{02}$: Pre-post scores on the PDQ-39 Parkinson’s Disease Quality of Life Scale will not differ between the two groups.

3. Is there a difference between change scores from posttest (Time 2) to the 4-week follow-up (Time 3) on either of the dependent measures (Self-Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson’s Disease Quality of Life Scale) between the PDCC and PDIT groups?
Hypotheses:

Hₐ₃: Time 2 – Time 3 change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale will not differ between the two groups.

H₀₄: Time 2 – Time 3 change scores on PDQ-39 Parkinson’s Disease Quality of Life Scale will not differ between the two groups.

4. Is there a difference between change scores from baseline (Time 1) to the 4-week follow-up (Time 3) on either of the dependent measures (Self-Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson’s Disease Quality of Life Scale) between the PDCC and PDIT groups?

Hypotheses:

Hₐ₅: Time 1 – Time 3 change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale will not differ between the two groups.

H₀₆: Time 1 – Time 3 change scores on the PDQ-39 Parkinson’s Disease Quality of Life Scale will not differ between the two groups.

Descriptive Analyses of Sample Characteristics

As previously noted in Chapter III, the records of all PD patients who received their care at the HPC were screened by the nurse clinical manager for eligibility for enrollment in the study based on criteria denoted in Table 1. Only 202 of the approximately 300 PD patients at the HPC were deemed to be potentially eligible for the study. Of the 202 potential participants who were mailed information about the study, 62 (30.6%) returned letters notifying the investigator that they were interested in possibly
participating in the study. All 62 of these respondents were screened for eligibility either by phone or home visit, but only 41 satisfied all eligibility inclusion criteria and were enrolled in the study. This section reports the findings of the descriptive data analysis conducted on the 41 participants.

The mean age of the 41 participants in the sample was 67.6 years (range 48 to 78 years) (Table 4). The sample comprised 58.5% (n = 24) males and 41.5% (n = 17) females. The PDCC (experimental) group (N = 21) included 12 males (57.1%) and 9 (42.9%) females. The PDIT (control) group (N = 20) included 12 males (60%) and 8 (40%) females.

Two participants (1 male, 1 female) withdrew from the PDCC group prior to the inception of the study. The PDCC male participant withdrew because he considered his diagnosis of PD to be questionable and chose to undergo a trial withdrawal of all PD medications and to obtain further medical evaluations of his symptoms before engaging in an educational seminar. The PDCC female participant had planned to relocate to warmer climates for the winter, and, due to timing, elected to withdraw from the study. Also prior to inception of the study, 1 male participant in the PDIT group chose to withdraw due to multiple chronic health care problems, indicating that he no longer wanted to participate in the study. Two participants (1 male, 1 female) in the PDIT (control) group withdrew after participating in the first session due to health and transportation issues. One male participant in the PDCC (experimental) group chose to withdraw from the study after the first session because he did not want to participate in the collaborative small group process nor share his personal health information with the
group. Thus, the total number of participants who remained in the study was reduced to 35.

Table 4

*Sample and Group Characteristics*

<table>
<thead>
<tr>
<th>Variable</th>
<th>PDIT ((n = 20))</th>
<th>PDCC ((n = 21))</th>
<th>Total ((N = 41))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (in years)</td>
<td>67.2</td>
<td>68</td>
<td>67.6</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>12</td>
<td>24</td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Married</td>
<td>16</td>
<td>18</td>
<td>34</td>
</tr>
<tr>
<td>Divorced</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Widowed</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Separated</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Partnered – Not married</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Years of Education (Mean ([SD]))</td>
<td>15.6 (3.1)</td>
<td>14.1 (3.5)</td>
<td></td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Retired</td>
<td>16</td>
<td>19</td>
<td>35</td>
</tr>
<tr>
<td>Years living with PD (Mean ([SD]))</td>
<td>7.6 (5.4)</td>
<td>6.5 (4.5)</td>
<td>–</td>
</tr>
<tr>
<td>Number of Comorbid Illnesses (Mean ([SD]))</td>
<td>5.1 (1.6)</td>
<td>5.0 (2.4)</td>
<td>–</td>
</tr>
<tr>
<td>MMSE Score (Mean ([SD]))</td>
<td>28.9 (1.4)</td>
<td>28.8 (1.2)</td>
<td>–</td>
</tr>
</tbody>
</table>

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Of the original 41 enrolled participants, the majority \( (N = 35; 85.3\%) \) of these community-dwelling participants were married \( (n = 34; 82.9\%) \) or cohabited with a partner \( (n = 1; 2.4\%) \). Of the 6 remaining participants, 2 (4.9%) were single and had never married, 1 (2.4%) was widowed, 2 (4.9%) were divorced, and 1 (2.4%) was separated. With respect to race, 37 (90.2%) were Caucasian and 4 (9.8%) were multiracial. Only 1 (2.4%) of the 41 participants indicated having any Spanish/Hispanic origins.

The mean number of years of education for the sample was 14.8 years (range 12 to 23 years). Mean score for the participants on the Mini-Mental State Examination (maximum score of 30 points) was 28.85 (range 26 to 30 points) with a standard deviation \( (\sigma) \) of 1.28. The 41 participants reported that they had attempted to learn more about PD by accessing Internet resources \( (n = 12; 46.3\%) \), attending a PD support group \( (n = 17; 41.5\%) \), attending PD education offerings \( (n = 21; 51.2\%) \), obtaining PD education materials from their physicians \( (n = 27; 65.9\%) \), or from other sources such as newspaper articles, magazines, or friends \( (n = 5; 12.2\%) \). Six participants (14.6%) were engaged in either full-time or part-time employment; 35 (85.4%) were retired. Two individuals (4.8%) had either self-elected to quit working or had their employment terminated due to their PD. Another female participant (2.4%) reported that she was terminated from her job due to her PD while she was enrolled in the study.

All 41 participants reported that they had some type of health care coverage. However, 4 (9.8%) participants reported that they made decisions regarding medication usage and choice of health care providers based on their ability to pay for these services.
Seven participants (17.1%) indicated that they based their decision of whether or not to participate in health care programs, such as patient education and exercise programs, on their ability and willingness to pay incurred out-of-pocket costs not covered by their insurance.

The mean number of years living with PD was 7.0 years (range 0 to 18 years). Six (14.6%) of the 41 participants had undergone Deep Brain Stimulator implantation surgery for control of their PD symptoms. Over 73% of the participants rated their general health status as excellent ($n = 1; 2.4\%$), very good ($n = 16; 39.0\%$), or good ($n = 13; 31.7\%$), whereas 26.9% rated their general health either as fair ($n = 7; 17.1\%$) or poor ($n = 4; 9.8\%$).

All 41 of the participants reported taking at least one prescribed PD medication to control their PD symptoms (range 1 to 5 medications) (Figure 1). Most commonly prescribed PD medications included: levodopa (Sinemet [$n = 29; 70.7\%$] and Sinemet CR [$n = 12; 29.3\%$]); dopamine agonists (Mirapex [$n = 10; 24.4\%$] and Requip [$n = 6; 14.6\%$]); COMT-inhibitor medication, either separately (Comtan [$n = 2; 4.9\%$]) or in combination with levodopa and carbidopa, i.e., Stalevo ($n = 9; 22.0\%$). Eleven (26.8%) of the 41 participants were taking antidepressant medications, whereas 8 (19.5%) were taking antianxiety medications. Three (7.3%) of the 41 participants who reported having difficulty with executive functioning were taking Aricept; 1 (2.4%) of the 3 was also taking Namenda to treat this symptom.

All of the participants had at least two or more comorbid illnesses with which to contend (Figure 2). Thirty-five (85.4%) of 41 participants reported having up to 6 additional comorbid illnesses; 6 (14.6%) participants had $\geq 7$ comorbidities coexisting.
Figure 1. Use of Prescribed Parkinson's Medications in Middle-Stage PD Patients.

with their PD. Overall, participants reported having a mean of 4.5 comorbid illnesses (Figure 2). The most frequently occurring comorbid illnesses diagnosed in this sample were: cardiovascular disease ($n = 18; 43.9\%$); hypertension ($n = 17; 41.5\%$), dyslipidemia ($n = 11; 26.8\%$); arthritis ($n = 30; 73.2\%$); impaired vision ($n = 39; 95.1\%$) with presbyopia and cataracts being the most commonly reported problems; cancer ($n = 26.8\%$); altered sense of smell ($n = 26; 63.4\%$); altered sense of taste ($n = 6; 14.6\%$); mood disorders reported as anxiety ($n = 15; 36.6\%$) and depression ($n = 19; 46.3\%$); insomnia ($n = 20; 48.8\%$); and diabetes mellitus ($n = 5; 12.2\%$).

Thus, several participants were taking multiple medications to control symptoms associated with other comorbid illnesses as well as to manage their PD symptoms. Of
Figure 2. Number of Comorbid Illnesses Present in a Sample of Community-Dwelling Patients With Middle-Stage Parkinson's Disease.

note, is the frequency of nonmotor PD symptoms such as impaired vision, altered sensory function of smell and taste, and insomnia and mood disorders reported by the participants of this sample. Nonmotor symptoms of PD have more recently gained the attention of researchers and clinicians as negatively influencing the QOL of PD patients. Nine (21.9%) participants reported either that they used or needed to use hearing aids.

Patients With Middle-Stage Parkinson's Disease

Along with these distributional sample characteristics, tests of skewness and kurtosis were conducted to determine whether or not the sample could be described using parametric measures. Baseline (Time 1) data were available for 38 of the participants who remained in the study on the dependent measure, self-efficacy. The
baseline results reported by group for all 38 participants on the self-efficacy measure yielded a $M = 7.00$, $SD = 1.60$; skewness was $-.833$, and kurtosis was $-.450$ (Table 5).

Table 5

<table>
<thead>
<tr>
<th>Time</th>
<th>$N$</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Standard Error</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>38</td>
<td>3.17</td>
<td>9.17</td>
<td>7.01</td>
<td>.26</td>
<td>1.60</td>
</tr>
<tr>
<td>2</td>
<td>33</td>
<td>4.33</td>
<td>8.83</td>
<td>7.10</td>
<td>.21</td>
<td>1.18</td>
</tr>
<tr>
<td>3</td>
<td>34</td>
<td>3.00</td>
<td>9.00</td>
<td>6.94</td>
<td>.25</td>
<td>1.44</td>
</tr>
</tbody>
</table>

Baseline results for the PDIT group ($n = 19$) were $M = 7.10$, $SD = 1.56$; skewness $= -.799$ and kurtosis $= -.511$. The baseline results for the PDCC group ($n = 19$) were $M = 6.9$, $SD = 1.6$; skewness was $-.907$, and kurtosis was $-.303$. Because assumptions of normality were not met, the Mann-Whitney U test was used for between group analyses within a single-time period (Time 1).

Baseline (Time 1) data were available for only 31 of the 38 participants who remained in the sample on the dependent measure of PD-HRQOL because some failed to complete all items Table 6. The baseline results for all 31 participants on the $PDQ-39$ QOL measure yielded a $M = 25.83$, $SD = 14.14$; skewness $= .700$, and kurtosis $= -.120$. Baseline results for the PDIT group ($n = 17$) were $M = 27.4$, $SD = 14.99$; skewness $= .262$ and kurtosis $= -.978$. The baseline results for the PDCC group ($n = 14$) were $M = 23.95$, $SD = 13.35$; skewness $= 1.491$ and kurtosis $= 3.04$. 

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Table 6

*PDQ-39SI Summary Scores at Baseline (Time 1), Postintervention (Time 2), and 4 Weeks Postintervention (Time 3)*

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Error</th>
<th>Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic</td>
<td>Statistic</td>
<td>Statistic</td>
<td>Statistic</td>
<td>Std. Error</td>
<td>Statistic</td>
</tr>
<tr>
<td>Time 1</td>
<td>31</td>
<td>3.85</td>
<td>59.62</td>
<td>25.83</td>
<td>2.54</td>
<td>14.14</td>
</tr>
<tr>
<td>Time 2</td>
<td>26</td>
<td>4.49</td>
<td>60.26</td>
<td>30.91</td>
<td>2.87</td>
<td>14.66</td>
</tr>
<tr>
<td>Time 3</td>
<td>34</td>
<td>3.21</td>
<td>55.13</td>
<td>28.03</td>
<td>2.44</td>
<td>14.28</td>
</tr>
</tbody>
</table>

In summary, the sample was not normally distributed on either of the dependent measures, i.e., self-efficacy for PD disease self-management or PD-HRQOL. The next section will discuss the inferential statistical analysis conducted as related to the research questions and null hypotheses.

Inferential Analyses of Research Questions

*Group Equivalence at Baseline*

Inferential statistical analyses of the sample were first conducted to ascertain if the randomization process had produced assignment of roughly equivalent groups, i.e., groups with no systematic variability at Time 1 (baseline). For this purpose, Mann-Whitney U tests were used to analyze data collected from 21 participants (n = 9 PDCC participants; n = 12 PDIT participants) on the PDQ-39 QOL questionnaire at Time 1 (baseline). Although the PDQ-39 was administered to 14 participants in the PDCC group and 17 PDIT participants at baseline (N = 31), the PDQ-39 Summary Index (PDQ-39SI)
score which is used to calculate a respondent’s global QOL score, could be calculated for only 21 of the 31 participants due to missing data points on some of these PDQ-39s. However, separate baseline summary scores could be calculated for each of the eight subscales of the PDQ-39 for all participants who had completed the measure except for any subscale that contained missing data points. As noted in Chapter III, lower scores on the PDQ-39 and its subscales indicate higher QOL, whereas higher scores indicate lower QOL. The results of the Mann-Whitney U test conducted on the baseline PDQ-39 QOL scores available for both groups revealed that the PDCC and PDIT \( z = -0.75, p = .50 \) groups were not significantly different.

Mann-Whitney U test analysis of baseline data on the Self-Efficacy 6-Item Scale available for both groups also revealed that the PDCC and PDIT \( z = -0.28, p = .78 \) groups were not significantly different on this measure either. This substantiated that the randomization procedure resulted in assignment of equivalent groups of this sample, even though the data were not normally distributed.

Research Question Analysis

Inferential statistical testing of the null hypotheses was conducted using nonparametric statistical tests that included the following tests: Mann-Whitney U and the Wilcoxon matched-pairs signed-rank. For comparisons between the two groups over time, i.e., baseline to postintervention to 4 weeks postintervention, the parametric two-way factorial analysis of variance (ANOVA) repeated measures test was used. The parametric repeated measures ANOVA is frequently used in such instances (i.e., even when the distribution is not normal) because (a) there is no appropriate nonparametric
analog to this ANOVA, (b) it is regarded as a very robust test even when its assumption of normality (normal distribution) is violated, and (c) such violation should not significantly affect the results of the test (Beaumont, Lix, Yost, & Hahn, 2006; Myers & Well, 1995; Norman & Streiner, 2000).

**Research Question 1**

Is there a difference in pre-post test scores (Time 1 – Time 2) on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?

\[ H_{01}: \text{Pre-post scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale (Stanford University) will not differ between the two groups.} \]

The outcome (dependent) variable, self-efficacy for Parkinson’s disease self-management, and the independent variable, patient education method, were calculated for baseline to postintervention changes in test scores of participants \((N = 33)\) on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale*. Statistical significance of between group differences was determined using the Mann-Whitney U test. The pre-post self-efficacy scores were calculated and no statistical significance was noted \((U = 128.000, p = .77)\).

A repeated measures ANOVA was conducted to evaluate the effects of group and time (baseline to immediately postintervention) on the outcome (dependent) variable, self-efficacy. As seen in Table 7, the results of the ANOVA repeated measures test was not statistically significant either for group \((p = .87)\) or time \((p = .95)\).
Table 7

*Self-Efficacy: Baseline and Postintervention Group Comparisons*

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group</td>
</tr>
<tr>
<td>1</td>
<td>PDIT</td>
<td>16</td>
<td>7.08</td>
<td>1.69</td>
<td>.87</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>17</td>
<td>7.08</td>
<td>1.49</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>PDIT</td>
<td>16</td>
<td>7.14</td>
<td>.99</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>17</td>
<td>7.03</td>
<td>1.37</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>33</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thus, using either analysis approach, the results indicated that there was no statistically significant difference between the PDCC and PDIT groups in pretest and posttest scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale*. Therefore, the null hypothesis could not be rejected.

*Research Question 2*

Is there a difference in pre-post test scores (Time 1 – Time 2) on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?

\( H_{eq} \): Pre-post scores on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* will not differ between the two groups.

The outcome (dependent) variable, PD-HRQOL, and the independent variables, patient education method, were calculated for baseline to postintervention changes in
test scores of participants \((N = 21)\) on the *PDQ-39 Parkinson's Disease Quality of Life Scale*. Statistical significance was determined using Mann-Whitney U test. Results of the Mann-Whitney U test did not reveal any statistically significant effect of patient education method and group on the outcome variable, PD-HRQOL \((U = 53.50, p = .97)\).

A repeated measures ANOVA also was conducted to evaluate for the effects of group and time (baseline to immediately postintervention) on the outcome (dependent) variable, PD-HRQOL. As seen in Table 8, the results of the ANOVA repeated measures test indicated that neither group \((p = .40)\) nor time \((p = .31)\) had a statistically significant effect on the outcome (dependent) variable, PD-HRQOL.

Table 8

*PDQ-39 Quality of Life Summary Scores: Baseline and Postintervention Group Comparisons for Teaching Method/Group and Time*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>(N)</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDQ-39 SUM Baseline (Time 1)</td>
<td>PDIT</td>
<td>12</td>
<td>29.9</td>
<td>16.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>9</td>
<td>24.6</td>
<td>16.1</td>
<td></td>
</tr>
<tr>
<td>PDQ-39 SUM Immediate Postintervention (Time 2)</td>
<td>PDIT</td>
<td>12</td>
<td>31.9</td>
<td>13.4</td>
<td>.40</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>9</td>
<td>25.7</td>
<td>16.6</td>
<td>.31</td>
</tr>
</tbody>
</table>

Thus, the results of this analysis indicate that there is no statistically significant difference between the PDCC and PDIT groups in pretest and posttest scores on the *PDQ-39 Parkinson's Disease Quality of Life Scale*. Therefore, the null hypothesis could not be rejected.
Research Question 3

Is there a difference between change scores from posttest (Time 2) to the 4-week follow-up (Time 3) on either of the dependent measures (Self-Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson's Disease Quality of Life Scale) between the PDCC and PDIT groups?

Two null hypotheses associated with this research question are:

H_{a3}: Time 2 – Time 3 change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale will not differ between the two groups.

H_{a4}: Time 2 – Time 3 change scores on PDQ-39 Parkinson's Disease Quality of Life Scale will not differ between the two groups.

The nonparametric Mann-Whitney U test was used to evaluate the effect of the independent variable, elapsed time (4 weeks), on the stability of participants' change scores from immediately postintervention to 4 weeks postintervention, in self-efficacy of PD disease self-management as measured by the Self-Efficacy for Managing Chronic Disease 6-Item Scale. Although the mean ranks of change scores at postintervention (Time 2) to 4-week postintervention (Time 3) were greater for the PDCC (n = 16; Mdn = 18.9) group than the PDIT (n = 16; Mdn = 14.0) group, this result was not statistically significant (U = 89.0, p = .14). Wilcoxon matched-pairs signed-rank test analysis of self-efficacy change scores of both groups for Time 1 (baseline) to Time 2 (postintervention) (p = .84 PDIT; p = .76 PDCC) and Time 2 (postintervention) to 4-week postintervention (Time 3) (p = .30 PDIT; p = .28 PDCC) revealed similar findings that were not statistically significant. Of note, however, is that the change scores for Time 2 to Time 3
for the PDCC group revealed an increase in their self-efficacy scores (from 7.0 to 7.4), whereas the PDIT group experienced a decline in their mean self-efficacy scores (from 7.2 to 6.5), perhaps suggesting a trend in the expected direction.

Repeated measures ANOVA also was conducted to evaluate for the effects of elapsed time on stability of change scores between groups at postintervention (Time 2) to 4-week follow-up postintervention (Time 3) intervention) on the outcome (dependent) variable, self-efficacy (Table 9). Due to late responders at Time 3, the data analysis for Time 3 was conducted twice. As seen in Table 9, the results of the ANOVA repeated measures test indicated that neither group ($p = .34$) nor time ($p = .70$) had a statistically significant effect on change scores from Time 2 to Time 3 on the outcome (dependent) variable, self-efficacy for PD disease self-management. Therefore, the null hypothesis could not be rejected.

Table 9

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>$p$ value Group</th>
<th>$p$ value Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>PDIT</td>
<td>16</td>
<td>7.17</td>
<td>.99</td>
<td>.34</td>
<td>.70</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>16</td>
<td>6.97</td>
<td>1.39</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>PDIT</td>
<td>16</td>
<td>6.51</td>
<td>1.64</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>16</td>
<td>7.39</td>
<td>1.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>32</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Mann-Whitney U test and repeated measures ANOVA were used to conduct testing of null hypothesis, $H_{o4}$: Time 2 – Time 3 change scores on *PDQ-39 Parkinson’s Disease Quality of Life Scale* will not differ between the two groups. The Mann-Whitney U test was used to evaluate the effect of the independent variable, elapsed time (4 weeks), on participants’ scores from immediately postintervention to 4 weeks postintervention, in PD-HRQOL, as measured by the *PDQ-39 Parkinson’s Disease Quality of Life Scale*. The total number of participants for whom PDQ-39 Summary Index scores could be computed was decreased and varied for all time periods due to the problem of missing data points. Consequently, power was decreased. There was no statistical significance in change scores of both groups from Time 2 to Time 3 (4-week follow-up postintervention) ($U = 65.00$, $p = .77$).

Repeated measures ANOVA was conducted to evaluate the effects of elapsed time on change scores and any between group differences at postintervention (Time 2) to 4-week follow-up postintervention (Time 3) on the outcome (dependent) variable, PD-HRQOL (Table 10). As noted previously, the data analysis for Time 3 was conducted twice due to late responders at Time 3. As seen in Table 10, the results of the ANOVA repeated measures test indicated that neither group ($p = .89$) nor time ($p = .12$) had a statistically significant effect on the stability of change scores from Time 2 to Time 3 on the outcome (dependent) variable, PD-HRQOL. Therefore, the null hypothesis, $H_{o4}$, could not be rejected.
Table 10

*PDQ-39 Summary Scores and PD-HRQOL at Postintervention (Time 2) and Follow-up at 4 Weeks Postintervention (Time 3)*

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Group p value</th>
<th>Time p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDQ-39 SUM Time 1</td>
<td>PDIT</td>
<td>12</td>
<td>29.9</td>
<td>16.2</td>
<td>.40</td>
<td>.31</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>9</td>
<td>24.6</td>
<td>16.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDQ-39 SUM Time 2</td>
<td>PDIT</td>
<td>12</td>
<td>31.9</td>
<td>13.4</td>
<td>.89</td>
<td>.12</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>9</td>
<td>25.7</td>
<td>16.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDQ-39 SUM Time 2</td>
<td>PDIT</td>
<td>14</td>
<td>31.3</td>
<td>12.5</td>
<td>.89</td>
<td>.12</td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>12</td>
<td>30.4</td>
<td>17.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDQ-39 SUM Time 3</td>
<td>PDIT</td>
<td>14</td>
<td>28.8</td>
<td>14.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PDCC</td>
<td>12</td>
<td>28.0</td>
<td>17.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Research Question 4

Is there a difference between change scores from baseline (Time 1) to the 4-week follow-up (Time 3) on either of the dependent measures (*Self-Efficacy for Managing Chronic Disease 6-Item Scale* or *PDQ-39 Parkinson’s Disease Quality of Life Scale*) between the PDCC and PDIT groups?

The null hypotheses associated with this question were:

\[ H_0: \text{Time 1} - \text{Time 3} \text{ change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale} \text{ will not differ between the two groups.} \]
$H_{06}$: Time 1 – Time 3 change scores on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* will not differ between the two groups.

A post-hoc secondary analysis was conducted to assess for differences in change scores across all time points to determine if any meaningful change had occurred among participants within each group on either dependent measure or its subscales, i.e., *PDQ-39* subscales. The Wilcoxon matched-pairs signed-rank test was used to evaluate and rank (based on negative or positive sign) the difference scores on paired data from participants to evaluate the effect of the independent variable, elapsed time (7 weeks), on participants’ change scores from baseline (preintervention) to 4 weeks postintervention in self-efficacy of PD disease self-management as measured by the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* (Table 11).

As noted in Table 11, the Wilcoxon matched-pairs signed-rank test revealed no changes in participants’ difference scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* that were statistically significant at pretest to 4-week follow-up postintervention for all participants ($p = .86$) or between groups, PDIT ($p = .18$) and PDCC ($p = .36$). Therefore, the null hypothesis could not be rejected.

The Wilcoxon matched-pairs signed-rank test was used to evaluate and rank (based on negative or positive sign) the difference scores on paired data from participants within the two groups to evaluate the effect of the independent variable, elapsed time (7 weeks), on participants’ change scores from baseline (preintervention) to 4 weeks postintervention, PD-HRQOL as measured by the PDQ39 Summary Index score (SI) on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* (Table 12).
Table 11

Self-Efficacy: Scores From Baseline (Time 1) to Follow-up at 4 Weeks Postintervention (Time 3) for All Participants and by Patient Education Group Assignment (Wilcoxon Matched-Pairs Signed-Rank Test)

<table>
<thead>
<tr>
<th>Scale/Subscale</th>
<th>Pretest to Posttest</th>
<th>Posttest to Follow-up</th>
<th>Pretest to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Average</td>
<td>p</td>
</tr>
<tr>
<td>Self-Efficacy 6-Item Scale (All participants)</td>
<td>33</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>Self-Efficacy 6-Item Scale (PDIT Group)</td>
<td>16</td>
<td>7.1</td>
<td>7.2</td>
</tr>
<tr>
<td>Self-Efficacy 6-Item Scale (PDCC Group)</td>
<td>17</td>
<td>7.1</td>
<td>7.0</td>
</tr>
</tbody>
</table>

As noted in Table 12, the Wilcoxon matched-pairs signed-rank test revealed no statistically significant changes in participants' difference scores on the PDQ-39 Parkinson's Disease Quality of Life Scale at pretest to 4-week follow-up postintervention for all participants (p = .66) within both groups, PDIT (p = .73) and PDCC (p = .81). Therefore, the null hypothesis was not rejected. Computation of PDQ-39SI scores and matched comparisons across time for participants in both groups was problematic because of missing data points, which accounts for the different numbers and slightly different means in different analyses at the same time point.

The Wilcoxon matched-pairs signed-rank test did detect that four of the PDQ-39 subscales revealed statistical levels of significance with respect to change scores at varying time points. The four subscales (see Appendix L) were: Communication at Time 1 – Time 2 (p = .03) and Time 2 – Time 3 (p = .03) for all participants; Emotional Well-Being.
Table 12

**PD-HRQOL: Change Scores on the PDQ-39 QOL Questionnaire From Baseline (Time 1) to Postintervention (Time 2) to 4-Week Follow-up (Time 3) for All Participants and by Group**

<table>
<thead>
<tr>
<th>Scale/Subscale</th>
<th>Pretest to Posttest</th>
<th>Posttest to Follow-up</th>
<th>Pretest to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Average</td>
<td>p</td>
</tr>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td>PDQ-39SI Sum Score</td>
<td>21</td>
<td>29.7</td>
<td>29.2</td>
</tr>
<tr>
<td>(All participants)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDQ-39SI Sum Score</td>
<td>12</td>
<td>29.9</td>
<td>31.9</td>
</tr>
<tr>
<td>(PDIT Group)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDQ-39SI Sum Score</td>
<td>9</td>
<td>24.6</td>
<td>25.7</td>
</tr>
<tr>
<td>(PDCC Group)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(PDIT group) at Time 1 – Time 3 (p = .03); Mobility (PDCC group) at Time 2 – Time 3 (p = .04) and Stigma (PDCC group) at Time 2 – Time 3 (p = .02). These results might be considered interesting trends, but would not be considered significant after statistical corrections for multiple testing were applied.

Results of Participants’ Evaluation of Intervention Sessions

As noted in Chapter III, participants in both groups were asked to complete evaluation forms (see Appendix J) at the end of each session to assess the content delivered by the interdisciplinary health care professionals and the effectiveness of each presenter’s teaching methods. Each evaluation form consisted of 5 to 7 direct questions with scaled responses (scale range was 1 = not at all, 2 = low, 3 = medium, and 4 = high) and two open-ended questions. The two open-ended questions asked participants to
provide comments or suggestions regarding (a) improving the educational content that was offered at each session, and (b) topics that they wanted to have presented at future educational sessions.

The Mann-Whitney U test was used to analyze the evaluation responses from the two independent groups for each of the three sessions. No statistically significant findings were noted with the Mann-Whitney U test except for speech therapy content which almost reached a statistical level of significance \( (p = .052) \), indicating that the members of the PDCC group rated this session higher than members of the PDIT group at a level approaching significance. All presenters across all sessions received scores within the 3 to 4 range.

Sparse responses were given to open-ended questions, but distinct differences were noted between the two groups in that three participants in the PDIT suggested more “patient involvement” and “interactive” activities, but no one in the PDCC made such comments. Suggestions for future educational topics are noted in Table 13.

Summary

Results obtained from the 35 participants in this pilot study revealed no statistically significant differences between the two teaching methods in enhancing participants self-efficacy for self-managing their PD and other comorbidities. Further, there were no statistically significant differences noted between the two teaching methods in terms of enhancing the PD-HRQOL of participants. The scoring methodology for the PDQ-39 Quality of Life Questionnaire was problematic with respect to dealing with missing data points. Missing data points on the PDQ-39 resulted
Participant Suggestions for Future PD Education Presentations

<table>
<thead>
<tr>
<th>Future Education Topics Suggested by Parkinson’s Study Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance coverage</td>
</tr>
<tr>
<td>Resources for obtaining financial assistance</td>
</tr>
<tr>
<td>Community resources</td>
</tr>
<tr>
<td>Exercise demonstrations</td>
</tr>
</tbody>
</table>

in the inability to compute global PDQ-39SI QOL scores for some participants over time. Consequently, this led to further reduction in power of the study. Lastly, the role of peer mentors was not evaluated separately on the evaluation forms for the PDCC group.

Analysis of the null hypotheses for questions 1 through 4 resulted in lack of evidence to justify rejection of the null hypotheses for questions 1, 2, and 3. Based on the results of the Wilcoxon matched-pair signed-rank tests, it was shown that difference scores from Time 1 (baseline) to Time 3 (4 weeks follow-up postintervention) of participants within the two groups did differ, but were not statistically significant. Therefore, the null hypotheses for question 4 also could not be rejected.

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CHAPTER V

DISCUSSION

Chapter Overview

This chapter begins with a summary of results, followed by a discussion of how the results of the descriptive and inferential statistical analyses conducted on the outcome (dependent) measures of this study relate to outcomes of previous studies. Conclusions and clinical implications related to study findings also are presented. Study limitations and their impact on the results are summarized. Lastly, recommendations for future PD research studies are presented and briefly discussed.

Summary of Design and Results

The goals of this single-blind, randomly controlled intervention study were to collect evidence to determine the effectiveness of two paradigms of patient education and health care delivery models on influencing (a) perceived self-efficacy in disease self-management of PD, and (b) PD-HRQOL among middle-stage PD patients. A specialty clinic, the Hauenstein Parkinson Center, which offered a range of interdisciplinary health care services to Parkinson’s patients, was the single site selected to participate in the study. All participants in both groups attended three 2-hour patient education sessions taught by an interdisciplinary team of health care professionals who had expertise in specific content areas related to management of PD symptoms (Table 3). The PDIT
group \((n = 20)\) received the traditional paradigm and model of patient education. The PDCC group \((n = 21)\) received the emerging patient-health professional collaborative care paradigm (Bodenheimer et al., 2002), an experimental model of patient education. The duration of the intervention was 3 weeks. The 4-week period of no intervention that followed led to the total study duration of 7 weeks.

The *Self-Efficacy for Managing Chronic Disease 6-Item Scale* (Lorig et al., 1996) and *PDQ-39 Parkinson’s Disease Quality of Life Scale* (Jenkinson et al., 1998) measurement tools were used to assess participants’ outcomes on the dependent variables, self-efficacy and health-related quality of life (HRQOL). Measurements were taken at three points in time: (a) baseline, (b) after completion of the 3-week education sessions, and (c) at 4 weeks later.

Data collected from all participants were used to answer the following questions, which are shown here with their results:

1. Is there a difference between pre- and post-test scores (Time 1 – Time 2) on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?

   *Null Hypothesis 1 – Not rejected*

   \(H_{01}:\) Pre-post scores on the *Self-Efficacy for Managing Chronic Disease 6-Item Scale* (Stanford University) did not differ between the two groups.

2. Is there a difference between pre- and post test scores (Time 1 – Time 2) on the *PDQ-39 Parkinson’s Disease Quality of Life Scale* between Parkinson’s disease patients who participate in the PDCC or PDIT intervention?
Null Hypothesis 2 – Not rejected

$H_{o2}$: Pre-post scores on the PDQ-39 Parkinson's Disease Quality of Life Scale did not differ between the two groups.

3. Is there a difference between change scores from post-test (Time 2) to the 4-week follow-up (Time 3) on either of the dependent measures (Self-Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson's Disease Quality of Life Scale) between the PDCC and PDIT groups?

Null Hypothesis 3 – Not rejected

$H_{o3}$: Time 2 – Time 3 change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale did not differ between the two groups.

Null Hypothesis 4 – Not rejected

$H_{o4}$: Time 2 – Time 3 change scores on PDQ-39 Parkinson's Disease Quality of Life Scale did not differ between the two groups.

4. Is there a difference between change scores from baseline (Time 1) to the 4-week follow-up (Time 3) on either of the dependent measures (Self-Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson's Disease Quality of Life Scale) between the PDCC and PDIT groups?

Null Hypothesis 5 – Not rejected

$H_{o5}$: Time 1 – Time 3 change scores on the Self-Efficacy for Managing Chronic Disease 6-Item Scale did not differ between the two groups.
Null Hypothesis 6 – Not rejected

H_{06}: Time 1 – Time 3 change scores on the PDQ-39 Parkinson’s Disease Quality of Life Scale did not differ between the two groups.

Discussion of Results

Descriptive Data for the Sample

Bertram and Tanzi (2005) have noted that males have a slightly greater preponderance for developing PD than do females. This parallels the gender distribution seen in the nonnormally distributed sample in the current study, in that males (n = 24) comprised the majority of participants, whereas there were only 17 female participants. Mean age of participants was 67.6 years of age. The majority (n = 37) were Caucasian. All participants had at least a high school education and some had 23 years or more of education. The mean score of the participants on the Mini-Mental State Examination (MMSE) was 28.85 (range 26 to 30 points) with a standard deviation (σ) of 1.28.

The majority of the community-dwelling PD participants (n = 35) were married or cohabitated with a significant other, whereas 6 participants lived alone. The majority (n = 35) of the participants were retired, but 6 were engaged in either full-time or part-time employment. All participants had some type of health insurance coverage.

Mean number of years living with PD for the participants was 7.0 years (range 0 to 18 years). Despite living and coping with PD for several years, the majority of the participants and their spouses or partners were interested in obtaining more information about PD and anticipatory guidance concerning potential PD and related health
concerns. During the recruitment phase, spouses often expressed concern regarding participants’ PD symptom management, current health status, and uncertainty for management of participants’ future health care needs and caregiving demands.

The majority of participants were taking at least one (range 1 to 5) prescribed PD medication(s) and 70.7% were taking levodopa (Sinemet). All of the participants had at least one or more (range 1 to 13) comorbid illnesses in addition to PD. Cardiovascular related diseases, arthritis, and impaired vision were the most common comorbid illnesses reported by participants. Several participants reported having nonmotor symptoms associated with PD. Common nonmotor PD symptoms experienced by participants included: (a) mood disorders reported as anxiety and depression, (b) motor fluctuations reported as dyskinesias or freeze attacks (the “off” phenomenon due to wearing off of anti-PD medications), (c) cognitive changes reported as problems with executive functioning, (d) visual disturbances, (e) hallucinations, and (f) altered sense of smell and/or taste.

In summary, it could be said that these middle stage patients with PD were fairly representative of this segment of individuals with the disease. The sample included both males and females; showed a small degree of racial/ethnic diversity; varied in marital, living, and employment conditions; and exhibited a range of PD symptomatology and comorbid conditions. They shared an interest in learning more about their conditions, and, in some cases, wanting their spouses to learn more as well as evidenced by the number of spouses or partners that also attended the educational sessions.
Patient Education, Self-Efficacy, and Disease Self-Management

Although this was not a normally distributed sample, the demographic characteristics exhibited and PD symptoms reported by the participants were not unlike those commonly seen in the general population with respect to PD symptomatology and prior educational experiences (Bertram & Tanzi, 2005; Lang & Lozano, 1998; Nutt & Wooten, 2005; VanDenEeden et al., 2003). The majority of the participants reported that they had exerted some effort to educate themselves about PD by accessing information available from a variety of resources. As previously noted in the present study, the 41 participants reported that they had attempted to learn more about PD by accessing Internet resources (n = 12; 29.3%); attending a PD support group (n = 17; 41.5%); attending PD education offerings (n = 21; 51.2%); obtaining PD education materials from their physicians (n = 27; 65.9%); or from other sources such as newspaper articles, magazines, or friends (n = 5; 12.2%).

As a chronic, progressive neurodegenerative disease with no known cure, PD treatments are focused on secondary prevention strategies targeted to slow disease progression, manage symptoms, prevent complications, lessen the impact on patients' functional limitations, and thereby improve quality of life. Marks et al. (2005a, 2005b) have noted that secondary prevention strategies in chronic disease management require better disease self-management, and that can be promoted through collaborative patient education programs. Patient education programs that have used self-efficacy, a construct of social cognitive theory, as the underpinning of disease self-management education programs have had positive results in improving patient outcomes and system outcomes.
(Bandura, 1977, 1986, & 2004; Bodenheimer et al., 2002; Lorig, Sobel, et al., 2001; Lorig, Ritter, et al., 2002). Bodenheimer et al. (2002) noted that the goal of self-management education is to increase the patient's perceived self-efficacy (self-confidence), thereby improving patients' clinical outcomes and quality of life.

Lorig et al. (1996) developed the Chronic Disease Self-Management Program at Stanford University based on the philosophy of targeting prevention strategies to help patients learn to live better with their chronic diseases by delaying disability, minimizing suffering, and improving quality of life. Lorig et al. noted that their experience of conducting community-based arthritis patient education classes for over 12 years led to the conceptual development of the CDSMP. Patients' participation in these earlier community-based arthritis patient education programs were assessed based on patients' self-reported health behaviors, health status, and health care utilization (Lorig et al., 1996). Results of these patient assessments indicated that participants in the arthritis self-management patient education program had reported sustained outcomes of decreased pain and use of health care providers, which persisted up to 4 years (Lorig et al., 1996). These earlier patient assessments do not appear to have been based on any type of randomly controlled intervention studies.

To expand the chronic disability model of self-management of disease symptoms to other groups beyond patients with arthritis, Lorig et al. (1996) conducted a community-based needs assessment by holding a series of 11 focus group sessions with people who had multiple chronic health problems. Based on results of data collected from these focus groups, the framework, specific content, and structure (2.5-hour sessions conducted over 7 weeks) of the CDSMP emerged (Lorig et al., 1996). Over the
course of the 7-week self-management program, participants were taught self-
management health care strategies that could be used to deal with a broad range of
chronic diseases and related health issues. Self-care management strategies that were
taught during the 7-week sessions included: (a) disease information, (b) technical skills
relevant to management of specific diseases, (c) problem-solving skills, and (d)
collaboration with health care professionals. The concept of promoting self-efficacy was
and remains the underpinning of the CDSMP. The CDSMP also incorporates the use of
patient peer mentors and development of patient-written action plans based on problems,
goals, and objectives identified by the patient.

Lorig et al. (1996) reported that they had observed positive outcomes based on
their research with $N = 1,130$ male and female participants with a mean age of 64.4 years
(range 39.2 to 90.5 years) who had participated in Stanford University's, Chronic
Disease Self-Management Program or were enrolled in a comparison-control group over
the course of 12 years. These participants had been diagnosed and treated for a variety of
chronic health problems including, but not limited to, heart disease, arthritis, asthma,
diabetes, and osteoporosis.

Comparison of the PDCC Model to the Original CDSMP Model

The four key components (disease information, relevant technical skills, problem-
solving skills, and collaboration with health care professionals) recommended by Lorig et
al. (1996) were all incorporated into the PDCC education model that was viewed as the
experimental model in the current research. The comparison model (PDIT) incorporated
the first two elements and interaction with health care professionals, but did not include
teaching of problem-solving skills or patient peer mentors. The PDCC model emphasized problem-solving skills using peer mentors as well as further interaction with the health care professionals in the small group planning time.

Several differences can also be noted between how the model was implemented in the original research by the group at Stanford and in this small randomized control trial. A key difference is the nature of the population. The participants in the current research all had PD in the middle stages, compared with the earlier studies, which focused on patients with arthritis, heart disease, asthma, and diabetes. Another important difference was the 3-week duration of the education sessions in the current study, compared with the 7-week duration recommended by Lorig and her colleagues (1996).

Relating the Findings of This Study to Prior Research on Self-Efficacy

The lack of a clear effect of the PDCC treatment in this study can be interpreted with respect to prior research on collaborative care models with a variety of other populations with chronic disease conditions. The results of the current study provided no clear evidence of a positive effect of a peer-mediated collaborative educational model. On the other hand, the upward trend in mean self-efficacy scores from the baseline measurement of self-efficacy till 4 weeks posttreatment (especially when compared with the downward trend in scores for the participants in the traditional information transfer educational group) invites further interpretation and comparison with prior investigations in this area with similar, but not identical, populations and conditions. To review, PDCC participants' mean self-efficacy scores for the three time periods were: (a) 6.9 (baseline; \( n = 19 \)); (b) 7.0 (postintervention; \( n = 17 \)), and (c) 7.4 (4-week follow-up; \( n = 17 \)). PDIT

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participants' mean self-efficacy scores for the three time periods were: (a) 7.10 (baseline; \( n = 19 \)); (b) 7.2 (postintervention; \( n = 16 \)), and (c) 6.5 (4-week follow-up; \( n = 17 \)). Thus, the trajectory for the mean self-efficacy scores for the two groups appeared to be heading in the expected direction, but did not reach a level of statistical significance. These findings can be compared with findings from similar studies with a variety of other populations.

Lorig et al. (1996) used some of the specialized assessment tools developed at Stanford to measure outcomes for participants in the arthritis self-management program, who reported a 20% reduction in pain, improved control over stress and fatigue, and increased ability to perform ADLS (Marks et al., 2005a, 2005b). Lorig et al. (1996) noted that the arthritis CDSMP participants reported that these outcomes had been sustained for at least 4 years. The symptoms, as well as the disease progression course, differ for patients with arthritis, however, compared to those for patients with PD, who participated in the current study. The 7-week duration of the current study also was much shorter than the 4-year duration reported by Lorig and her colleagues, making comparison difficult. Differences in the disease processes would be likely to affect such long-term outcomes for patients with PD as well. Similar large-scale longitudinal investigations of patients with PD are needed to learn more about how the disease progression, and self-efficacy for dealing with its symptoms, might be affected.

Bodenheimer et al. (2002) (the Stanford research group, of which Lorig is a member) reviewed 10 studies reporting on the results of arthritis self-management patient education programs. The studies used a variety of outcome measures, but positive findings were reported as fewer physician visits, fewer hospitalizations, and less
health care costs than nonparticipant controls. Bodenheimer et al. compared these results with results reported by researchers studying diabetes and asthma disease self-management patient education programs, which did not have similar sustained results, to those reported to be sustained for 4 years by patients with arthritis. Those results suggest caution in expecting similar levels of effect for patients with all types of chronic conditions.

Summary of Findings of This Study Related to Prior Research on Self-Efficacy

In summary, inferential statistical analyses of PDCC and PDIT groups' self-efficacy scores for PD disease self-management indicated that none of the null hypotheses about changes in self-efficacy could be rejected for any of the time periods studied: (a) 3-week pre- to posttest period; (b) 4-week posttest to 4-week follow-up; or 7-week pretest to 4-week follow-up. The most defensible conclusion is that the choice of educational method made no difference and that no significant changes occurred in either of the dependent variables for either group.

On the other hand, the study was short, and PD is different from some of the other chronic conditions studied by prior researchers. Some trends in the direction of change in self-efficacy scores for the two groups suggest that extending the weeks of the intervention from 3 to 7, as recommended by Lorig and her colleagues (1996), would yield measurable results. A longer period of follow-up also might make it possible to detect differences based on educational method in the key construct of self-efficacy.
Patient Education and Health-Related Quality of Life

As introduced in Chapter II, the GPDSSC (2002) reviewed extant research regarding the role of self-efficacy and patient education for disease self-management specifically for patients with PD. They found limited existing research and initiated a study in six countries to determine which factors PD patients identified as being important to their HRQOL. The study enrolled 1,020 PD patients and 203 interdisciplinary clinicians who provided care to PD patients. A notable finding of the GPDSSC (2002) study was that development and implementation of conceptual models for health care delivery and clinical guidelines for care of PD patients has been hindered by lack of knowledge regarding the roles of self-efficacy and PD patient education for disease self-management.

Based on the findings of the GPDSSC, Findley (2002), chairperson of the GPDSSC, noted a lack of congruence between what PD patients and doctors value in terms of PD patients’ perceived HR-QOL. Further, Findley (2002) advocated for a restructuring of the patient-physician encounter that is aligned with the patient-professional collaborative health care delivery paradigm.

Measuring Parkinson’s Health-Related Quality of Life

Peto, Jenkinson, and Fitzpatrick (1998) conducted focus group sessions with PD patients to determine patient-identified factors that were considered to be indicators of PD-HRQOL. This gave rise to the development of the 65-item prototype of the PDQ-39 Quality of Life Scale which either can be self-administered or interviewer-administered.
Subsequently, they surveyed 359 PD patients from eight branches of the PD Society in
the United Kingdom and subjected responses to a factor analysis. Ultimately, the
redundant items in the original 65-item questionnaire were eliminated and the scale was
reduced to a total of 39 items that queried eight factors that PD patients identified as
denoting PD-HRQOL. The eight factors, each measured by a subscale that comprises the
PDQ-39, are: mobility, activities of daily living, emotional well-being, stigma, social
support, cognition, communication, and bodily discomfort (Peto et al., 1998).

The PDQ-39 QOL measures both motor and nonmotor symptoms of PD. Repeat
testing has shown that the PDQ-39 is sensitive to change (p < 0.01) and able to detect
minimally important differences on serial measures, as well as having good reliability,
validity, and reproducibility (Jenkinson et al., 1995; Peto et al., 1998, 2001). However,
missing data points on the PDQ-39 can make it difficult to assess global QOL for
respondents on serial measures because a summary QOL measure cannot be imputed
using the Expectation Maximization (EM) mathematical methodology, unless the sample
size is at least ≥ N = 200 (Jenkinson, Heffernan, Doll, & Fitzpatrick, 2006).

It was disappointing to be unable to use some of the data from some of the
participants in the current small study because some participants did not respond at
certain time points to particular items on the PDQ-39 (Jenkinson, Fitzpatrick, & Peto,
1998). Personal communication with one of the tool’s authors (Jenkinson, March 23,
2007), however, confirmed that missing data points could only be interpolated on the
Social Support Scale (which might differ depending on marital status), and not on any of
the other subscales. Because missing data points on other scales in the serial measures of
the PDQ-39 could not be imputed, it was not possible to compute PDQ-39SI global

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QOL across all three time points for some of the participants in this study. This meant a reduction in the power to find any statistically significant differences.

Although self-administration methods were used in this study, other research studies have used self-administration methods for gathering data with the PDQ-39 and have not reported similar difficulties. For example, using the self-administered PDQ-39, EQ-5D, and SF-36, Schrag, Jahanshahi, and Quinn (2000) assessed 124 probable PD patients from 15 general practices in the United Kingdom to identify the indicators of QOL in this population. These test measures were mailed to 124 PD patients; 78% completed and returned the questionnaires. Research findings revealed that depression was the strongest indicator of QOL of in PD patients. Schrag et al.'s (2000) findings mirrored the results reported by the GPDSSC (2002). The GPDSSC reported that 1,020 PD patients who participated in the study reported that 60% of the variability in their HRQOL was attributable to depressive symptomatology.

Mental and motor status, both of which are addressed by the scales, can also influence how individuals respond to questionnaires. Despite attaining a high MMSE score, a few patients in the current study reported having impaired executive functioning that required treatment with Aricept and Namenda. Impaired executive functioning precipitated the early retirement of one of the young-onset PD patients who functioned in an executive role. Although motor symptoms are recognized as the hallmark of PD, nonmotor symptoms are finally being recognized as having a significant impact on QOL in PD patients. Both motor and nonmotor symptoms have implications for the design of future educational studies and data gathering methods.
Relating the Findings of This Study to Prior Research on PD-HRQOL

As Jarman, Hurwitz, Cook, Bajekal, and Lee (2002) noted, a community-based, patient-professional collaborative care model was successfully implemented in the United Kingdom by specialist nurses who cared for PD patients \(N = 1,859\). Although PD patients reported a preserved sense of well-being, they did not report any significant change in health outcomes (Jarman et al., 2002). These findings suggested that the construct of HR-QOL may be difficult to affect with patient education for patients with PD. They are consistent with findings of the current study.

Shimbo et al. (2004) conducted a cross-sectional study in Japan to assess whether providing patient education to PD patients \(N = 762\) was related to improved PD-HRQOL as measured by the SF-36 survey, components of the UPDRS, and five questions about PD patient education related to disease process and treatments. The Japanese government had recently adopted a national health policy that provided reimbursement for patient education, especially for lifestyle-related chronic diseases and intractable diseases such as PD (Shimbo et al., 2004). The patient education satisfaction score was rated on a Likert scale of 1 to 5 (1 = not satisfied at all, to 5 = very satisfied). The mean PD patient education score was 2.96 \((SD = 0.88)\) which indicated that the patients were neither dissatisfied nor particularly satisfied with the PD education that they had received. Shimbo et al. (2004) further noted a positive association between PD patients’ level of satisfaction with PD patient education and their HRQOL scores. PD patients who reported greater satisfaction with PD patient education had higher HRQOL scores on each of the subscales of the SF-36, except for physical functioning and bodily
pain (Shimbo et al., 2004). These findings suggest that individuals may respond differently to receiving the same educational experiences based on other intrinsic differences.

Although individual differences were not a controlled variable in the current study, there were some indications that personal preference may have played a role. Support for this interpretation was indicated by the one patient who left the study after learning he had been randomized to the condition in which participants would talk with others about their condition. He withdrew from the study after attending the first session. Several members of the traditional group, on the other hand, indicated that they would have benefited from more opportunities to interact with others. Personal preference should be studied directly in future research.

Some QOL indicators are unique to the population of patients with PD. Nutt and Wooten (2005) noted that about 75% of PD patients initially experience bradykinesia which interferes with their ability to perform fine motor tasks. In the current study, the most common motor symptoms of PD reported by the majority of participants were tremor and bradykinesia. A few patients did report having difficulty with dressing-related activities such as buttoning clothing items. Maijama-Lyons and Shomon (2003) noted that bradykinesia can be exhibited as difficulty with fine motor tasks and initiating movement; change in gait; freeze attacks; masked facies; and speech and communication disturbances reported as dysphagia, hypophonia, and micrographia. Change in gait patterns, mobility, motor fluctuations noted primarily as dyskinesias, also were reported by most participants in the present study.
The majority of participants in this sample reported having speech and communication problems due to their PD. In the current study, only a few patients reported having swallowing problems. Miller, Noble, Jones, and Burn (2006) noted that 80-90% of PD patients experience hypophonia or other voice changes and 45-50% have articulation changes. Communication issues are easier to address than speech production issues, and future educational programs might be designed to focus on these differences.

The majority of participants in the current study also reported experiencing another cardinal symptom of PD—rigidity. As a result of the rigidity, several participants had complained that their sense of balance had been affected and, thus, they had experienced problems with falling. Two participants reported having sustained fractures due to their rigidity and balance problems. One male had sustained a hip fracture and had undergone total hip joint replacement surgery to treat the fracture. One female had sustained a humeral fracture and experienced delayed healing of the fracture due to the effect of PD-related tremorous activity on bone healing. These are challenging conditions to address, and anticipating such issues may influence how participants perceive their HRQOL.

**Summary of Findings of This Study Related to Prior Research on PD-HRQOL**

In summary, statistical analyses of PDCC and PDIT groups’ mean PDQ-39SI (summary index) QOL scores showed that the null hypotheses could not be rejected for any of the time periods measured. In interpreting these results and looking for any trends, it is important to bear in mind that higher scores on this instrument signal lower perceptions of PD-related QOL. PDCC participants’ mean PDQ-39SI summary QOL
scores across the three time periods were: (a) 24.0 (baseline; \( n = 14 \)); (b) 30.4 (postintervention; \( n = 12 \)), and (c) 28.0 (4-week follow-up; \( n = 17 \)). PDIT participants' mean PDQ-39SI QOL scores across the three time periods were: (a) 27.4 (baseline; \( n = 17 \)); (b) 31.3 (postintervention; \( n = 14 \)), and (c) 28.3 (4-week follow-up; \( n = 17 \)).

According to these findings, the trend for both groups was for perceived QOL to get somewhat worse immediately following the educational sessions (although not significantly worse). One possibility is that information about problems expected with PD might have been perceived with new clarity, and, as a result, patients felt less optimistic about their HR-QOL issues. Four weeks later, these perceptions again moved in the more positive direction (as reflected in the lower mean scores), although again, not significantly so.

As discussed in this section, there may be several reasons for the lack of significance in this study that could be investigated in future research. Measuring perceived QOL after educational sessions also brings with it a number of special challenges. One concern in the current study was the loss of data from several participants who did not complete certain items. It would be helpful in future studies to institute a process to ensure that all items are completed at the time of the data gathering activity.

Conclusions and Clinical Implications

The results of this study did not support a conclusion that one educational method was preferable to the other in terms of effects either on perceived self-efficacy or
HRQOL. The results of the course evaluations, however, did suggest that participants of both groups evaluated the sessions as being generally helpful to them.

This study offered some indications that clinicians should consider individual preference when designing patient education activities. As noted, 1 participant did withdraw from the experimental group (PDCC) because he preferred not to share his personal information during the small group, peer mentoring component of the collaborative care group. On the other hand, 3 participants in the traditional group commented on their session evaluations that they would have preferred a more interactive group process. This suggests that individual preference is an important variable, which may have been obscured by the current experimental design with random assignment to groups and choice of dependent measures.

Given the chronic, progressively degenerative nature of PD, it was not surprising that participants' self-efficacy and QOL scores did not change over the 7-week duration of the intervention to reach a statistical level of significance. However, Peto et al. (2001) noted that minimally important changes detected on the PDQ-39 QOL questionnaire, based on patients' responses, may represent clinically significant changes in QOL to the patient even though they might not reach a statistical level of significance. The results of this study should not be taken as indicating that patient education programs are of no value.

Session evaluations submitted by each participant indicated that they valued both the content presented in each of the sessions as well as the effectiveness of each of the presenters. A few participants indicated that each 2-hour session should have been
assigned to only one presenter so more content could have been provided to participants and more time allocated for questioning.

**Study Limitations**

This study had some significant limitations. First, the small sample size \( N = 41 \) of this pilot study was impacted further by attrition of 6 participants, thereby reducing the power to detect any significant results. Second, it focused on a fixed population, i.e., only middle-stage PD patients, recruited from a single PD specialty clinic who volunteered to participate in the study. Third, the intervention was of short duration, lasting only 3 weeks, compared to the model recommended by Lorig et al. (1996), which ran 7 weeks. The total time since pretest to the follow-up measure in the current study was only 7 weeks, limiting the ability to detect any longer term effects. Fourth, the study could have benefited from a third no-treatment comparison group, which would allow observation of any effects due to the natural progression of the disease. Fifth, a major issue that significantly impacted the ability to assess and compare QOL across all time points for both groups was the scoring methodology of the PDQ-39SI and the problem of dealing with missing data. Finally, limited funding resources were available to conduct the study on a larger scale over a longer period of time.

**Recommendations for Future Research**

The research agenda for PD should focus on both bench and translational research studies. Longitudinal studies, involving all stages of PD patients, which focus on patient and caregiver education, need to be conducted to assess factors that promote
patients’ QOL and self-efficacy for disease self-management. A no-treatment comparison group should also be included. As dictated by research ethics, a no-treatment comparison group should not receive less than standard of care treatment during interventional studies. If the experimental intervention is shown to be more efficacious than standard of care treatment, then the no-treatment comparison group should be offered the opportunity to receive the experimental intervention upon completion of the study.

Further research needs to address the role and needs of caregivers of PD patients, including factors that prognosticate caregiver burnout and likelihood of long-term care placement of PD patients. Future studies should involve multiple centers including community-based private neurology, internal medicine, family practice clinics, and PD specialty clinics to compare quality and effectiveness of care based on patients’ and systems outcomes.

As noted in Chapter IV, post-hoc analysis conducted with the Wilcoxon matched-pairs signed-rank test (see Appendix L) did reveal that four of the PDQ-39 subscales (i.e., communication, emotional well-being, mobility, and stigma) reached statistical levels of significance with respect to change in difference scores in predicted directions at varying time points and based on group assignment. Although no statistical test was used to correct for multiple comparisons, results noted on these subscales may warrant further research. For example, interventions could be implemented to address PD patient issues encompassed by each of these subscales, such as rehabilitation needs involving physical and occupational therapies or speech therapy.

The role of telemedicine in increasing PD patients’ and caregivers’ access to health care services, such as rehabilitation professionals, that can help patients maintain
and restore their functional abilities, promote independence and mobility, and limit
disability, needs to be pursued and funded. Application of telemedicine to monitor
changes in PD patients’ health status and adherence or nonadherence to prescribed
treatment regimens such as use of PD medications, also should provide ample fodder for
future research since extant research on these topics is limited. Telemedicine technology
also can be used to deliver patient and caregiver education that can be tailored to meet
the specific health care information needs of PD patients and their caregivers. Patient and
caregiver education may encompass information relevant to management of comorbid
chronic diseases as well as PD information. Telemedicine technology can be used to
provide specialized training and continuing education to health care professionals living
in rural areas who provide care to PD patients. Although the initial financial investment
in telemedicine technology may be expensive, over time it may be shown to be a more
cost-effective strategy for delivering health care services and monitoring health status in
some patient populations such as rural PD patients with limited access to transportation
services.

Health services research and policy analyses studies need to be conducted to
develop public policies designed to better meet the current and future health and social
issues with which PD patients and families have to contend. This will become an even
greater need given the expected increase in PD prevalence and other chronic diseases
over the next few decades coupled with the demographic aging trend in the U.S. These
factors will likely exert a costly and burdensome impact on the nation’s health system
and its other social infrastructures. Some study participants expressed concern over the
impact that their PD symptoms had on their ability to continue working. Some stated
that they had been compelled to seek early retirement, and two had had their jobs terminated due to their PD symptoms. Given the protections provided by the American Disabilities Act (http://www.usdoj.gov/crt/ada/adahom1.htm), 2 participants reported that they had retained legal counsel in an attempt to regain their jobs, but to no avail. Thus, it may be worthwhile to reexamine the American Disabilities Act to ascertain if the rights of people with disabilities are being adequately protected or if it needs to be amended given changing U.S. demographics.

Lastly, policies need to be developed and implemented that support research studies to investigate genetic and environmental factors that trigger the development of PD and fund essential bench research that may result in development of targeted therapies to treat, prevent, or cure PD. Specifically, federal legislation that supports the advancement of stem cell research needs to be enacted and adequately funded. Such legislation also needs to encompass all types of stem cell research, including the use of human embryonic stem cells, for development of targeted therapies to be used in treatment and prevention of human diseases. Prior federal legislation that impedes scientific progress such as stem cell research would need to be either amended or rescinded. The Dickey Amendment that was passed in 1996 by the U.S. House of Representatives is an example of such legislation. The Dickey Amendment prohibited the Department of Health and Human Services and the National Institutes of Health from appropriating federal funds for use in research that involves the creation, endangerment, or destruction of human embryos. It was attached as a rider, Section 128 of Public Law 104-199, to the Consolidated Appropriations Act for the Departments of Health and Human Services, Education, and Labor in 1996 (Congressional Research Service, 2002,

In the meantime, public policies must continue to be developed and implemented that fund intervention research targeted to address better methods for living well both with, and in spite of, Parkinson’s disease. Despite its limitations, participants assessed the informational content and disease-management strategies offered by both educational models in this interventional research study as having positive value for them. Further, the report of the GPDSSC (2002) substantiates the need for more research into factors which contribute to PD-HRQOL and promote development of health care delivery models and clinical guidelines to improve the care management of PD patients.
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Appendix A

Conceptual Health Care Delivery Models
MODEL 1

Conceptual Model of Patient Self-Efficacy and Parkinson’s Disease Self-Management Education and Their Impact on Parkinson’s Disease Quality of Life – (L. Pearl-Kraus)

Development of Action Plans Based on Patient-Identified Problems and Mutually Established Short-term Goals and Objectives

PD Patient’s Implementation or Nonimplementation of Action Plans

Impact on Parkinson’s Disease Quality of Life
MODEL 2

Conceptual Model for Collaborative Care and Patient Education for Self-Management of Parkinson's Disease (L. Pearl-Kraus)

Patient – Professional Partnership (Collaborative Care)

Parkinson's Disease Patient

Personal Expertise of Lived Experience and Life Situation

Patient's Self-Efficacy for PD Self-Mgt.

Informed Choices

Patient's Established Goals & Action Plans for Self-Mgt. of PD

Implementation of Action Plan(s) for Attainment of Goal(s)

Nonimplementation of Action Plan(s) for Attainment of Goals

Impact on PD Quality of Life

Parkinson Disease Interdisciplinary Health Care Professional Team Members

- Physicians
- NPs/CNSs/PAs
- Nurses
- Pharmacists
- Nutritionists
  - Rehabilitation Professionals
  - Neuropsychologist
  - Psychiatrist
  - Physical Therapist
  - Occupational Therapist
  - Speech/Language Pathologist
  - Social Worker

Patient Teaching Problem Solving Skills Sharing Information Education

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MODEL 3

Conceptual Model for Traditional Care and Patient Education in Parkinson’s Disease – (L. Pearl-Kraus)

Parkinson’s Disease Interdisciplinary Health Care Team Members (Prof)
- Physicians
- NPs/CNSs/PA
- Nurses
- Pharmacists
- Nutritionists
- Rehab. Professionals
- P.T.
- O.T.
- Neuropsych
- Physiatrist
- S.W.
- SLP

Development Implementation of Prescribed Interdisciplinary Treatment Plan(s) for Parkinson’s Disease Patient

Patient Education
- Disease Education
- Information on Technical Skills (e.g.: handout on exercise)

Patient Non-Adherence to Prescribed Treatment Plan

Patient Adherence to Prescribed Treatment Plan

Impact on Parkinson’s Disease Quality of Life

Patient Common Chronic Diseases and Health-Related Problems

Identify Parkinson’s Disease Patient’s Health Care Problems and Patient Educational Needs

Patient’s Need for Design Modification of Living Environment

Patient’s Need for Behavioral Modification

Issues Related to Patient’s Nonadherence Identified by Interdisc. Health Team

Interventions to Resolve Pt’s Reason(s) for Nonadherence Implemented by Health Care Personnel

Abbreviations
NP – Nurse Practitioner  CNS – Clinical Nurse Specialist  P.A. – Physician Assistant
P.T. – Physical Therapist  O.T. – Occupational Therapist; Neuropsychologist & Physiatrist;
SW – Social Worker  SLP – Speech-Language Pathologist
Appendix B

Human Subjects Institutional Review Board
Letters of Approval
Date: February 8, 2007

To: Nickola Nelson, Principal Investigator  
    Lorraine Pearl-Kraus, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number: 06-07-03

This letter will serve as confirmation that the changes to your research project “Parkinson’s Disease Education, Disease Self-Management, and Self-Reported Quality of Life Outcomes” requested in your memo dated 2/8/2007 (2 questions added to follow-up) have been approved by the Human Subjects Institutional Review Board.

The conditions and the duration of this approval are specified in the Policies of Western Michigan University.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 19, 2007
Date: August 14, 2006

To: Nickola Nelson, Principal Investigator
   Lorraine Pearl-Kraus, Student Investigator for dissertation

From: Mary Lagerwey, Ph.D., Chair

Re: HSIRB Project Number: 06-07-03

This letter will serve as confirmation that your research project entitled “Parkinson’s Disease Education, Disease Self-Management, and Self-Reported Quality of Life Outcomes” has been approved under the full category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 19, 2007
Date: July 19, 2006

To: Nickola Nelson, Principal Investigator
Lorraine Pearl-Kraus, Student Investigator for dissertation

From: Mary Lagerwey, Ph.D., Chair

Re: HSIRB Project Number: 06-07-03

This letter will confirm that your research project entitled “Parkinson’s Disease Education, Disease Self-Management, and Self-Reported Quality of Life Outcomes” was reviewed under the full category of review on July 19, 2007 by the Human Subjects Institutional Review Board.

Before final approval can be given please address each of the following concerns. We expect that you will find the revisions requests to be productive and that you will revise your protocol according to our suggestions or in similar ways. If you think a particular revision is not in the best interest of the human subjects in your study, or you think an entirely different approach to the issue is best, please provide a written explanation and/or call us for consultation.

The board has no major concerns.

The following required revisions are listed in the order they appear in the protocol:

1. Informed Consent Process section of the protocol outline: Please clarify the role of the witness and why having a witness is necessary.

2. Research Procedure section of the protocol outline:
   • Please assure that all investigators are appropriately trained regarding their roles for this project.
   • Please provide an explanation for why you will consult the participants’ medical charts.
   • How are peer mentors compensated for their involvement in the study?

3. Benefits of Research section of the protocol outline: If the intervention is helpful, will it be offered to the control group?

4. Confidentiality of Data section of the protocol outline:
   • Please omit any references to anonymity, as participation will not be anonymous. Instead, assure that participant’s identities will be kept confidential.
   • You are asking some questions that provide contact information, not data. Please provide a rationale for requesting this information. Also, in order to protect participants’ confidentiality, please do not inquire about the name of the person’s physician or of their insurance provider.

Walwood Hall, Kalamazoo, MI 49008-5456

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6. Consent Document:
- Please use second person language (e.g., 'you') consistently throughout the document.
- Please ask for permission to access the participants' medical records.
- Please provide references for alternative sources of education for participants who do not want to participate in this study.
- Please do not refer to the study as a clinical trial.
- In the section entitled “What about Confidentiality?” please delete any references to anonymity. Instead, please assure confidentiality.

Individual board members brought up the following suggestions. HSIRB approval is not contingent upon your response to these suggestions.

1. Research Procedure section of the protocol:
- There may be a potential bias if the researcher is both providing and evaluating the training.
- Consider requesting that the data be added to the patient files.
- The 20-30 minutes socialization time may confound the control group intervention.

2. Consent Document:
- You may want to shorten the consent form.

3. HIPAA Consent Document:
- In order to reduce potential confusion, you may want to consistently refer to Nickola Nelson using the same name.

In a cover letter to the HSIRB, indicate whether you have made the requested change; addressed the issue in a different way than the one the reviewers suggested; are directing the reviewers to the pages in your protocol that address the issue; or are providing a justification for not making the requested change.

Please submit your cover letter and one copy of the revised protocol with the changes highlighted within the document to the HSIRB, 251W Walwood Hall (East Campus). Once granted, your approval will expire on July 19, 2007 so submitting revisions in a timely manner will mean you have more time for data collecting. Remember to include the HSIRB project number (above).

Conducting this research without final approval from the HSIRB is a violation of university policy as well as state and federal regulations.

If there is anything you don’t understand about these comments, you are welcome to call the research compliance coordinator (387-8293) for consultation.
To: Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C
0-11002 12th Avenue NW
Grand Rapids, MI 49534-6743

Re: Amendment/Revision for: “Parkinson’s Disease Education, Disease Self-Management and Self-Reported Quality of Life Outcomes”
IRB File #06-0828-05

Date: February 13, 2007

This is to inform you that Saint Mary’s Health Care Institutional Review Board has received and reviewed your revised letter to study participants of the above captioned study containing two additional follow up questions.

It has been determined that this change is minor and does not increase the risk to the participants in the study. Furthermore, the additional questions do not demand revisions in the approved consent document, study protocol or investigational brochure. Therefore, by means of an expedited process, this letter is approved for use in your study, effective February 19, 2007.

Thank you for keeping the IRB informed of these changes. The renewal date for this study will remain August 28, 2007 with a progress report due July 1, 2007.

Sheryl Veurink-Balicki, RN, MSN, CEN
IRB Chairperson

Copy: File
8/28/2006

Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C
0-11002 12th Avenue NW
Grand Rapids, MI 49534-6743

RE: New Study Protocol: "Parkinson’s Disease Education, Disease Self-Management and Self-Reported Quality of Life Outcomes"

Dear Dr. Pearl-Kraus:

On August 28, 2006 Saint Mary’s Health Care IRB met and reviewed the aforementioned study, the associated consent document, the HIPAA disclosure document, questionnaires and communication documents. During our conversation you indicated a change you wish to make in the consent document. The IRB noted the need to change Saint Mary’s Health Care’s name on page 4 of 6. The statement on page 5 of 6 regarding the approval of the consent document by Western Michigan University IRB remains acceptable as stated for Saint Mary’s IRB purposes.

With the changes noted above in the consent document, Saint Mary’s IRB approves this study and associated documents effective August 28, 2006 until August 28, 2007. We will need to receive the updated consent document before full implementation of the study can begin.

IRB monitoring procedures demand that you complete a progress report no later than July 1, 2007. Should the study be completed before that time, a progress report covering the appropriate time frame and written notification that the study is closed is due at that time.

Any additional changes in the study protocol and or associated documents must receive our IRB approval before they are implemented.

Any safety incidences occurring as a result of the study must be submitted in writing to Saint Mary’s IRB within ten days of your knowledge of them.

Sincerely,

Sister Myra Bergman
IRB Chair

cc: Nickola W. Nelson, PhD, CCC-SLP
    Leslie Neuman, MD
August 22, 2006

Laurie Pearl-Kraus, RN, PhD-c, CS, FNP-C
0-11002 12th Avenue
Grand Rapids, MI 49534-6743

Dear Ms. Pearl-Kraus:

This is to inform you that the Saint Mary's Health Care Research Committee has completed its review of your protocol entitled, "Parkinson's Disease Education, Disease Self-Management & Self-Reported Quality of Life Outcomes."

Your protocol has received full approval and will be forwarded on to the Saint Mary's Health Care Institutional Review Board. You will be advised of time and place for the protocol presentation to this committee. For questions regarding IRB presentation, please phone Cindy Johnston at (616) 752-6198.

Should you have any questions or concerns, please feel free to contact me at 752-6413.

Sincerely,

David Baumgartner, M.D.
Chairman, Saint Mary's Health Care Research Committee

c: Nickola W. Nelson, PhD, CCC-SLP
Leslie Neuman, MD
Sr. Myra Bergman/Cindy Johnston
File
Appendix C

Study Recruitment Materials (Letter to Prospective Participants and Study Brochure)
Dear ____________________________,

I am writing to inform you of a research study that we will be offering to interested Parkinson’s patients who receive care at the Hauenstein Parkinson’s Center. The study will be conducted at the facilities of the Hauenstein Parkinson’s Center by researchers from the College of Health and Human Services at Western Michigan University. They will be investigating the effectiveness of two health care-patient education methods for teaching disease management and how they impact the quality of life for Parkinson’s patients. Patients who accept the invitation to participate will be asked to commit to attend three two-hour, patient education sessions that will be taught by various health care professionals who are members of our interdisciplinary health care team at the Hauenstein Parkinson’s Center. Patients also will be asked to complete two brief questionnaires at three points during the study that are designed to assess their Parkinson’s disease quality of life and sense of how well they can manage their Parkinson’s disease and related symptoms.

Here’s what you will learn about:
♦ Information to help you manage your Parkinson’s disease
♦ Medicines used to treat Parkinson’s disease, their importance, and how to manage them
♦ Exercises to help increase your mobility, strength, balance, and flexibility
♦ Ways to prevent injuries by make your home safer and more user friendly
♦ Ways to improve speech and communication skills that may have been impacted by Parkinson’s
♦ Available community resources and services and how to access them
♦ How to manage other chronic diseases that you may

If you are interested in finding out more about this study and possibly participating in it, a researcher, Lori Pearl-Kraus, RN, PhD-c, CS, FNP-C, from Western Michigan University will contact you to explain the study further and to answer any questions. A study brochure is enclosed which describes the study and eligibility requirements for participating in it. If you are willing to permit us to share your name, address, and phone number with these researchers solely for the purpose of allowing them to contact you to explain the study to you, please fill out and return the enclosed, postage-paid response form directly to Lori Pearl-Kraus. Shortly after receipt of your returned response form, Lori will contact you to set up a time to meet with you and explain the study to you. If you have any questions regarding this request, please feel free to contact either myself or Julie Sager, RN, BSN, nurse manager, at the Hauenstein Parkinson’s Center at 616-752-5400.

Sincerely,

Dr. Leslie Neuman,
Medical Director – Hauenstein Parkinson’s Center

Enclosures
PD Patient Response Form

If you are interested in learning more about this study and possibly participating in it, please mail this prepaid form by ______________(date) to Lori Pearl-Kraus, RN, PhD-c, CS, FNP-C, who will contact you about next steps.

If you are willing to have Lori Pearl-Kraus contact you to explain this study further to you, please provide your name, address, phone number, and preferred times below:

Name:
Phone number(s):
Address:

Please circle the best day and time to call you:

Monday  Tuesday  Wednesday  Thursday  Friday  Saturday  Sunday  
Morning  Afternoon  Evening

What is your year of birth? ______________

(year)

Do you have access to reliable transportation? Yes _____  No _____
The Parkinson's Patient Education and Disease Management Study is an important research project intended to study two educational methods for teaching patients with Parkinson's disease (PD) to manage their treatments and symptoms. It will also study the impact of these two educational methods on the quality of life for patients with PD.

Who is sponsoring the Parkinson's Patient Education and Disease Management Study?

This research project is sponsored by Western Michigan University in Kalamazoo, Michigan and the Hauenstein Parkinson's Center at St. Mary's Medical Center in Grand Rapids, Michigan. The study is coordinated by a group of researchers from Western Michigan University. We will be recruiting a total of 48 men and women to participate in the Parkinson's Patient Education and Disease Management Study.

Why study Parkinson's Patient Education and Disease Management?

Studying new approaches to teaching Parkinson patients about their disease and how to manage it may help them to improve their mobility and balance, speech and communication skills, improve their use of medications, promote safer living environments, maintain their independence, and improve their quality of life. This may also help to reduce injuries in PD patients. All of these things can help to reduce the cost of health care while improving the quality of care and the lives of PD patients.

Who can participate in the Parkinson's Patient Education and Disease Management Study?

You may be able to participate in this study if:
- You are a man or woman between the ages of 30 and 80 years old.
- Your Parkinson's symptoms affect both sides of your body (in the middle stages of Parkinson's disease).
- You have not been diagnosed with dementia.
- You are able to hear good enough to participate in large and small group interactions.
- You are able to speak, read, write, and understand English.
- You have an educational level of 9th grade or higher.
- You have a telephone (land line or cellular) in your home.
- You have access to reliable transportation to and from the Hauenstein Parkinson's Center.
• You will be available on the planned dates for the educational sessions (one 2-hour session held one day per week for 3 consecutive weeks this Fall).

What will happen if I participate in the Parkinson’s Patient Education and Disease Management Study?

If you decide to participate in our study, you will read and sign consent forms that explain the Parkinson’s Patient Education and Disease Management Study and protection of your health information in more detail.

You will then be assigned by chance to participate in one of the two patient educational and disease management groups offered in this study. You will also be asked to complete a patient general information form. Two brief screening tests will be given to you to assess your stage of Parkinson’s disease and mental status.

If you choose to participate in this study, you will be asked to commit to attending three two-hour, patient education sessions that will be taught by various health care professionals that will teach you about ways to deal with your PD symptoms. You will be asked to complete two brief questionnaires at three points during the study (at the beginning of the study, upon completion of the 3-week intervention, and one month after completing the study). You will also be asked to complete a patient general information form and a brief evaluation form at the end of each session.

The study will be completed in seven weeks. It is important for you to plan to stick with the study until it ends. However, if you change your mind, you may leave the study at any time for any reason.

Why might I want to participate in the Parkinson’s Patient Education and Disease Management Study?

As a participant in the Parkinson’s Patient Education and Disease Management Study, you will be a partner in medical research and may benefit from having the chance to gain knowledge and skills related to management of your Parkinson’s disease. You may also benefit from having the opportunity to discuss your health concerns with professionals and other patients. The results of this study may also benefit other PD patients and their families by helping us to understand how educational programs help patients learn to manage their disease. Please discuss this brochure with your doctor, family, and friends.

How can I join the Parkinson’s Patient Education and Disease Management Study?

If you are interested in participating, or want to find out more about the study, please contact Dr. Leslie Neuman, medical director, or Julie Sager, RN, BSN, nurse manager, at the Hauenstein Parkinson’s Center at 616-752-5400.
Appendix D

Study and HIPAA Consents
Hauenstein Parkinson’s Center at St. Mary’s Medical Center  
Grand Rapids, Michigan

Western Michigan University  
College of Health and Human Services  
Interdisciplinary Health Studies Program

CONSENT FOR RESEARCH

PARKINSON’S PATIENT EDUCATION, DISEASE MANAGEMENT, AND QUALITY OF LIFE OUTCOMES STUDY

Study Number: WMU HSIRB Project Number: 06-07-03  
SMHC HSIRB Project Number: 06-0828-05

Sponsors: St. Mary’s Medical Center and Hauenstein Parkinson’s Center and Western Michigan University, College of Health and Human Services.

Principal Investigator: Nickola Nelson, PhD, CCC-SLP  
Co-Principal/Student Investigator: Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C

We are inviting you to participate in a research study entitled, “Parkinson’s Patient Education, Disease Management, Quality of Life Outcomes Study.” This study includes only patients who chose to take part in it.

WHY IS THIS STUDY BEING DONE?

This research is intended to study two educational methods for teaching patients with Parkinson’s disease (PD) to manage their treatments and symptoms. It will also study the impact of educational methods on the quality of life for patients with PD. This study is being conducted as partial fulfillment of the requirements for the degree of Doctor of Philosophy for Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C.

WHO IS CONDUCTING THIS STUDY?

If you decide to take part in this study, you will be taking part in a clinical trial conducted by the Hauenstein Parkinson’s Center at St. Mary’s Medical Center in Grand Rapids, Michigan and Western Michigan University’s College of Health and Human Services in Kalamazoo, Michigan.
HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study will enroll 48 patients who are 30 years of age and not more than 80 years old and who have Parkinson's symptoms that affect both sides of their body (middle stage PD).

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate, we will ask you to attend one two-hour, patient education session per week for three consecutive weeks. The sessions will include information about:

- Medications
- Exercise
- Communication Skills
- Social Support

Before you start participating in the study, you will be asked to fill out two brief questionnaires. One will assess how your Parkinson's disease is affecting your quality of life; the other will assess how you feel about your ability to manage your disease. You will be asked to complete these questionnaires at three points during the study: (a) at baseline (entry into study), (b) after completion of the two-hour sessions offered over three consecutive weeks, and (c) one month after completion of the educational sessions. You will also be asked to fill out an evaluation form after each session.

HOW LONG WILL I BE IN THIS STUDY?

As a participant, you will be enrolled in this study for a total period of 7 weeks (consisting of 3 weeks of two-hour educational sessions with a followup mailing of two study questionnaires to be filled out by you at one month after completion of the educational sessions).

WHAT ARE THE RISKS OF THE STUDY?

Although we believe that the educational session may provide some benefits to you, there may be unforeseen risks as well, as in all research. We foresee the following possible risks with this study: (1) inconveniences, such as, time spent doing the interviews, reviewing the materials, completing questionnaires; (2) fatigue; (3) emotional distress due to confronting health concerns; (4) participating in a group process; (5) concerns regarding confidentiality of personal data; and (6) difficulty in arranging transportation to and from the educational sessions.

Attempts to minimize inconveniences to the participants will include scheduling interviews and other meetings at times and safe locations that are convenient for the participant. To minimize participants' potential fatigue and emotional distress, scheduled periods (breaks)
for relaxation and social support which may be derived from having the opportunity to interact with others, have been incorporated into each of the three educational sessions. To minimize potential risks that participants may incur due to participating in a group process, ground rules that protect and respect the rights of each individual will be established for participating in the group process and agreed upon by consensus of each group.

WHAT ABOUT CONFIDENTIALITY?

Anonymity is a risk that exists with any research project, especially during interviews and group interactions. Attempts will be made to minimize risks associated with loss of confidentiality and anonymity by using a pseudonym in lieu of participant’s legal name on respondent’s questionnaires. Given the very nature of the study’s intervention, however, it is not possible to assure absolute anonymity to study participants. The only persons that will have access to participant’s study-related materials will be Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C, doctoral advisor (Principal Investigator) Dr. Nickola Nelson at Western Michigan University, Dr. Leslie Neuman, medical director of the Hauenstein Parkinson Center, and biostatistician consultant. Others who will interact with the participants during the training sessions, and thus be aware of who is participating in the study, will include several health care professionals. However, none of these helpers will be able to associate your survey responses with you as an individual. All of the information collected from you will be held in strictest confidence and you will not be identified in any reports of the research results. That means that your name or any other personal identifiers will not appear on any papers on which this information is recorded. The forms will all be coded, and the investigators will keep a separate master list with the names of participants and the corresponding codes in locked cabinets. Once the data have been collected and analyzed, the master list will be destroyed. All other forms will be retained for at least three years in a locked file in the principal investigator’s office at Western Michigan University.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

One way in which you may benefit from this activity is by having the chance to gain knowledge and skills related to management of your Parkinson’s disease and a chance to discuss your health concerns with professionals and other patients. The results of this research may benefit other patients with Parkinson’s disease and their families in their understanding of how educational programs help patients learn to manage their disease.

WHAT ARE THE COSTS?

There will be no charge for any of these sessions, and we will not be able to pay you to participate in the study. Neither you nor your insurer will bear the costs of this intervention. You will be responsible for providing your own transportation to and from the educational sessions that will held at the Hauenstein Parkinson’s Center. Free parking is available in the St. Mary’s Medical Center visitor parking lots.
If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or additional treatment will be made available to you except as otherwise stated in this consent form. In the unlikely event of any injury from this research, you will not receive reimbursement, compensation, or free medical treatment. Your hospital and/or medical care will continue under the care of your personal physicians and incurred expenses will be billed to your insurer in the usual manner.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. You may decide not to accept our invitation to participate in this activity without any penalty or loss of access to services you would otherwise receive. You may also decide to quit at any time during the study without prejudice or penalty or reduction in your usual care. You will have access to the results of this research study when they become available. You may contact the researchers to request that a copy of the study results be mailed to you.

**WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions or concern about this study, you may contact either doctoral research student, Lorraine Pearl-Kraus, RN, MSN, CS, FNP-C, at 616-391-6292 or faculty advisor, Nickola W. Nelson, Ph.D., CCC-SLP, at 269-387-7990. You may also contact the Chair, Human Subjects Institutional Review Board (269-387-8293) or the Vice President for Research at Western Michigan University (269-387-8298) if questions or problems arise during the course of the study. If you have any questions about your rights as a research study participant, you may also contact the Human Subjects Institutional Review Board representative, Sister Myra Bergman, at St. Mary’s Medical Center at 616-752-6090.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board at Western Michigan University and St. Mary’s Medical Center in Grand Rapids, as indicated by the stamped date and signature of the board chair in the upper right corner. Do not participate in this study if the stamped date is more than one year old.
SIGNATURE

Your signature below indicates that you have and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature (Participant) ____________________________ Date __________

Consent obtain by ____________________________ Date __________

Researcher’s Initials ____________________________ Date __________

Signature of Witness (optional) ____________________________ Date __________
Authorization to Use or Disclose (Release)
Personal Health Information for Research

PARKINSON'S PATIENT EDUCATION, DISEASE MANAGEMENT,
AND QUALITY OF LIFE OUTCOMES STUDY

Study Number:

1. What is the purpose of this form?

According to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, patients must provide written authorization for the release of their Personal Health Information (PHI). Western Michigan University and the Hauenstein Parkinson’s Center at St. Mary’s Medical Center are organizations that do research to learn about ways to treat and to improve the care of patients with Parkinson’s disease. Researchers would like to use your personal health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

Researchers want to extract and use the portions of your medical record that they will need for the research study in which you may agree to participate. If you agree to participate in a Western Michigan University research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments that you may have received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, CT scans, MRIs, X-rays, and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status and the status of your disease
- tissue and/or blood samples, associated data related to the analysis of the samples
- numbers or codes that will identify you, including but not limited to your social security number, medical record number, birthdate, telephone number, address, and/or email address

3. Why do the researchers want my personal health information?

Western Michigan University will collect your personal health information and share it with the Hauenstein Parkinson’s Center at St. Mary’s Medical Center if you choose to
participate in this research study, or to evaluate your eligibility for this study. Western Michigan University researchers will use your information for the follow Parkinson's disease research study WMU HSIRB Project Number: 06-07-03; SMHC HSIRB Project Number: 06-0828-05.

4. Who will be able to use my personal health information?

Western Michigan University and the Hauenstein Parkinson's Center at St. Mary's Medical Center will use your personal health information for research purposes only. As part of this research, they may provide your information to the following groups. As required by law, the following groups also have the right to review your original records.

- Western Michigan University researchers and their staff
- The Human Subjects Institutional Review Board at Western Michigan University
- The Human Subjects Institutional Review Board at St. Mary's Medical Center
- The Food and Drug Administration (FDA)
- Public health agencies and other government agencies as authorized or required by law
- Other people or organizations assisting with Western Michigan University's research efforts
- Central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your personal health information to those groups listed above.

5. How will information about me be kept private?

Western Michigan University and the Hauenstein Parkinson's Center at St. Mary's Medical Center will keep all personal health information confidential to the fullest extent possible. Western Michigan University and the Hauenstein Parkinson's Center will not release personal health information about you to others, except as authorized by this form, or required by law. If your personal health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. What if I do not authorize you to collect and release my personal health information?

If you decide not to authorize release of your personal health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot, however, be in this research study if you do not agree to release your personal health information, or information relating to medical benefits for this research study.
7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. What happens if I want to withdraw my authorization?

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new personal health information will be used for research. However, researchers may continue to use the personal health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. He/She will make sure your written request to withdraw your authorization is processed correctly.

Principal Investigator: Nickola W. Nelson, Ph.D., CCC-SLP
Charles Van Riper Professor of Speech Pathology and Audiology (2005-2008)
Director, Ph.D. in Interdisciplinary Health Studies
College of Health and Human Services
Western Michigan University
1903 W. Michigan
Kalamazoo, MI 49008-5355
office: 269-387-7990
fax: 269-387-8912 e-mail: nickola.nelson@wmich.edu

9. How long will this authorization last?

If you agree by signing this form that researchers can use your personal health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time, but you must do so in writing.

10. What are my rights regarding my personal health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your personal health information as pertains to this study that are kept by Western Michigan University and the Hauenstein Parkinson’s Center. You do not have the right to review and/or copy records kept by Western Michigan University or other researchers associated with this research study.
SIGNATURES

I agree that my personal health information may be used and disclosed for research purposes described in this form. I will receive a signed copy of this form.

Signature of Patient: ___________________________ Date: ______________

Printed Name of Patient: __________________________

Signature of Person Obtaining Authorization: ______________________________

Printed Name of Person Obtaining Authorization: ___________________________
Appendix E

Measurement Scales
Measurement Scales

Modified Hoehn & Yahr Scale
(for Staging Severity of Parkinson’s disease)

1. Stage 0 = No signs of disease.
2. Stage 1 = Unilateral disease.
3. Stage 1.5 = Unilateral disease plus axial involvement.
5. Stage 2.5 = Mild bilateral disease, with recovery on pull test.
6. Stage 3 = Mild to moderate bilateral disease; some postural instability; physically independent.
7. Stage 4 = Severe disability; still able to walk or stand unassisted.
8. Stage 5 = Wheelchair bound or bedridden unless aided.

Retrieved from: MD Virtual University’s website for Parkinson’s Disease Rating Scales. The Modified Hoehn & Yahr Scale is incorporated within the Unified Parkinson’s Disease Rating Scale which is available on the WorldWideWeb at: http://www.mdvu.org/pdf/updrs.pdf
Mini-Mental State Examination (MMSE)

Screening Tool: The Mini-Mental State Examination (MMSE)

Patient ___________________________ Examinee ________________________

Date ____________

Maximum Score = 30 Points

Orientation

5 • What is the (year) (season) (date) (day) (month)?
5 • Where are we (state) (country) (town) (hospital) (floor)?

Registration

3 • Name 3 objects (Ball, Flag, Tree): 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat until he/she learns all 3. Count trials and record.

Trials __________________

Attention and Calculation

5 • Serial 7’s. 1 point for each correct answer. Stop after 5 answers.

(Alternatively spell “world” backward.

Recall

3 • Ask for the 3 objects repeated above. (Give 1 point for each correct answer.)

Language

2 • Name a pencil and watch.
1 • Repeat the following “No ifs, ands or buts.”
3 • Follow a 3-stage command:
   “Take a paper in your hand, fold it in half and put it on the floor.”
1 • Read and obey the following CLOSE YOUR EYES.
1 • Write a sentence.
1 • Copy the design shown.

Total Score

ASSESS level of consciousness along a continuum _________________________

Alert  Drowsy  Stupor  Coma


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How to obtain permission to use the Mini-Mental State Examination:
The Mini-Mental State Examination is copyright protected. Materials can be purchased through www.minimental.com. (Note: Permission to use the MMSE needs to be obtained and materials purchased from the American Psychological Association which now holds the copyright for this test.)

The Mini Mental State Examination (MMSE)

By: Lenore Kurlowicz, PhD, RN, CS, and Meredith Wallace, PhD, RN, MSN

WHY: Cognitive impairment is no longer considered a normal and inevitable change of aging. Although older adults are at higher risk than the rest of the population, changes in cognitive function often call for prompt and aggressive action. In older patients, cognitive functioning is especially likely to decline during illness or injury. The nurses’ assessment of an older adult’s cognitive status is instrumental in identifying early changes in physiological status, ability to learn, and evaluating responses to treatment.

BEST TOOL: The MMSE is a tool that can be used to systematically and thoroughly assess mental status. It is an 11-question measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall and language. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment. The MMSE takes only 5-10 minutes to administer and is therefore practical to use repeatedly and routinely.

TARGET POPULATION: The MMSE is effective as a screening tool for cognitive impairment with older, community dwelling, hospitalized and institutionalized adults. Assessment of an older adult’s cognitive function is best achieved when it is done routinely, systematically and thoroughly.

VALIDITY/RELIABILITY: Since its creation in 1975, the MMSE has been validated and extensively used in both clinical practice and research.

STRENGTHS AND LIMITATIONS: The MMSE is effective as a screening instrument to separate patients with cognitive impairment from those without it. In addition, when used repeatedly the instrument is able to measure changes in cognitive status that may benefit from intervention. However, the tool is not able to diagnose the case for changes in cognitive function and should not replace a complete clinical assessment of mental status. In addition, the instrument relies heavily on verbal response and reading and writing. Therefore, patients that are hearing and visually impaired, intubated, have low English literacy, or those with other communication disorders may perform poorly even when cognitively intact.

MORE ON THE TOPIC:

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Parkinson’s Disease Questionnaire (PDQ-39) and Quality of Life

DUE TO HAVING PARKINSON’S DISEASE, how often have you experienced the following, DURING THE LAST MONTH?

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or cannot do</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Had difficulty doing the leisure activities which you like to do?</td>
<td></td>
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<tr>
<td>2. Had difficulty looking after your home, housework, cooking?</td>
<td></td>
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<tr>
<td>3. Had difficulty carrying bags of shopping?</td>
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<td>4. Had problems walking a half mile?</td>
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<tr>
<td>5. Had problems walking 100 yards?</td>
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<tr>
<td>6. Had problems getting around the house as easily as you would like?</td>
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<td>7. Had difficulty getting around in public?</td>
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<tr>
<td>8. Needed someone else to accompany you when you went out?</td>
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<tr>
<td>9. Felt frightened or worried about falling over in public?</td>
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<tr>
<td>10. Been confined to the house more than you would like?</td>
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<tr>
<td>11. Had difficulty washing yourself?</td>
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<tr>
<td>12. Had difficulty dressing yourself?</td>
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<tr>
<td>13. Had problems doing up buttons or shoe laces?</td>
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<tr>
<td>14. Had problems writing clearly?</td>
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<td>15. Had difficulty cutting your food?</td>
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<td>16. Had difficulty holding a drink without spilling it?</td>
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<td>17. Felt depressed?</td>
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<td>18. Felt isolated and lonely?</td>
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<tr>
<td>19. Felt weepy or tearful?</td>
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<td>20. Felt angry or bitter?</td>
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<tr>
<td>21. Felt anxious?</td>
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<tr>
<td>Due to having Parkinson's disease, how often during the last month have you...</td>
<td>Never</td>
<td>Occasionally</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always or cannot do</td>
</tr>
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<tr>
<td>22. Felt worried about your future?</td>
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<tr>
<td>23. Felt you had to conceal your Parkinson’s from people?</td>
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<tr>
<td>24. Avoided situations which involve eating or drinking in public?</td>
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<tr>
<td>25. Felt embarrassed in public due to having Parkinson’s disease?</td>
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<tr>
<td>26. Felt worried by other people’s reaction to you?</td>
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<td>27. Had problems with your personal relationships?</td>
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<tr>
<td>28. Not had support in the ways you need from your spouse or partner?</td>
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<tr>
<td>29. Not had support in the ways you need from your family or close friends?</td>
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<tr>
<td>30. Unexpectedly fallen asleep during the day?</td>
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<tr>
<td>31. Had problems with your concentration, for example, when reading or watching TV?</td>
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<tr>
<td>32. Felt your memory was bad?</td>
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<tr>
<td>33. Had distressing dreams or hallucinations?</td>
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<tr>
<td>34. Had difficulty with your speech?</td>
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<tr>
<td>35. Felt unable to communicate with people properly?</td>
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<tr>
<td>36. Felt ignored by people?</td>
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<tr>
<td>37. Had painful muscle cramps or spasms?</td>
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<tr>
<td>38. Had aches and pains in your joints or body?</td>
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<tr>
<td>39. Felt unpleasantly hot or cold?</td>
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</tr>
</tbody>
</table>
The instructions for scoring the PDQ-39 are as follows:

Sum of scores for each question in dimension divided by 4 x number of questions in dimension and then x 100 to get a percent.

Total Score (PDQ-39SI): Sum of scores for questions 1-39 divided by 4 x 39 and then x 100.

**Subscales of Test**

**Mobility:** Sum of scores for questions 1-10 divided by 4 x 10 and then x 100.

**Activities of Daily Living (ADL):** Sum of scores for questions 11-16 divided by 4 x 6 and then x 100.

**Emotional Well-being:** Sum of scores for questions 17-22 divided by 4 x 6 and then x 100.

**Stigma:** Sum of scores for questions 23-26 divided by 4 x 4 and then x 100.

**Social Support:** Sum of scores for questions 27-29 divided by 4 x 3 and then x 100. If respondents indicate they do not have a spouse or partner (question 28), then social support can be calculated as follows:

\[
\text{Social support} = \frac{(\text{scores of questions 27 + 29})}{(4 \times 2)} \times 100
\]

**Cognition:** Sum of scores for questions 30-33 divided by 4 x 4 and then x 100.

**Communication:** Sum of scores for questions 34-36 divided by 4 x 3 and then x 100.

**Bodily Discomfort:** Sum of scores for questions 37-39 divided by 4 x 3 and then x 100.

For the scoring:

- Never = 0
- Occasionally = 1
- Sometimes = 2
- Often = 3
- Always or cannot do = 4

**Reference**


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Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

### Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

### Characteristics

Tested on 605 subjects with chronic disease

<table>
<thead>
<tr>
<th>No. of items</th>
<th>Observed Range</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Internal Consistency Reliability</th>
<th>Test-Retest Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>1-10</td>
<td>5.17</td>
<td>2.22</td>
<td>.91</td>
<td>NA</td>
</tr>
</tbody>
</table>
Source of Psychometric Data


Comments

This 6-item scale contains items taken from several SE scales developed for the Chronic Disease Self-Management study. We use this scale now, as it is much less burdensome for subjects. It covers several domains that are common across many chronic diseases, symptom control, role function, emotional functioning and communicating with physicians. For internet studies, we add radio buttons below each number. There are 2 ways to format these items. We use the format on this document, the other is shown on the web page. A 4-item version of this scale available in Spanish.

References


This Scale Is Free To Use Without Permission

Stanford Patient Education Research Center
1000 Welch Road, Suite 204
Palo Alto CA 94304
(650) 723-7935
(650) 725-9422 Fax
self-management@stanford.edu
http://patienteducation.stanford.edu
Funded by the National Institute of Nursing Research (NINR)
Appendix F

Patient Demographic Form
Participant Information Sheet

1. Name: _________________________________________ 2. Study ID#: _____
   (First) (Middle) (Last)

3. Home Address: __________________________________________
   (Street)
   (Apt. #)
   (City) (State) (9 digit zip code)

   Alternate/Winter address: __________________________________________
   (Street)
   (Apt. #)
   (City) (State) (9 digit zip code)

4. Home Phone Number: ___- ____- ____
   Alternate/Winter Phone #: ____- ____- ____
   Cell phone # ______- ______- ______

5. E-mail address (if available) ________________________________

6. Date of Birth: ____________________________
   (Month/Day/Year)

7. Year diagnosed with Parkinson’s Disease: ______________________
   (Month/Day/Year)

8. Hoehn & Yahr PD Stage: (circle one) 0 1 1.5 2 2.5 3 4 5

9. What is your marital status? (circle one)
   (a) Single, never married   (b) Married   (c) Divorced   (d) Widowed
   (e) Separated   (f) Live with partner, but not married

10. Race (circle only one)
    (a) White or Caucasian   (b) Black or African American
    (c) Native Hawaiian or Pacific Islander   (d) Asian
    (e) American Indian or Native Alaskan   (f) Unknown

11. Ethnicity (Spanish/Hispanic Origin): (circle all that apply)
    (a) Not Spanish
    (b) Spanish/Hispanic Origin:
        Mexican Central America
        Puerto Rican South America
        Cuban Other ______________________
    (c) NOS (Not otherwise specified)   (d) Unknown
12. Do you have any insurance coverage? (check one)  Yes ____  No ____
   If yes, who is the insurer? (check all that apply)
   (a) Government _____  (b) Private insurer _____
       Medicare _____
       Medicaid _____
       Both Medicare & Medicaid _____
       Military or Veteran’s Administration _____

13. Do you ever make choices based on your ability to pay for: (mark an X on appropriate response)
   (a) medications?  Yes ____  No ____
   (b) seeing health care providers?  Yes ____  No ____
   (c) taking part in health care programs that charge a fee?  Yes ____  No ____

14. If employed, please provide employer and occupational information?
   Position: ____________________________
              (Job title)
   Employer: ___________________________
              (Name of company)
   Address: _______________________________________
              (Street)
              (City) (State) (9 digit zip code)
   Phone Number: _____- _____- _______

15. Years of education completed? (circle the highest year of school that you have completed)

   1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23+  
   (primary) (high school) (college/university) (graduate school)

16. Do you ever use hearing aids?  (check the appropriate response)
    Yes ____  No ____

17. Has anyone ever suggested that you might need hearing aids? (check the appropriate response)
    Yes ____  No ____

18. Would it help you to have an assistive listening device when you come to the learning activities? (check the appropriate response)
    Yes ____  No ____
19. **When listening in a large group activity, which statement best describes you?** (check only one appropriate response)
   - I almost never have trouble hearing and understanding what the speaker says if the speaker uses a microphone.
   - I sometimes have trouble hearing and understanding what the speaker says if the speaker uses a microphone.
   - I almost always have trouble hearing and understanding what the speaker says even if the speaker uses a microphone.

20. **When talking in a small group?** (check only one appropriate response)
   - I almost never have trouble hearing and understanding, even if other people are talking somewhere else in the room.
   - I sometimes have trouble hearing and understanding, particularly if other people are talking somewhere else in the room.
   - I almost always have trouble hearing and understanding even when the room is really quiet.

21. **Please provide the names, addresses, and phone numbers of two people (other than spouse or partner) who can be reached in case of an emergency.**
    
    **A.**
    - **Name:** _____________________________ **Relationship:** ____________
    - **Address:** ____________________________
      (Street) (City) (State) (9 digit zip code)
    - **Home Phone Number:** ____-____-_____
    - **Mobile/Cell Phone Number:** ____-____-_____

    **B.**
    - **Name:** _____________________________ **Relationship:** ____________
    - **Address:** ____________________________
      (Street) (City) (State) (9 digit zip code)
    - **Home Phone Number:** ____-____-_____
    - **Mobile/Cell Phone Number:** ____-____-_____

22. **Personal physician information (in case of emergency):**
    - **Name:** _____________________________
    - **Address:** ____________________________
      (Street) (City) (State) (9 digit zip code)
    - **Office Phone Number:** ____-____-_____

23. **Who is the neurologist that monitors your Parkinson’s disease?**
    - **Name:** _____________________________
    - **Address:** ____________________________
      (Street) (City) (State) (9 digit zip code)
    - **Office Phone Number:** ____-____-_____

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24. What have you done to learn more about Parkinson's disease? (check all that apply)
   ___ Internet resources
   ___ Attended PD support group
   ___ Attended PD education offerings
   ___ PD education materials provided by physician's office

25. What is your preferred method of learning? (check all that apply)
   ___ Auditory (being told how to do something)
   ___ Visual (being shown how to do something)
   ___ Both audio and visual learning
   ___ By demonstration

26. Please check YES or NO to show us what types of chronic conditions you have. (please mark an X for the appropriate response)
   Diabetes
   Heart Failure
   History of Heart Attack
   High Blood Pressure
   History of Stroke
   Abnormal heart rhythm
   Disease affecting blood vessels
   & circulation (indicate type: ______________) YES ___ NO ___
   Kidney disease
   Asthma
   Emphysema or COPD (Chronic Obstructive Pulmonary Disease) YES ___ NO ___
   Other lung disease
   (Indicate type: ______________) YES ___ NO ___
   Arthritis or other joint disease
   Cancer (either in remission or cured)
   Vision problems
   (Indicate type: ______________) YES ___ NO ___
   Problems with sense of smell
   YES ___ NO ___
   Other chronic condition
   (Indicate type: ______________) YES ___ NO ___
27. Please check YES or NO to show us what types of medications that you take every day. (please mark an X for the appropriate response)

<table>
<thead>
<tr>
<th>Medication Description</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription pain medicine</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Over-the-counter pain medicine</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to strengthen the heart</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to treat heart rhythm</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Water pill (diuretic)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to treat high blood pressure (other than a diuretic or in combination with a diuretic, for example, zestoretic)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to treat low blood count (anemia)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Eye drops to treat glaucoma</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Eye drops to treat dry eye</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Inhaler for breathing problems</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Pills for breathing problems</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Pill to control blood sugar</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Insulin to control blood sugar</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to control depression</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to feel calm (control anxiety)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Sleeping pill</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Medicine to control seizures</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

28. In general, do you think that your health is: (check one)

- Excellent
- Very Good
- Good
- Fair
- Poor

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Appendix G

Script to Contact Participants for Consent Form
RESEARCHER: We would like to invite you to participate in some interesting research on “Parkinson’s Patient Education, Disease Management, and Quality of Life Outcomes.” This research project intends to study two educational methods for teaching patients with Parkinson’s disease (PD) how to manage their treatments and symptoms. It will also study the impact of educational methods on the quality of life for patients with PD. This is a voluntary research project in which you may choose to either participate in or not. You have the right to refuse to participate in this study at any time.

If you agree to participate in this research, you will be involved in a study that may help health care providers determine effective ways of teaching Parkinson’s patients to better manage their disease and improve their quality of life. If you agree to participate, we will ask you to attend one two-hour, patient education session per week for three consecutive weeks. The sessions will include important information for Parkinson’s patients about medications, exercises, communication skills, and social support. Before you start participating in the study, you will be asked to fill out two brief questionnaires to assess how Parkinson’s disease is affecting your quality of life and how you feel about your ability to manage your disease. You will be asked to complete these questionnaires at three points during the study: (a) at baseline (entry into study), (b) after completion of the two-hour sessions offered over three consecutive weeks, and (c) one month after completion of the educational sessions. You will also be asked to fill out an evaluation form after each educational session.

Thank you for your interest in the “Parkinson’s Patient Education, Disease Management, and Quality of Life Outcomes Study.” If you wish, I will be glad to schedule an informational meeting with you to discuss this study and participation requirements in further detail. During this meeting, I would plan to review the consent forms for this study. If you were interested in enrolling in the study, I would also review with you the eligibility requirements for participating in it and screen you for your eligibility to enroll. If you are determined to be eligible for enrolling in this research, then next steps for participating in the study will also be discussed at this time.

Time:

Place:

If you have any questions or concerns about this study prior to this meeting, please contact me (Lori Pearl-Kraus) at 616.453.3923 or 616.391.6292.
Appendix H

Letter and Response Form to Potential Peer Mentors
Letter to Potential Patient Peer Leader

Dear ________________,

I am writing to inform you of a research study that we will be offering to Parkinson’s patients who receive care at the Hauenstein Parkinson’s Center. The study will be conducted at the facilities of the Hauenstein Parkinson’s Center by researchers from the College of Health and Human Services at Western Michigan University. They will be investigating the effectiveness of two patient education and disease management methods and how they impact the quality of life for Parkinson’s patients. Patients will be asked to attend three two-hour, patient education sessions that will be taught by various health care professionals who are members of the interdisciplinary health care team at the Hauenstein Parkinson’s Center. Patients will also be asked to complete two brief questionnaires at three points in time that will assess their Parkinson’s disease quality of life and disease self-management ability.

An important aspect of this research study, will be the mentoring of study participants by their fellow patient peers who have been diagnosed with Parkinson’s disease and have been living with it for some time. Patient peers who have had to deal with the diagnosis of Parkinson’s and its impact on their physical health, social interactions, and overall well-being, can be very helpful in teaching other Parkinson’s patients about their disease and ways to effectively manage it, which may enhance the quality of life for these patients. I would like to invite you to consider sharing your expertise and lived experience as a Parkinson’s patient, by participating in this research study as a Patient Peer Leader. Prior to the start of the research study, you would receive training as a Patient Peer Leader. You would also need to be able to attend all three of the two-hour educational sessions for the study’s participants. If you have been diagnosed as having Parkinson’s disease for at least six (6) months or longer and would like to find out more about this research study and the opportunity to become a Patient Peer Leader, one of the researchers from Western Michigan University will be glad to contact you.

If you are willing to permit us to share your name, address, and phone number with the researchers solely for the purpose of allowing them to contact you to explain the study and the Patient Peer Leader role to you, please fill out and return the enclosed, postage-paid postcard to the Hauenstein Parkinson Center. Shortly after receipt of your returned postcard, the researchers will contact you to set up a time to meet with you and explain the study to you. If you have any questions regarding this study, please feel free to contact either myself or Julie Sager, RN, BSN, nurse manager, at the Hauenstein Parkinson’s Center at 616-752-5400.

Sincerely,

Dr. Leslie Neuman,
Medical Director – Hauenstein Parkinson’s Center

Ljp:52606

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Potential PD Patient Peer Leader Return Postcard

If you are interested in learning more about this study and possibly participating in it as a patient-peer leader, please return this post-card by ______________ (date) to the Nurse Manager of the Hauenstein Parkinson’s Center (HPC), and Lori Pearl-Kraus, RN, MSN, CS, FNP-D, will contact you about next steps.

Will you give your permission to the HPC to give your contact information (name, address, and phone number) to the research investigators so they can contact you? If so, provide the preferred times, address, and phone number below:

Name:
Phone number(s):
Address:

Please circle the best day and time to call you:

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning</td>
<td>Afternoon</td>
<td>Evening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What is your year of birth? ______________ (year)

In what year were you diagnosed as having Parkinson’s disease? ______

Do you have access to reliable transportation? Yes _____ No _____

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Appendix I

Letter Accompanying Mailing of Follow-up Surveys to Study Participants
Dear (name of study participant):

Thank you for your participation in the patient educational sessions for the, "Parkinson's Disease Self-Management and Self-Reported Quality of Life," research study that was recently conducted at the Hauenstein Parkinson's Center. We hope that this educational intervention has helped you to gain additional insight into the management of your Parkinson's disease.

In order for us to know if this educational intervention was helpful to you and may be helpful in improving the quality of life for other Parkinson's patients, we would appreciate it if you would complete the enclosed questionnaires, the PDQ-39 Parkinson's Disease Quality of Life Questionnaire and the Self-Efficacy Measure, within this next week. To determine how effective this program has been for PD patients and its potential benefit to others, it is important for you to give your honest responses to these questions, as well as other suggestions that you may have for improving the program. After you have completed them, please use the enclosed self-addressed, postage-paid envelope and return them to the researchers listed below.

Once again, thank you for participating in this study and your time and effort spent in completing these study forms. If you have any questions about the study or these forms, please feel free to contact the principal investigator of the study, Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C, at 616-391-6292 or 616-453-3923.

Sincerely,

Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C
Doctoral Student and Principal Investigator

Nickola W. Nelson, Ph.D., CCC-SLP
Co-Principal Investigator and
Director, Ph.D. in Interdisciplinary Health Studies
College of Health and Human Services
Western Michigan University

Ljpk:52606
Letter to Study Participant (revised)

Dear (name of study participant):

Thank you for your participation in the patient educational sessions for the “Parkinson’s Disease Self-Management and Self-Reported Quality of Life” research study that was recently conducted at the Hauenstein Parkinson’s Center. We hope that this educational intervention has helped you to gain additional insight into the management of your Parkinson’s disease.

In order for us to know if this educational intervention was helpful to you and may be helpful in improving the quality of life for other Parkinson’s patients, we would appreciate it if you would complete the enclosed questionnaires, the PDQ-39 Parkinson’s Disease Quality of Life Questionnaire and the Self-Efficacy Measure, within this next week. To determine how effective this program has been for PD patients and its potential benefit to others, it is important for you to give your honest responses to these questions, as well as other suggestions that you may have for improving the program. We would appreciate it if you would also please answer the additional questions below. After you have completed all items, please use the enclosed self-addressed, postage-paid envelope and return them to the researchers listed below. Please mail these questionnaires back to us by ______________, 2007.

Once again, thank you for participating in this study and your time and effort spent in completing these study forms. If you have any questions about the study or these forms, please feel free to contact the principal investigator of the study, Lorraine J. Pearl-Kraus, PhD-c, RN, CS, FNP-C, at 616-391-6292 or 616-453-3923.

Sincerely,

Lorraine J. Pearl-Kraus, PhD-c, RN, CS, FNP-C
Doctoral Student and Principal Investigator

Nickola W. Nelson, Ph.D., CCC-SLP
Co-Principal Investigator and Director, Ph.D.
in Interdisciplinary Health Studies
College of Health and Human Services
Western Michigan University

PLEASE ANSWER THESE ADDITIONAL QUESTIONS*:

1. Has there been any change(s) in your Parkinson’s medications since you enrolled in this study? Yes____ No_____ (if yes, please write down the changes.)

__________________________________________________________________________

2. If you have had any medication changes, do you think that these changes have affected your quality of life? Yes____ No_____ (If yes, please describe those changes.)

__________________________________________________________________________

*As before, all aspects of this research project are voluntary and you may decide to decline to answer any question without penalty.

ljpk:020107
Appendix J

Participant Evaluation Forms for Intervention Sessions
TITLE: Evaluation Form for Parkinson's Disease Patient Education Session #1

DATE: _______________________________ at Hauenstein Parkinson's Center

To assist us in evaluating the effectiveness of this educational session and to make recommendations for its future offerings, please complete this evaluation form by circling the appropriate rating.

SESSION EVALUATION

KEY: 1 = NOT AT ALL  2 = LOW  3 = MEDIUM  4 = HIGH

1. I found this information on Parkinson's disease was helpful to me.  1  2  3  4

2. I thought this information about medications used to treat Parkinson's disease was helpful to me.  1  2  3  4

3. Were the meeting facilities satisfactory?  1  2  3  4

4. How would you rate (insert nurse's name) teaching effectiveness?  1  2  3  4

5. How would you rate (insert pharmacist's name) teaching effectiveness?  1  2  3  4

6. How do you think that the educational content of this session could be improved?
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

7. What topics/subject areas would you like presented at future educational sessions?
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
TITLE: Evaluation Form for Parkinson’s disease Patient Education Session #2

DATE: _______________________________ at Hauenstein Parkinson’s Center

To assist us in evaluating the effectiveness of this educational session and to make recommendations for its future offerings, please complete this evaluation form by circling the appropriate rating.

SESSION EVALUATION

KEY: 1 = NOT AT ALL  2 = LOW  3 = MEDIUM  4 = HIGH

1. I found the information on exercise and improving mobility in Parkinson’s disease was helpful to me. 1 2 3 4

2. I thought the information about making home environment changes to make it safer and more functional was helpful to me. 1 2 3 4

3. Were the meeting facilities satisfactory? 1 2 3 4

4. How would you rate (insert physical therapist’s name) teaching effectiveness? 1 2 3 4

5. How would you rate (insert occupational therapist’s name) teaching effectiveness? 1 2 3 4

8. How do you think that the educational content of this session could be improved?

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

9. What topics/subject areas would you like presented at future educational sessions?

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________
TITLE: Evaluation Form for Parkinson’s Disease Patient Education Session #3

DATE: ____________________________ at Hauenstein Parkinson’s Center

To assist us in evaluating the effectiveness of this educational session and to make recommendations for its future offerings, please complete this evaluation form by circling the appropriate rating.

SESSION EVALUATION

KEY:  1 = NOT AT ALL  2 = LOW  3 = MEDIUM  4 = HIGH

1. I found the information on accessing community agencies and services was helpful to me.  1  2  3  4

2. I thought the information about ways to improve my speaking voice was helpful to me.  1  2  3  4

3. I thought the information about ways to improve my other communication skills was helpful to me.  1  2  3  4

4. I thought the information about ways to conserve my energy was helpful to me.  1  2  3  4

5. Were the meeting facilities satisfactory?  1  2  3  4

6. How would you rate (insert social worker’s name) teaching effectiveness?  1  2  3  4

7. How would you rate (insert speech therapist’s name) teaching effectiveness?  1  2  3  4

8. How do you think that the educational content of this session could be improved?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

9. What topics/subject areas would you like presented at future educational sessions?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Appendix K

Reminder Letter to Study Participants to Complete and Return Follow-up Surveys
Reminder Letter to Study Participant

Dear (name of study participant):

Thank you for your participation in the patient educational sessions for the, "Parkinson's Disease Management and Self-Reported Quality of Life," research study that was recently conducted at the Hauenstein Parkinson's Center. We hope that this educational intervention has helped you to gain additional insight into the management of your Parkinson's disease.

In order for us to know if this educational intervention was helpful to you and may be helpful in improving the quality of life for other Parkinson's patients, we would appreciate it if you would complete the questionnaires that were recently mailed to you, the PDQ-39 Parkinson's Disease Quality of Life Questionnaire and the Self-Efficacy Measure, within this next week. To determine how effective this program has been for PD patients and its potential benefit to others, it is important for you to give your honest responses to these questions, as well as other suggestions that you may have for improving the program. In case you misplaced the questionnaires, we are enclosing new copies of these questionnaires for your convenience. After you have completed them, please use the enclosed self-addressed, postage-paid envelope and return them to the researchers listed below. If you have already completed and just recently mailed these forms, please accept our appreciation for taking the time to do so and discard these extra copies.

Once again, thank you for participating in this study and your time and effort spent in completing these study forms. If you have any questions about the study or these forms, please feel free to contact the principal investigator of the study, Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C, at 616-391-6292 or 616-453-3923.

Sincerely,

Lorraine J. Pearl-Kraus, RN, PhD-c, CS, FNP-C
Doctoral Student and Principal Investigator

Nickola W. Nelson, Ph.D., CCC-SLP
Co-Principal Investigator and
Director, Ph.D. in Interdisciplinary Health Studies
College of Health and Human Services
Western Michigan University

Ljpk: 52606
Appendix L

Subscales Depicting Stability of Change Scores on the PDQ-39 QOL Questionnaire from Baseline (Time 1) to Postintervention (Time 2) to 4-Week Follow-up (Time 3) for All Participants and by Group Assignment
Table L.1

**PD-HRQOL: Stability of Change Scores on the PDQ-39 QOL Questionnaire from Baseline (Time 1) to Postintervention (Time 2) to 4-Week Follow-up (Time 3) for All Participants**

<table>
<thead>
<tr>
<th>Scale/Subscale</th>
<th>Pretest to Posttest</th>
<th>Posttest to Follow-up</th>
<th>Pretest to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Average</td>
<td>p</td>
</tr>
<tr>
<td><strong>PDQ-39</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum Score</td>
<td>21</td>
<td>27.7</td>
<td>.34</td>
</tr>
<tr>
<td>Mobility</td>
<td>28</td>
<td>35.2</td>
<td>.88</td>
</tr>
<tr>
<td>Activities of Daily Living</td>
<td>30</td>
<td>28.5</td>
<td>.67</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>31</td>
<td>26.7</td>
<td>.19</td>
</tr>
<tr>
<td>Stigma</td>
<td>31</td>
<td>17.7</td>
<td>.91</td>
</tr>
<tr>
<td>Social Support</td>
<td>30</td>
<td>14.7</td>
<td>.13</td>
</tr>
<tr>
<td>Cognition</td>
<td>30</td>
<td>31.5</td>
<td>.21</td>
</tr>
<tr>
<td>Communication</td>
<td>30</td>
<td>26.4</td>
<td>.03</td>
</tr>
<tr>
<td>Bodily Discomfort</td>
<td>31</td>
<td>41.1</td>
<td>.10</td>
</tr>
</tbody>
</table>

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Table L2

**PD-HRQOL: Stability of Change Scores on the PDQ-39 QOL Questionnaire from Baseline (Time 1) to Postintervention (Time 2) to 4-Week Follow-up (Time 3) for PDIT (Information Training) Group Participants**

<table>
<thead>
<tr>
<th>Scale/Subscale</th>
<th>Pretest to Posttest</th>
<th>Posttest to Follow-up</th>
<th>Pretest to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Average</td>
<td>p</td>
</tr>
<tr>
<td></td>
<td>Pre-</td>
<td>Post</td>
<td></td>
</tr>
<tr>
<td>PDQ-39</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum Score</td>
<td>12</td>
<td>29.9</td>
<td>.48</td>
</tr>
<tr>
<td>Mobility</td>
<td>15</td>
<td>39.8</td>
<td>.51</td>
</tr>
<tr>
<td>Activities of Daily Living</td>
<td>15</td>
<td>30.6</td>
<td>.83</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>14</td>
<td>25.3</td>
<td>.06</td>
</tr>
<tr>
<td>Stigma</td>
<td>14</td>
<td>15.2</td>
<td>.28</td>
</tr>
<tr>
<td>Social Support</td>
<td>14</td>
<td>11.3</td>
<td>.18</td>
</tr>
<tr>
<td>Cognition</td>
<td>14</td>
<td>27.2</td>
<td>.79</td>
</tr>
<tr>
<td>Communication</td>
<td>14</td>
<td>20.8</td>
<td>.08</td>
</tr>
<tr>
<td>Bodily Discomfort</td>
<td>14</td>
<td>42.9</td>
<td>.16</td>
</tr>
</tbody>
</table>
Table L3

**PD-HRQOL: Stability of Change Scores on the PDQ-39 QOL Questionnaire from Baseline (Time 1) to Postintervention (Time 2) to 4-Week Follow-up (Time 3) for PDCC (Collaborative Care) Group Participants**

<table>
<thead>
<tr>
<th>Scale/Subscale</th>
<th>Pretest to Posttest</th>
<th>Posttest to Follow-up</th>
<th>Pretest to Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Average</td>
<td>p</td>
</tr>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td></td>
</tr>
<tr>
<td><strong>PDQ-39</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sum Score</td>
<td>9</td>
<td>24.6</td>
<td>.37</td>
</tr>
<tr>
<td>Mobility</td>
<td>13</td>
<td>29.8</td>
<td>.36</td>
</tr>
<tr>
<td>Activities of Daily Living</td>
<td>15</td>
<td>26.4</td>
<td>.38</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>17</td>
<td>27.9</td>
<td>.90</td>
</tr>
<tr>
<td>Stigma</td>
<td>17</td>
<td>19.9</td>
<td>.40</td>
</tr>
<tr>
<td>Social Support</td>
<td>16</td>
<td>17.7</td>
<td>.44</td>
</tr>
<tr>
<td>Cognition</td>
<td>16</td>
<td>31.2</td>
<td>.11</td>
</tr>
<tr>
<td>Communication</td>
<td>16</td>
<td>31.2</td>
<td>.17</td>
</tr>
<tr>
<td>Bodily Discomfort</td>
<td>17</td>
<td>39.7</td>
<td>.34</td>
</tr>
</tbody>
</table>
Appendix M

Research Planning Tool
# Research Planning Tool: Variables Related to Research Questions

## Dependent and Independent Variables

<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Dependent Variable</th>
<th>Independent Variable(s)</th>
<th>Confounding Variables</th>
<th>Statistical Test(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 1:</strong></td>
<td>Is there a difference in pre-post test scores (Time 1 – Time 2) on the Self-Efficacy for Managing Chronic Disease 6-Item Scale between Parkinson's disease patients who participate in the PDCC or PDTT intervention?</td>
<td>Self-reported Perceived Self-Efficacy (in Disease Self-Management Skills)</td>
<td>Patient Education Method (2 levels: Experimental &amp; Control)</td>
<td>Descriptive statistics: Frequencies, percentages, means, and standard deviations were used to describe characteristics of sample population and to conduct tests of skewness and kurtosis. Inferential statistics: Independent t-test, Chi-square, Fisher's Exact, and Mann-Whitney U test measures were used to analyze between group differences at pre-test time (Time 1 - baseline) to verify equivalent groups were achieved by randomization process. Repeated measures ANOVA were used to analyze between group differences on the dependent measure, <em>Self-Efficacy</em>, from baseline to post-intervention (Time 1 – Time 2) and from post-intervention to 4-week follow-up post-intervention (Time 2 – Time 3).</td>
</tr>
</tbody>
</table>

*Demographic variables (age, gender, race, ethnicity, marital status, education, financial)*

*Duration of Illness*

*Stage/Severity of Illness*

*# of prescribed medications*

*Change in medication regimen*

*Comorbidities*

*Health beliefs/Values*

*Health perceptions*

*Social Support*
<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Dependent Variable</th>
<th>Independent Variable(s)</th>
<th>Confounding Variables</th>
<th>Statistical Test(s)</th>
</tr>
</thead>
</table>
| **Question 2:**    | Self-reported Perceived PD-Health-related QOL | Patient Education Method (2 levels: Experimental & Control) | • Health beliefs/Values  
• Health perceptions  
• # of prescribed medications  
• Change in medication regimen  
• Comorbidities  
• Caregiver Support  
• Social Support Systems  
• Duration of Illness  
• Stage/Severity of Illness  
• Demographic variables (age, gender, race, ethnicity, marital status, education, financial) | Descriptive statistics:  
Frequencies, percentages, means, and standard deviations were used to describe characteristics of sample population and to conduct tests of skewness and kurtosis.  
Inferential statistics:  
Independent t-test, Chi-square, Fisher’s Exact, and Mann-Whitney U test measures were used to analyze between group differences at pre-test time (Time 1 - baseline) to verify equivalent groups were achieved by randomization process.  
Repeated measures ANOVA were used to analyze between group differences on the dependent measure, PD-HRQOL, from baseline to post-intervention (Time 1 – Time 2) and from post-intervention to 4-week follow-up post-intervention (Time 2 – Time 3). |
| **Question 3:**    | Maintenance of change (from pre-post tests) scores on perceived self-efficacy in disease self-management of PD and PD-39 Quality of Life Scale one month after completing intervention | Elapsed Time (4-weeks) | • Health beliefs/Values  
• Health perceptions  
• # of prescribed medications  
• Duration of Illness  
• Stage/Severity of Illness  
• # of prescribed medications  
• Change in medication regimen  
• Comorbidities  
• Caregiver Support  
• Social Support Systems  
• Demographic variables (age, gender, race, ethnicity, marital status, education, financial) | Inferential statistics:  
Repeated measures ANOVA were used to analyze between group differences of change scores on both dependent measures, Self-Efficacy and PD-HRQOL, from baseline to post-intervention (Time 1 – Time 2) and from post-intervention to 4-week follow-up post-intervention (Time 2 – Time 3). |
<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Dependent Variable</th>
<th>Independent Variable(s)</th>
<th>Confounding Variables</th>
<th>Statistical Test(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 4:</strong> Is there a difference between change scores from baseline (Time 1)</td>
<td>Differences in change (from pre-post-4 week follow up tests) scores on perceived</td>
<td>Elapsed Time (7 weeks)</td>
<td>• Health beliefs/Values</td>
<td>Inferential statistics:</td>
</tr>
<tr>
<td>to the four-week follow-up (Time 3) on either of the dependent measures (Self-</td>
<td>self-efficacy in disease self-management of PD and PD-HRQOL one month after</td>
<td></td>
<td>• Health perceptions</td>
<td>Repeated measures ANOVA were used to analyze between group differences of change</td>
</tr>
<tr>
<td>Efficacy for Managing Chronic Disease 6-Item Scale or PDQ-39 Parkinson’s Disease</td>
<td>completing intervention</td>
<td></td>
<td>• # of prescribed medications</td>
<td>scores on both dependent measures, <strong>Self-Efficacy and PD-HRQOL</strong> from baseline to</td>
</tr>
<tr>
<td>Quality of Life Scale) between the PDCC and PDIT groups?</td>
<td></td>
<td></td>
<td>• Duration of Illness</td>
<td>4-week follow-up post-intervention (Time 1 – Time 3). Nonparametric Wilcoxon</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Stage/Severity of Illness</td>
<td>Matched-Pairs Signed-Ranks test also was used to analyze difference of change</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• # of prescribed medications</td>
<td>scores on both dependent measures, <strong>Self-Efficacy and PD-HRQOL</strong> from baseline to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Change in medication regimen</td>
<td>4-week follow-up post-intervention (Time 1 – Time 3).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Comorbidities</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Caregiver Support</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Social Support Systems</td>
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<td>• Demographic variables (age, gender, race, ethnicity, marital status, education,</td>
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