

A Case Study Analysis of Sleep Disturbance in the Parkinson's Disease Patient with

Deep Brain Stimulation

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Abstract

Parkinson's disease (PD) is a neurodegenerative movement disorder and a leading cause of neurological disability in the older adult population. Historically, the research and treatment of PD has focused on the associated motor symptoms. Now the non-motor symptoms such as sleep disturbance are becoming an increased focus for researchers. Deep brain stimulation (DBS) is a surgical intervention that has proven to be beneficial for PD motor symptom management. There are claims from the literature that DBS may assist with the phenomenon of sleep disturbance. A case study analysis was done to explore this concept in the DBS-PD patient population using the framework of the Symptom Management Theory. From the analysis of the subjective and objective data gathered it is clear that the phenomenon of sleep disturbance in this population is multifaceted and that DBS may play a role in managing the phenomenon of sleep disturbance for this population.

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Chapter One: Introduction to the Study

Introduction

Parkinson's disease (PD) is a neurodegenerative movement disorder characterized by an individual's progressive difficulty performing coordinated muscle movements. It is one of the leading causes of neurological disability in the older adult population (Backer, 2006). In addition to the well-known motor symptoms of PD, there is a significant array of accompanying non-motor symptoms affecting these individuals (Chaudhuri & Naidu, 2008). Of these non-motor symptoms, Backer (2006) reports that sleep disturbance is one of the five most distressing, affecting a noteworthy 60-98% of this population (Dhawan, Healy, Pal & Chaudhuri, 2006).

Presently, the main focus of treatment for PD focuses on modifying the motor symptoms caused by the progressive degeneration of the basal ganglia and subsequent loss of dopamine. Historically, the treatment for PD was mainly pharmacological, but a surgical development, *deep brain stimulation* (DBS), is proving beneficial for the treatment of many motor symptoms related to this disorder. Follow-up studies of this population suggest that DBS may have the additional benefit of reducing PD related sleep disturbances (Chaudhuri et al., 2002) in addition to improved motor control.

The purpose of this chapter is to provide background regarding the significant impact of sleep disturbance in PD and how the novel therapy, DBS, may be a potential modifier in this regard. This background will help to provide substance to the underlying principles, research questions, and assumptions that will be guiding the study methodology based upon the statement of the problem.

Statement of the Problem

In Canada, there are approximately 100,000 people living with PD and a significant portion are over the age of 65 (Canadian Brain & Nerve Health Coalition, 2007). Traditionally, the motor symptoms associated with this disorder have received a significant amount of clinical attention, but there are also many debilitating non-motor symptoms associated with this disease. The collection of non-motor signs and symptoms associated with this disorder include, but are not limited to: neuropsychiatric symptoms such as depression, hallucinations, and change in the ability to perform executive functions including decision making (Jankovic, 2008); autonomic dysfunction that includes symptoms such as sexual dysfunction, orthostatic hypotension, and urinary issues (Jankovic, 2008); gastrointestinal symptoms secondary to autonomic dysfunction such as drooling, dysphagia, and weight loss (Chaudhuri, Healy & Schapira, 2006; Jankovic, 2008); sensory changes such as pain, parasthesia, and vision changes (Chaudhuri et al., 2006); and sleep disorders including insomnia and restless leg syndrome (RLS; Chaudhuri et al., 2006; Jankovic, 2008). As a result of the under-recognition of the myriad of potential and complex non-motor symptoms associated with this disorder, there has been the implication that the individual's health care team under-appreciates the patient's experiences with these non-motor symptoms (Backer, 2006; Chaudhuri et al., 2007; Chaudhuri et al., 2006; Jankovic, 2008). This lack of information is supported by the literature, which reveals little to no documentation regarding the patient's experience with these non-motor symptoms until recently. This implication is concerning and has been acknowledged by this movement disorders clinicians who are now beginning to undertake research in this area. Despite this beginning research the

understanding of the patients' experiences regarding the non-motor symptoms is limited. Therefore, a gap in information remains that provides opportunity for future research utilizing alternate approaches to fully represent the patients' experiences.

A staggering number of individuals (60-98%) with PD experience sleep pattern disturbances during their illness trajectory (Dhawan et al., 2006; Gjerstad, Wentzel-Larsen, Aarsland, & Larsen, 2007). This large proportion of people is particularly concerning given that the benefits of healthy sleep patterns are well established (Chaudhuri, Martinez-Martin, Brown et al., 2007).

A variety of theories supporting the benefits of healthy sleep are found in the literature with the three most recognized theories being humoral, restitution, and cognitive. *Humoral theory* proposes that chemical toxins are cleared from the body and brain during sleep; *restitution theory* suggests that the body grows and repairs itself during sleep; and *cognitive theory* supports the maintenance of learning and memory during sleep (Culebras, 2002; Hodgson, 1991). Conversely, disrupted sleep patterns can lead to: cognitive and behavioural impairments such as impaired short term memory, impaired problem solving, and labile mood; pathophysiological changes such as the development of insulin resistance or altered immune responses; a decreased ability to manage co-morbidity such as with control of hypertension or diabetes; and decreased social functioning that includes impaired work performance and social interactions (Lee, 2003). Consequently, alterations to an individual's holistic health, secondary to sleep disturbance, negatively influence his/her quality of life (Stein, Belik, Jacobi & Sareen, 2008).

In addition to traditional pharmacotherapy, select PD patients (i.e., those that respond to dopamine evidenced by improved motor control) can receive a biomedical option for control of their debilitating motor symptoms. Deep brain stimulation (DBS) for PD (DBS-PD) consists of the surgical implantation of electrodes into the brain. The most common insertion site is bilaterally into the sub-thalamic nucleus. The mechanism of action for DBS is not well understood but it is thought to work through a combination of processes (Chang & Chou, 2006) that maximize the synchronicity between the sub-thalamic nucleus and other structures of the basal ganglion (Moyer, Danish & Finkel, 2007). These mechanisms may include overriding the pathological activity of the basal ganglia, stimulating other dopamine producing cells in the brain and potentially stimulating other structures in the brain that were not previously considered as part of the PD pathophysiological process (Moyer et al., 2007).

A further benefit of DBS may be the improvement of PD related sleep disturbances. Researchers are beginning to explore this possible benefit through experimental trial (Ancoli-Israel, 2005) and with the development and application of disease specific measurement tools (Chaudhuri et al., 2002; Chaudhuri et al., 2004; Tse et al., 2005). While it is important to measure the potential improvements in this group's sleep patterns, key information regarding the patient's perspective about what has specifically improved is absent in the literature. The addition of the patients' voices would complement the current clinical research and increase our understanding of the overall clinical situation as it relates to sleep disturbance (Rusinova, Pochard, Kentish-Barnes, Chaise, & Azouly, 2009).

While initial evidence supports DBS as a symptom management tool for PD sleep disturbance, the main challenge is this evidence is limited in scope and provides only a partial view of the patients' experiences regarding this phenomenon. In addition, the objective evidence supporting these claims has mainly been generated from polysomnographic sleep study (PSG), which is not easily accessible, as the primary data source. In order to provide evidentiary support of the benefits of DBS as an effective symptom management tool for sleep disturbance in this population further work must be undertaken. Thus, the main purpose of this case study analysis was to explore the phenomenon of DBS-PD sleep disturbance from a holistic perspective. The goal of this exploration was to contribute to the existing knowledge surrounding potential sleep benefits from this surgical intervention and investigate the patients' experience as they pertain to sleep health using readily accessible clinical tools. Addressing these goals will assist in drawing attention to the significant clinical and quality of life challenges that sleep disturbances pose for this group. The study findings may also contribute to the development of DBS-PD patient assessment strategies, sleep interventions and support PD research as a whole.

Research Study Questions

The following questions were developed to address the study objectives:

1. Does DBS provide a symptom management strategy for sleep disturbance in the Parkinson's disease patient population?
2. Do the measurements captured by the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman & Kupfer, 1989), the Parkinson's disease

- Sleep Scale (PDSS; Chaudhuri, Pal, DiMarco et al., 2002), and actigraphy relate to the patient perspective of their sleep and possible sleep disturbance?
3. How do the DBS-PD patients describe the experience of living with and managing the phenomena of disease related sleep-disturbance throughout their illness?
 4. What factors do patients identify as influencing their sleep?
 5. What are the patients' perceptions of how the factors influencing sleep have affected their quality of life?

Assumptions

The presentation of the researcher's assumptions facilitates an understanding of the theoretical underpinnings of the research questions generated and the research methodology. This declaration provides clarification of the theoretical and historical perspectives particular to the researcher's context of the study (Thorne, Joachim, Paterson & Cam, 2002). Thus, this section situates the researcher within the context of the research study.

The nursing paradigm encompasses the dynamic relationships between the person, environment, and health and illness (McEwen, 2007). The assumptions within the Theory of Symptom Management ([TSM]; Dodd, Janson, Faccione et al., 2001; Humphreys et al., 2008) support this worldview. This theory, which will provide a framework for this study, clearly states the following assumptions.

1. The study of symptoms is based on the gold standard of individual perception and self-report.

2. The symptom may or may not be present at the time but the potential risk for development of the symptom is high.
3. Non-verbal patients can experience symptoms and their caregiver's interpretation of these symptoms is taken to be correct.
4. Symptom management strategies can involve individuals, communities, and families.
5. Symptom management is a dynamic process (Kozuki & Froehlicher, 2003; Voss et al., 2007).

Implied within the theory are the assumptions that individuals have a choice in what symptom management strategy is attempted, that a partnership exists between the client and health care provider, and effective symptom management requires an understanding of all symptom concepts.

Therefore, the above assumptions based upon the structure and philosophy of the TSM, in addition to the literature of DBS-PD effect on sleep disturbance, have been adapted to this study as follows:

1. The DBS-PD population under study will have experienced a problem with sleep.
2. The use of actigraphy as a study method will be manageable by this population.
3. The clinical under-appreciation of patients' sleep disturbance experiences has affected negative symptom experiences and impacted quality of life.
4. The patients' experiences with PD sleep disruption are complex and combined ways of gathering information offer a more comprehensive approach to

understanding the symptoms and symptom management strategies experiences and outcomes for patients with PD-DBS.

Definition of Terms

The following is a list of terms encountered in this research thesis:

1. *Sleep disturbance* can be categorized as either sleep deprivation resulting from an inadequate amount of sleep or sleep disruption resulting from fragmented sleep during the night (Lee, 2003, p. 363).
2. *Sleep stages*. There are three stages of NREM sleep, N1, N2, and N3 and one stage of REM sleep (R). Wakefulness is considered a stage in the scoring of human sleep (Silber et al., 2007).
3. *Non-rapid eye movement sleep (NREM)* or synchronized sleep, has three stages (i.e., Stages N1-N3) that progress through a continuum of sleep depth and arousal potentials from light to deep or slow-wave sleep (Silber et al., 2007).
4. *Rapid eye movement (REM)* sleep is typically characterized by EEG patterns similar to those while awake, dreaming predominance, large rolling eye movements, and muscle atonia (Carskadon & Dement, 2005; Silber et al., 2007).
5. *Actual sleep time* is the amount of time determined by actigraphy that is scored as sleep between sleep start and sleep end by the Actiware-Sleep algorithm (Mini Mitter Company, Inc., 2003) .
6. *Sleep latency* is the length of time needed for sleep onset after going to bed (Mini Mitter Company, Inc., 2003).
7. *Sleep onset* is considered under normal circumstances for adult populations, to occur through NREM sleep (Carskadon & Dement, 2005, p. 14). During

actigraphy use *sleep start* represents the time of *sleep onset* and is determined automatically by the acti-watch as the first 10 minute period that no more than one epoch is scored as mobile (Mini-Mitter Company, Inc. 2003).

8. *Sleep efficiency* is an index of the amount of time in bed that is spent sleeping compared to the time spent in bed. The following formula calculates this parameter (Mini Mitter Company, Inc., 2003).

$$\frac{\text{Actual sleep time (100)}}{\text{Time in bed}}$$

9. *Wake time after sleep onset (WASO)* is the calculated amount of time spent awake after sleep onset. This may be from one main event or from a combination of numerous events (Mini Mitter Company, Inc., 2003).
10. *Actigraphy* refers to the measurements of an individual's movement from a portable, small watch-like device that contains an accelerometer and data processor. This unit detects and records trends in activity and rest patterns that correlate to sleep wake patterns (Acebo & LeBourgeois, 2006; Morgenthaler et al., 2007; Sadeh & Acebo, 2002).
11. *Polysomnographic Sleep study (PSG)* is the continuous recording of specific physiologic variables during sleep and typically records brain wave changes (electroencephalogram), eye movements (electrooculogram), muscle tone (electromyogram), respiration, heart rhythm, (electrocardiogram), and leg movements (Hirshkovitz & Kryger, 2005).
12. *Artifact* is the unwanted or irrelevant data that occurs because of extraneous events such as when the actigraph is off the wearer or during times of heavy activity, such as with exercise (Mini Mitter Company, Inc., 2003).

13. *Epoch* is the time period that the actigraph accumulates activity counts before saving collected data to memory and resetting to zero (Carskadon & Dement, 2005). The standard epoch length for the Actiwatch-64 is 30 seconds. This setting will capture 2880 epochs per day for a maximum data collection period of 11 days (Mini Mitter Company, Inc., 2003).
14. *Sleep Fragmentation Index* is a measure of the amount of interruption of sleep by physical movement (Van den Berg, Miedema, Tulen, Hofman, Neven & Tiemeir, 2009) calculated by summing the minutes moving percentage with the minutes immobile percentage (Mini Mitter Company, Inc., 2003).
15. *Wearing-off* can be defined as a generally predictable recurrence of motor or non-motor symptoms that precedes a scheduled dose of anti-parkinsonian medication and usually improves with anti-Parkinsonian medication (Stocchi, 2006).

Summary

In conclusion, sleep disturbances are a significant non-motor problem for those affected by PD that the health care team has not fully recognized. The recent development and utilization of DBS for the control of PD related motor symptoms may also provide an ameliorating effect on the sleep disturbances experienced in this population. In order to understand sleep disturbance in PD, and specifically the impact of DBS on this phenomenon, further knowledge is required. This study attempted to address this knowledge gap by combining a variety of approaches to explore the potential benefits of DBS for sleep disturbance. These approaches will combine quantitative and qualitative methods to complement the existing knowledge in this area and fully depict the patients' experiences.

Chapter Two: Review of the Literature

Introduction

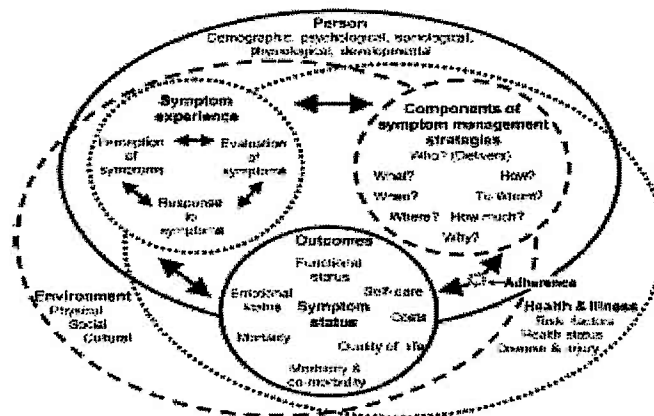
The purpose of this chapter is to provide a review of the literature surrounding the phenomenon of sleep disturbance as it relates to the DBS-PD population. The Theory of Symptom Management ([TSM]; Humphreys et al., 2008) is a deductive mid-range theory and provided the framework for facilitating the information process related to this complex topic by: guiding the literature review to clarify the purpose of the study, providing rationale for the chosen study methods, and guiding the discussion of the findings. In the current chapter, a brief overview of the theory precedes a review of the literature that informs the current research. With the exception of seminal works, literature for this review was gathered from PubMed, CINAHL and Scopus, and limited primarily to articles published from 1995 onward.

Theory of Symptom Management

The Theory of Symptom Management (Humphreys et al., 2008) is a deductive mid-range theory directly based upon its predecessor, the Symptom Management Model (Dodd et al., 2001). The original Symptom Management Model (Larsen, Carrieri, Dodd et al., 1994) focused on three symptom concepts, the symptom experience, symptom management strategies, and symptom outcomes. Dodd et al. (2001) expanded the conceptual model to incorporate the nursing worldview concepts of person, health and illness, and environment (see Figure 1). This last revision has become the present theory that exemplifies the symptom management process as a multifaceted and complex process (Linder, 2010) supported by a multi-modal approach (Caldwell & Miaskowski, 2000; Voss et al., 2006).

The TSM has had diverse applications to nursing research that have helped to establish its growth and acceptance from a model into a theory (Humphreys et al., 2008). Examples of relevant research applications are: paediatric sleep disturbance secondary to cancer (Gedaly-Duff, Leek, Nail, Nicholson & Johnson, 2006), the sleep patterns of battered women (Humphreys, Lee, Neyla & Marmar, 1999), chronic disease management related to HIV (Eller, Corless, Bunch et al., 2005; Spirig, Moody, Bateguay & DeGeest, 2005) and depression (Heilmann, Coffey-Love & Frutos, 2004). No evidence was found to support application of the theory to the study of sleep disturbances in patients with PD or DBS-PD, use in clinical practice, or use in quantitative studies with the exception of one, mixed methods research study regarding caregiver sleep in oncology (Hearson, 2007). Thus, this limitation in the application of the theory provides an excellent opportunity to use the theory in a new way. This will enhance our knowledge of the symptom experiences of PD related sleep disturbances and the possible benefits of DBS as a symptom management strategy.

Figure 2.1 Theory of Symptom Management



Reprinted with permission. Dodd et al., 2001. Advancing the science of symptom management. *Journal of Advanced Nursing*, 33(5), 668-676.

A symptom, as defined by the TSM, is the subjective experience reflecting changes in a person's biopsychosocial function, sensation, and cognition. In contrast, a sign, such as the development of a unilateral arm rest tremor in PD (Hobson, 2003), is an abnormality which is indicative of disease and detectable by the individual or by others. The combination of signs and symptoms leads individuals to seek health care and guides health care providers in their assessment and detection of changes to health. A failure on the part of either party to recognize the symptoms or the impact of the symptoms, or implement appropriate symptom management can negatively influence an individual's participation in meaningful activity and decrease his/her quality of life (Dodd et al. 2001; Larsen et al., 1999). Therefore, by using the concept of *symptoms* to guide the literature review surrounding DBS-PD sleep disturbance, there is the opportunity to comprehend the patients' experiences. This will provide the opportunity to gain further knowledge to expand assessment strategies such as the use of actigraphy, predict outcomes based upon interventions such as DBS, and provide opportunities to educate health care providers and patients regarding this phenomenon.

Within the TSM there are three concepts that influence an individual's unique symptom experience. These are the subjective symptoms experience, symptom management strategies, and the outcomes of symptom status that are encompassed by the three domains of nursing: person, environment, and health and illness. Understanding these three symptom concepts provides context for the application of the theory as it applies to the methods of this research as well as future discussion of the findings.

The *symptom experience* is comprised of the relationships between the perception of symptoms, the evaluation of symptoms, and the subsequent response. In regards to the

symptom experience the gold standard of evaluation is an individual's subjective view through a combination of perception, evaluation, and response to the noted symptoms (Ahlberg, Ekman, Wahlgren & Gaston-Johannson, 2004; Dodd et al., 2001; Larsen et al., 1994). While the subjective evaluation of symptoms is a cornerstone of the theory, this concept also incorporates the use of objective indicators that provide the means for health care providers to assess individual experience in measureable and standardized ways. This dual assessment ability increases the breadth of understanding of the symptom experiences and decreases the potential for health care providers to place their own values on the symptom experience (Stevens, 2000).

The second concept, *symptom management strategies*, facilitates the development of specific and measureable interventions based on patient centered goals (Dodd et al., 2001; Trygstad, Bucher & Dowling et al., 2002). This concept includes the relationships established between patients, families, and the health care system.

The third concept, *outcomes of symptom status*, is determined through a combined or sequential assessment of the management strategy on the symptom experience. This concept includes seven outcome measures: functional status, self-care, costs, quality of life, morbidity and co-morbidity, mortality and emotional status (Ahlberg et al., 2004; Dodd et al., 2001).

The Physiology of Human Sleep

Sleep is a multi-phasic process that makes up about one-third of a normal, healthy individual's life. It is an "altered state of consciousness from which a person can be aroused by sensory or other stimuli, which distinguishes it from coma" (Barker, 2008, p. 200). In order to appreciate the experience of sleep disturbance in patients with PD or

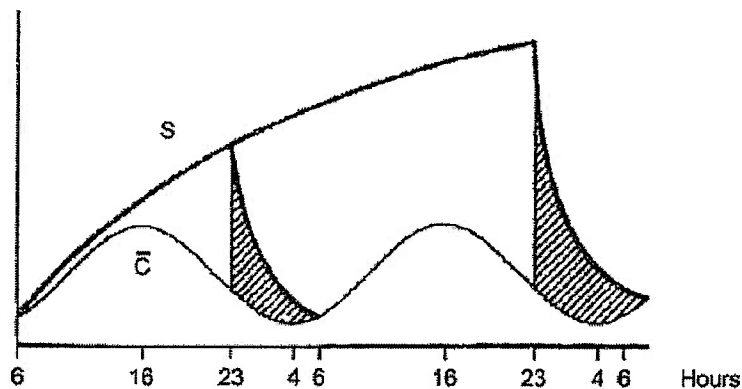
DBS-PD, a basic understanding of the behavioural and physiological characteristics of sleep is required.

There are characteristic behaviours and physiological changes associated with sleep. These behaviours include: periods of sleep follow periods of wakefulness (Cluydts, De Valck, Verstraten & Theys, 2002; Craven, 2003; Lack & Wright, 2007; Page, Berger, & Johnson, 2006; Richardson, 2005), the eyes are normally closed and the individual is usually recumbent (Craven & Hirnle, 2003; Dement, 2005), the muscles relax and purposeful muscle movements diminish (Craven & Hirnle, 2003; Lee, 2003). Some of the physiological changes associated with sleep include: a slowing of brain wave activity (Carskadon & Dement, 2003; Dement, 2005; Lee, 2003; Tobler, 2005), a decreased variability in heart rate, the development of a rhythmic and deeper respiratory rate, decreased body temperature (Lack & Wright, 2007; Lee, 2003), and a decrease in saliva and urine production (Franzini, 2005).

The development and maintenance of sleep patterns are a result of complex interactions between biological functions of the brain. Sleep occurs when stimulation switches from the posterior hypothalamus to the anterior hypothalamus with a simultaneous change from sympathetic to parasympathetic regulation. This change causes a dampening of wakefulness stimulation provided by the reticular activating system (Lee, 2003; McGinty & Szymusiak, 2005). These sleep processes are synchronized by a complex cycle of neurotransmitters (e.g. dopamine, hypocretin, serotonin and melatonin), thermoregulation, and sensory inputs interpreted by the brainstem, thalamus, and diencephalon (Jones, 2005).

The circadian rhythm system and homeostatic sleep drive provide a further influence to sleep patterns (Figure 2.2). These two processes maintain the rhythmical process of sleep and wake cycles and are a property of all higher forms of life. The circadian rhythm is regulated by the suprachiasmatic nuclei (SCN), the principal time-keeper of the brain (Hastings, 1998), and is primarily influenced by the 24-hour cycle of light and dark (Richardson, 2005). Complementing the circadian rhythm system is the homeostatic sleep drive. The homeostatic sleep drive is the gradual increase of the need to sleep in response to prolonged wake time. Conversely, with the appropriate amount of sleep to restore wakefulness, the need for sleep diminishes (Richardson, 2005; Sack, 2002).

Figure 2.2 The Circadian Rhythms and Homeostatic Sleep Drive



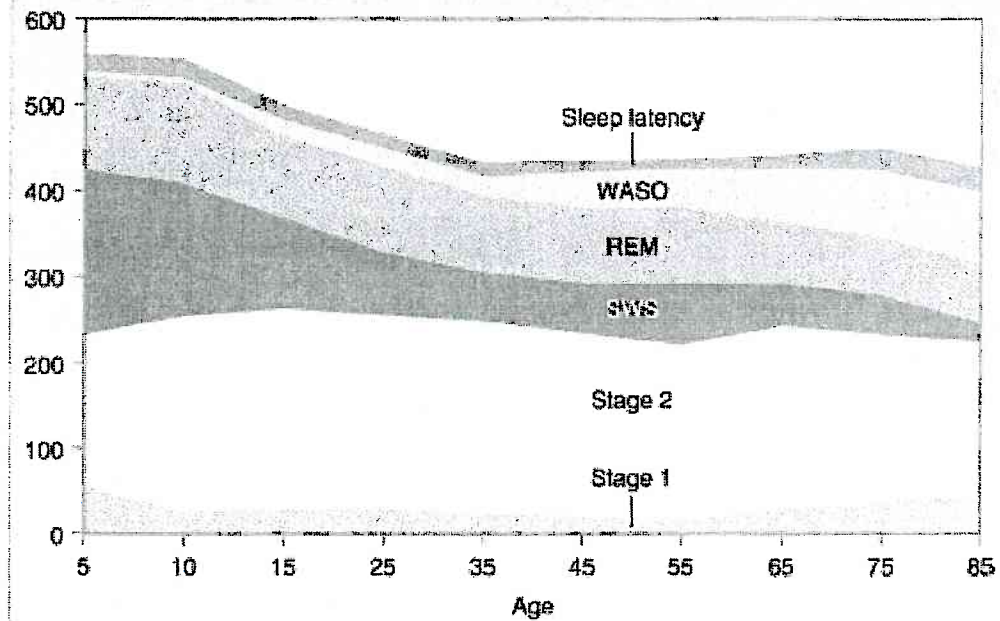
The two-process theory of sleep involving the homeostatic process (s) and the circadian process (c) with sleep time represented by the striped segments. Reprinted with permission from, Chokoverly, S. (1999). *Sleep Disorder Medicine*, (2nd, ed., p. 143). Boston: Butterworth-Heinemann.

Sleep is divided into two cyclical states, non rapid eye movement (NREM) and rapid eye movement (REM) with each of these states having characteristic properties on electroencephalogram (EEG; Culebras, 2002). NREM, or synchronized sleep, has three stages that progress through a continuum of sleep depth and arousal potentials from light

(Stages N1-N2) to deep or slow-wave sleep (Stage N3; Silber et al., 2007). During NREM sleep, brain function maintains physiologic regulatory functions with maintained muscle response (Carskadon & Dement, 2005). In contrast, REM sleep (Stage R) is characterized by EEG patterns similar to being awake, dreaming predominance, large rolling eye movements, and with the exception of select muscle groups involved with respiration, vision, and reproduction, there is generalized muscle atonia (Culebras, 2002; Silber et al., 2007).

Sleep is a dynamic process throughout the life-span that is affected by numerous factors such as age, stress, and gender. In the first year of life, the stages of sleep are less defined, with the sleep cycles being divided over a 24-hour period rather than being consolidated into night-time (Collop, Salas, Delago & Gamaldo, 2008; see Figure 2.3). Additionally, in the first year there is a predominance of active sleep, similar to REM, that shifts to a slow-wave sleep (SWS) predominance during the second year (Figure 2.3; Collop et al., 2008; Lee, 2003). During the second decade of life, the amount of time in SWS begins to decrease and this change continues as age increases (Collop et al., 2008). Further sleep pattern changes experienced by the older adult include decreased sleep efficiency, the development of circadian rhythm changes (Ancoli-Israel, 2005; Vitiello, 2006), and a weakening of the homeostatic sleep drive (Collop et al., 2008). During sleep study research of young, middle-aged and older-adults ($N=50$) completed by Campbell and Murphy (2006) age related changes to sleep length were identified. In particular, two findings were significant: that the older adults slept less than the younger adults did and that the older adults had absences of REM or the later stages of NREM (i.e., N3) sleep.

Figure 2.3 A Representation of Sleep Stage Predominance in Relation to Age.



A representation of the ratio of sleep stage predominance correlated to age. Reprinted with permission Carskadon, M.A. & Dement, W.C. (2005). Normal human sleep. In M.H. Kryger, T. Roth & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (4th ed., pp. 13-23). Philadelphia: Elsevier Saunders.

The literature also supports specific changes to sleep related to gender. In general, women have better sleep quality when compared with men that is evidenced by longer sleep times, shorter sleep-onset latency, and higher sleep efficiency (Berg et al. 2009; Bliwise, 2005). Notwithstanding this comparison, women generate more sleep-related complaints than men (Berg et al., 2009; Bliwise, 2005; Krishnan & Collop, 2006) even when other variables, such as sleep behaviours and pharmacotherapy, are controlled for (Edéll-Gustafson, Svanborg & Swahn, 2006). The literature further suggests that these sleep related changes have a strong link to differences in sex hormones. These sleep changes increase with the onset of puberty and are further affected by the female menstrual cycle (Bliwise, 2005). Berg et al. (2009) noted that these changes continue post menopause and that may also be affected by individuals' sleep hygiene habits.

The stress that individuals experience is also a strong influence on sleep. Stressors may include one of or a combination of psychological, physical, personal, or environmental components that can play a role in disrupting sleep patterns (Lee, 2003). Stress causes wide-spread changes to the physiological maintenance of the human body that can negatively affect individuals' abilities to cope with daily living (McCance, Forshee & Shelby, 2008). Stress responses alter sleep by affecting the neurochemical matrix that supports sleep (e.g., altered norepinephrine, histamine, and serotonin levels) and often cause hyperarousal (Lee, 2003).

Additional psychological variables, such as depression also play a role in the maintenance of sleep wake patterns. Depression is one of the most common mood disorders throughout the world, affecting almost all age groups (Takahashi, 2006). It is an altered emotional state characterized by the following symptoms as listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV-TR; 2000): extreme sadness; cognitive changes such as forgetfulness or difficulty concentrating; physiological changes such as anorexia or insomnia; and behavioural changes such as a lack of motivation or social withdrawal. Current theory regarding the development of depression supports a complex relationship between factors such as genetic predisposition, environmental (e.g., stress), neurochemical balance (e.g., serotonin, norepinephrine, and dopamine), and person factors (e.g., coping ability or other comorbidity) (Takahashi, 2006).

Sleep abnormalities are commonly associated with depression and can include such problems as difficulty initiating and maintaining sleep, a perception of not enough quality sleep, and reports of disturbing dreams (Benca, 2005). These subjective sleep

complaints in depressed patients are substantiated by PSG analysis of depressed individuals showing changes to sleep patterns that include increased WASO, increased SL, decreased TST, decreased SWS, and REM abnormalities (Benca, 2005). While depression is common amongst the general population (DSM-IV-TR, 2000) it is also well documented as a co-morbid symptom of PD, estimated at affecting 40-50% of the population (Borek, Kohn & Friedman, 2006; Schrag et al., 2007). Further evidence suggests that depression is also a potential complication of DBS-PD (Amik & Grace, 2006; Chang & Chou, 2006). Therefore screening for depression in the PD population is vital.

The Symptom Experience of Sleep Disturbance in Parkinson's Disease

The Response to Symptoms

Chronic sleep disruption affects individuals on a wide-scale and causes changes to normal physiologic and social functioning. While the information regarding patients' responses to sleep pattern disruption in PD is limited, there is a body of evidence supporting the general negative impacts of sleep loss in this population. It is established that the long term effects of sleep disturbances and sleep loss cause pathophysiological responses (i.e., altered immune, metabolic and endocrine function, and the development of co-morbidities); cognitive behavioural changes (i.e., fatigue, memory impairment, difficulties with problem solving) (Hodgson, 1991; Lee, 2003); emotional impairments, and social dysfunction (Culebras, 2002; Lee, 2003).

Despite the evidence supporting the benefits of healthy sleep patterns, in general, maladaptive sleep behaviours do not receive significant clinical attention (Thorpy & Adler, 2005). This is unfortunate because, as discussed, the ability to preserve healthy

sleep patterns and habits promotes a wide-range of positive health and social behaviours while not doing so has negative consequences such as increasing the risk of developing comorbidities, worsening of present symptoms, and experiencing social dysfunction. Therefore, sleep disturbance, when combined with the challenges of personal health care already imposed on an individual with chronic illness, further stress an already fragile individual.

While more research is occurring about the phenomenon of sleep disturbance in PD there remains a scarcity of literature specific to the individual responses of PD. To address this knowledge gap sleep disturbance literature from other chronic illness groups will be considered. In one example, Bröstrum, Strömberg, Dahlstrom and Fridlund (2004) conducted a cross-sectional study of heart failure patients and found that sleep disturbances significantly influenced almost all dimensions measured by the SF-36 quality of life measurement tool. Yngman-Uhlin and Edéll-Gustafson (2005) studied self-reported sleep quality in a group ($N=55$) of home peritoneal dialysis patients. From the sample, 95% complained of sleep maintenance issues. The difficulties with sleep maintenance were related to health and illness factors (e.g., pruritis), personal factors (e.g., fear) and environmental factors (e.g., difficulty managing movement in bed). This sleep disruption caused fatigue that limited individuals' abilities to perform self-care activities. As a result, 28% of the sample could not continue the study because of the undue burden the documentation placed on them.

For individuals with PD, the impact of sleep disturbance, in addition to the challenges imposed by the illness, can be devastating. Notably, sleep disturbance is reportedly one of the five most distressing symptoms experienced in PD (Backer, 2006).

There is a paucity of literature related to the experiential response of sleep disturbances in PD and the lack of acknowledgment of this problem by clinicians is well documented (Chaudhuri et al., 2007).

The first consideration of this symptom analysis is why PD sleep pattern disruptions may occur and the existing literature consistently references that these sleep disruptions are the result of a combination of factors. Firstly, there are pathophysiological changes to the brainstem and thalamocortical pathway (Dhawan et al., 2006) that alter the brain's neurochemical makeup of certain neurotransmitters such as dopamine and hypocretin (Rye & Jankovic, 2002; Thannickal, Lai & Siegel, 2007). In addition there are person factors such as age and coping skills; health and illness factors such as disease severity, PD pharmacotherapy, and additional co-morbidities (Ancoli-Israel, 2005; Freedom, 2007); and environmental factors such as living conditions and spousal support (Adler & Thorpy, 2005; Freedom, 2007) that further impact an individual's sleep.

The pharmacotherapy used in PD may play a large role in the development of sleep disturbances. Standard in the treatment of PD is the use of levodopa in combination with carbidopa (Sinemet®) to supplement dopamine to increase motor control. Unfortunately, these medications lose efficacy and wear off throughout the day or night and lead to what is conventionally called "*on and off periods*". *On* periods relate to the times when patients experience good mobility and response to medication. *Off* periods related to impaired mobility (i.e., bradykinesia, rigidity, and tremor) and non-motor symptoms experienced by patients with a non-optimal response to medication. The experience of on and off periods is individual and takes a variety of forms (Müller & Russ, 2006) Further, the trend for some of these medications is that when used at low

doses they may improve sleep but at higher doses can cause excessive daytime sleepiness and/or sleep disruption from nightmares or hallucinations (Schwietzer, 2005). There is also the suggestion that levodopa may change the architecture of sleep by altering REM and SWS times (Schweitzer, 2005). Additionally, the other common PD pharmacological agents such as the ergot dopamine agonists (e.g., bromocriptine) (Comella, Morrissey & Janko, 2005) and non-ergot agonists (e.g., pramipexole, ropinirole), cause daytime sleepiness while anticholinergic medications or those with anticholinergic side effects (e.g., amantadine) can cause either sleepiness or insomnia (Schwietzer, 2005). Thus there is increased debate over the relationship between PD, PD related sleep disturbance and the role of the dopaminergic medications considering the prevalence of sleep disturbance in PD (Romigi, Brusa, Marciani et al., 2005). Regardless, the fact is that PD prevalence increases with age and the older adult has a higher chance of experiencing an age related sleep change. These changes can be further compromised by pharmacotherapy and should be an important clinical care concern.

PD Related Sleep Disturbance.

The literature is consistent regarding the common sleep disorders experienced by individuals living with PD. The three main sleep disorders affecting this group are parasomnias, insomnias, and excessive daytime sleepiness. In addition, this population can also be affected by periodic limb movement disorder (PLMD) and restless leg syndrome (RLS). Further disruption of sleep in PD may be related to other non-motor symptoms such as those associated with autonomic dysfunction (e.g., nocturia and night-time sweating); pain (Jankovic, 2008), and comorbid depression, which is also reported as another of the most well-known non-motor symptoms of this disorder (Chaudhuri,

Healy & Schapira, 2006). The motor symptoms of PD will also play a further role in sleep disturbance. The increasing severity of PD leads to more frequent sleep disturbance that correlates to an increased need for pharmacotherapy to control motor dysfunction at night (Dhawan et al., 2006).

REM behaviour disorder (RBD) is a parasomnia characterized by vigorous and potentially harmful limb movements associated with dreaming in REM sleep (Adler & Thorpy, 2005; Gjerstad, Boeve, Wentzel-Larsen et al., 2007). RBD is not a common parasomnia in the general population, with a prevalence of less than 1% (Dhawan et al., 2006) but in PD, there is a noteworthy increase of RBD, of up to 47% with a male predominance (Adler & Thorpy, 2005; Dhawan et al., 2006). Schenk, Bundlie and Mahwold (1996) reported in a longitudinal analysis of males, over the age of 50 years, who were diagnosed with RBD ($N=29$) that 11 of the subjects were eventually diagnosed with PD. Therefore, due to the high prevalence of RBD in PD, RBD is considered an early diagnostic symptom potentially indicative of early PD related brain degeneration (Boeve et al., 2007) and any indication of RBD requires clinical attention and follow-up.

The insomnias associated with PD include difficulties initiating and/or maintaining sleep (Freedom, 2007; Pal et al., 1999). In a community based study of sleep disorders in PD ($N=89$), Gjerstad, Wentzel-Larsen and colleagues (2007) reported insomnia rates of 55%, with a slightly higher predominance for females ($p<0.05$). The cause of these insomnias may be related to the pathophysiological changes within the brain aggravated by a combination of person, environmental and health and illness factors (Dhawan et al., 2006; Freedom, 2007; Pal et al., 1999; Thorpy & Adler, 2005).

Periodic limb movement disorder (PLMD) and restless leg syndrome (RLS) are common sleep related disorders in the older adult population and may occur together or independently of one another (Brown, 2002). The characteristic behaviour of RLS is the urge to move, usually the legs, during the evening and night. There is an underlying discomfort associated with this disorder, such as the “creepy-crawlies”, that leads to difficulty initiating sleep. Related to RLS is PLMD, which is the repetitive movement of limbs once asleep causing sleep maintenance difficulties. The cause of each disorder is poorly understood, but for both situations, dopaminergic medication is the most often recommended treatment. Interestingly, in a study evaluating nocturnal sleep and daytime sleepiness, Kaynak, Kisiltan, Benbir and Uysal (2005) measured an increase in RLS symptoms associated with dopamine treatment. If this is established, those with PD may be at risk for worsening of an underlying disorder or development of additional nocturnal limb movement symptoms.

Excessive daytime sleepiness (EDS) is a problem of wakefulness and is the overwhelming feeling of the need to sleep occurring during the day. At its most severe, EDS leads to sudden onset of sleep or *sleep attacks*. This phenomenon is a significant problem in PD, occurring in 15-22% of the population (Dhawan et al., 2006; Hobson, Lang, Wayne-Martin et al., 2002; Ondo, Dat Vong, Khan et al., 2001) and related to a combination of disease severity and pharmacotherapy (Arnulf et al., 2002; Dhawan et al., 2006; Gjerstad, Alves, Wentzel-Larsen et al., 2006; Hobson et al., 2002; Tandberg, Larsen & Karsles, 1999). Accordingly, due to this high prevalence in PD and the potential negative outcomes to social function and personal safety, standard assessment of EDS should be part of all PD related care.

The Perception and Evaluation of Symptoms

The TSM states that the gold standard for understanding an individual's perception of symptoms is self-report but dependent upon the situation, the opinion of caregivers is valid (Dodd et al., 2001). In addition, the theory recognizes that there is often an overlap between what is understood from the individual's perception or interpretation of the symptom when compared to a quantitative evaluation of a symptom. Unfortunately, in the realm of general health care, the clinical evaluation of sleep pattern disturbance symptoms in patient care may be overlooked. This lack of attention may be related to a combined lack of knowledge on the part of the patient and the health care provider (Dodd et al., 2001) and is further substantiated in the literature surrounding PD (Chaudhuri et al., 2002; Jankovic, 2008).

While self-report may be the gold standard for assessing the perception of a symptom there are drawbacks to using self-report instruments. These limitations include the ability of an individual to adequately communicate what is being experienced, combined with potential limitations of the tools being used for assessment. To combat this limitation regarding reporting discrepancy, it is necessary that the tool is specific to the symptom being discussed and treated. In relation to PD care, self-report tools are being utilized to capture the symptoms associated with sleep disturbance in this patient population. Presently, a commonly referenced tool is the Parkinson's' Disease Sleep Scale (PDSS) developed by Chaudhuri and colleagues (2002). The PDSS shows promise as an objective measure of sleep disturbance in the PD population despite initial results of reliability and validity testing being inconclusive (Tse et al., 2005). To address this concern, recent research undertaken by Perez-Lloret et al. (2009) used the PDSS to

compare sleep evaluations in PD with sleep logs and actigraphy. Significant correlations occurred between the PDSS and the sleep logs for sleep quality, daytime somnolence, nocturnal psychosis, and nocturnal motor symptoms. The relationship increased between the PDSS and sleep logs when patients presented with higher disease severity scores as determined by the Hoehn and Yahr staging tool. Actigraphy results correlated significantly with nocturnal psychosis and nocturia but were not as strong with the sleep diary compared to the PDSS. Despite this outcome, Perez-Lloret and colleagues felt that this study proved the validity of using actigraphy in the population in addition to the PDSS. Therefore, the PDSS is establishing itself as a valid, disease specific tool for the subjective assessment of sleep disturbance in PD.

The literature is consistent when referencing that the gold standard of objective evaluation and diagnosis for most sleep disorders is polysomnographic study (PSG). PSG analysis involves recorded and analysed measurements of brain function (EEG), muscle movement (EMG), ocular movements (EOG), respiratory function, cardiac rhythm, sleep onset, and arousals. However, the scoring and interpretation of these results takes trained experts and access to a sleep monitoring facility (Carskadon & Rechtschaffen, 2005). While portable units for home sleep studies are a recent advancement in sleep monitoring, they are providing inconsistent results (Chervin, 2005). Thus, when a prompt assessment of a potential sleep disturbance is required alternative and accessible methods are required.

Fortunately, there are simpler and more accessible ways to objectively measure the outcomes of sleep or sleep disturbances. Actigraphy is an activity measurement device that contains an accelerometer within a small watch like apparatus that records

trends in activity levels that can be correlated to wakefulness or sleep (Labyak & Bourguignon, 2002). In normal healthy individuals, actigraphy has proven useful as a diagnostic tool for detecting sleep (Ancoli-Israel, 2005; Cuellar et al., 2007) and the evaluation or diagnosis of certain sleep disorders such as insomnia, circadian rhythm disorders, excessive sleepiness, and RLS/PLMD (Ancoli-Israel, 2005; Morgenthaler et al., 2007). The literature supports that actigraphy correlates with PSG to identify sleep and sleep disruptions (Cuellar et al., 2007; Koch et al., 2006) and that actigraphy is also proving beneficial in special populations such as in paediatrics or those receiving dementia care to identify sleep and activity patterns (Littner et al., 2003; Morgenthaler et al., 2007).

In order to increase the validity of the actigraphic data gathered and control for data artifact certain standards must be considered. These include the body placement of the actigraph, the length of recording, and corroborating data evidence (Acebo & LeBourgeois, 2006; Sadeh & Acebo, 2002). The minimum recommended time for actigraphy application is three days with seven days being preferable. The longer time span for recording activity and rest patterns gives a fuller understanding of variations in individual's sleep patterns (Acebo & LeBourgeois, 2006; Littner et al., 2003; Morgenthaler et al., 2007). Another recommendation when collecting actigraphy data is the completion of a sleep/activity diary to corroborate data (Lockley, Skene & Arendt, 1999; Morgenthaler et al., 2007).

The traditional placement of an actigraph is on the non-dominant wrist (Littner et al., 2003). Initial research regarding valid alternative placement areas for special populations such as in tetraplegia (Spivakm Oskenberg & Catz, 2007) is beginning but

present research trials of alternative placement areas such as the ankle or trunk, led to conflicting correlations between activity and rest patterns (Sadeh & Acebo, 2002). As the use of actigraphy expands to include future special populations, the research into validating placement will need to keep pace.

The expansion of research into the clinical application of actigraphy in special populations is beginning to include movement disorders. Initially, there had been questions about the utility of actigraphy in populations with movement disorders (Sadeh & Acebo, 2002), but recent studies using actigraphy have been successful in furthering the understanding of the PD experience (Comella, Morrissey & Janko, 2004; Katayma, 2001; Nass & Nass, 2009).

There is beginning research supporting the potential use of actigraphy for PD. Comella, Morrissey and Janko (2004) studied PD patient ($N=22$) motor response to night-time pergolide using actigraphy. This application helped to establish that night-time pergolide significantly decreased median sleep efficiency ($p < .049$) and increased sleep fragmentation ($p < .034$). Katayama (2001) used wrist-worn actigraphy in a PD population ($N=8$) to determine the effects of dopamine agonist therapy on PD diurnal motor fluctuations. In this research study, actigraphy assisted in determining which participants had a stable response to dopamine throughout a 24-hour period versus those who demonstrated dopamine related circadian changes evidenced by either afternoon akinesia, morning akinesia, or wearing off. Therefore, Katayma determined that actigraphy would be valuable in the assessment of individuals' drug responsiveness. Further argument supporting actigraphy in the PD population came from a study determining the extent of PD night-time hyperkinesia completed by Nass and Nass

(2009). They completed a comparative analysis between PD patients ($n=17$) and controls ($n=69$) where actigraphy was used to record activity levels over a consecutive three day period. This research concluded that there is a difference in circadian activity patterns in PD when compared to a control group with the strongest change in circadian activity occurring in the female population ($n=8$; $p<.05$).

In addition, actigraphy has the added advantage of portability, which allows individuals to maintain natural sleep and wake behaviours within the comfort of their home environments (Cuellar et al., 2007; Koch et al., 2006). A limitation of actigraphy relates to the patient's ability to manage the device and appropriately record information on the accompanying sleep diary. Despite these potential limits, the benefits are many, and actigraphy is appropriate for clinical use in the assessment for potential sleep disruption (Koch et al., 2006; Littner et al., 2003).

To support the data acquired from actigraphy, sleep logs are a simple way for individuals to record habitual sleep behaviours in real time (Spielman, Yang & Glovinsky, 2005). In normal healthy adults there is significant correlation with actigraphic data in the capture of sleep parameters such as SO, WASO and TST (Carney, Lajos & Waters, 2004; Libman, Fichten, Bailes & Amsel, 2000; Lockley, Skene & Arendt, 1999; Martin & Eastman, 2009). The patient typically completes these logs or diaries over a two-week period to record bedtime, approximate SO, approximate WASOs, and final wake time (Malow, 2005; Morgenthaler et al., 2007).

A benefit of the sleep log is that it is better able to depict nocturnal variations in sleep than a retrospective sleep questionnaire, and relies less on memory (Libman et al., 2004). While these logs are straightforward, there are drawbacks. Firstly, patients may

obsess about the information gathered by these logs to the point that they impair their own sleep (Speilman, Yan & Glovinsky, 2005). Secondly, patients may over- or under-represent their sleep habits due to a lack of awareness of actual time or a need to please the researcher (Carney, Lajos & Waters, 2004; Wesetermeyer, Sutherland, Freerks et al., 2007). Thirdly, individuals with PD may experience visual, sensory, and fine motor difficulties that make completing written material difficult (Chaudhuri, Healy & Shapira, 2006).

Two of the most frequently used tools in the assessment of sleep disorders in the general population are the Epworth Sleepiness Scale (ESS; Johns, 1993) and the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). The ESS (see Appendix C; Johns, 1993) was developed to screen for excessive daytime sleepiness as a symptom of obstructive sleep apnea (OSA). Therefore, the tool is a measure of wakefulness; it rates the propensity for an individual to fall asleep in eight scenarios during waking hours. The ESS is utilized in the assessment of sleep disorders in areas beyond OSA (Broström, Strömberg et al., 2004; Eliasson & Lettieri, 2007) including extensive use in PD, including DBS (Arnulf, Konofal, Merino-Andreau, 2002; Chaudhuri et al., 2002; Iranzo, Valledoriola, Santamaria, Tolosa & Ruma, 2002). Therefore, this tool would be appropriate for DBS-PD sleep disruption assessment and potential daytime impacts.

The PSQI (Buysse, et al. 1989) uses an interval scale to assess sleep quality. In a systematic review of 22 sleep measurement tools by Devine, Hakim and Green (2005), the PSQI had the highest reliability, validity, and internal consistency of the sample. This tool is also simple to use and there is access to accurate translations. The PSQI has also

been used extensively in PD research, inclusive of DBS (Iranzo et al., 2002; Kaynak, Kisiltan, Kaynak, Benbir & Uysal, 2005).

Depression is a common occurrence in PD that can have a negative impact on sleep patterns. Depression-rating scales are commonly used in clinical practice but there is conflicting information about which tools are best used in those with PD. In this end, Schrag and colleagues (2007) undertook a systematic review of nine tools commonly used to assess depression in PD. Each tool proved valid and met the intended purpose to either diagnose or determine severity of depression, but the widely used revised Beck Depression Inventory (BDI-II) proved to be reliable and valid in the assessment for depression in PD (Schrag et al., 2006). Therefore, using a tool that can accurately screen for depression will be beneficial in understanding DBS-PD sleep disturbance.

Symptom Management Strategies for Sleep Pattern Disturbance in PD

The goal of any symptom management strategy is to prevent negative outcomes via any one or a combination of biomedical, professional, or self-care strategies in a present or potential situation. The nature of the strategies developed are based upon the state of the science in order to provide evidenced based health management, teaching, or assessment (Dodd et al., 2001; Larsen et al., 1999). In addition, the process of developing symptom management strategies is a dynamic and goal oriented patient focused process. Continual assessment is needed in order to evaluate identified symptom objectives and plan accordingly when previously identified outcomes may not be attainable.

Two things are necessary for successful application of symptom management interventions: the development of a relationship between the individual and the health care provider as well as specific information regarding the intervention (i.e. who, what,

where, when, why, and how much). Interventions can be a targeted application of treatment to individuals or groups but can also use the individuals themselves as the therapeutic intervention. Trygstad and colleagues (2002) used this aspect of person in an environmental intervention study of group therapy for people with schizophrenia experiencing auditory hallucinations. The group therapy setting facilitated the development of new coping strategies surrounding the impact of auditory hallucination through the interactions between expert and naïve patients.

The treatment of sleep disorders is based on the signs and symptoms presented by individuals or an underlying pathological cause, after a thorough sleep and physical assessment. Factors to consider prior to initiating pharmacologic therapy include the aetiology of the sleep disturbance and concurrent PD medications (Page, Berger, & Johnson, 2006). Optimizing PD patient medications regarding timing, dosing and route is important to minimize night-time side effects, support night-time movement, and maximize daytime functioning. Other pharmacologic interventions to promote sleep can be considered, but must be weighed against potential side effects and safety concerns related to the risk older adults' face when taking any sedating medication (Ancoli-Israel, 2005). As a result, when patients are using pharmacotherapy for an underlying sleep disorder, frequent clinical follow-up is recommended to assess for any medication side-effects and patient safety concerns.

Disorders such as insomnia, RLS, and parasomnias are often treated with medication such as hypnotics and benzodiazepines (Cuellar, Rogers, Hisgham & Volpe, 2007). Unfortunately, there is often significant costs associated with these medications (Cuellar et al., 2007) and there is the increased risk of experiencing adverse reactions and

side-effects when dealing with an aged population (Ancoli-Israel, 2005) as is generally found in the PD population (Canadian Brain and Nerve Health Coalition, 2007). Other sleep disorders, such as obstructive sleep apnea, often require technological intervention and significant lifestyle modifications. These lifestyle changes, in part, have focused on sleep hygiene and working with individual's lifestyle patterns to promote rest in the afternoon (Crabb, 2001).

Pharmacologic treatment of insomnias include the addition of one of the newer benzodiazepine receptor agonists (e.g., zopiclone, zolpidem); they appear to be a relatively safe option for the short-term treatment of sleep disturbances in the older adult (Ancoli-Israel, 2005; Béphage, 2005). The side effects associated with this pharmacological treatment include cognitive changes, daytime drowsiness, hallucinations, and anxiety. Modafanil, a stimulant, is prescribed to promote wakefulness; however, common side effects include mood changes, diarrhea, dry mouth, and prolonged wakefulness (Cuellar et al., 2007). The treatment of RLS should include the correction of any diagnosed underlying iron deficient anemia with iron supplementation, which may ameliorate the symptoms of this disturbance (Lee, 2003). Treatment of PLMD and ongoing symptoms of RLS may require additional pharmacotherapy, such as dopaminergic medications (Montplaisir et al., 2005).

Non-pharmacologic interventions used in the treatment of sleep disturbance can include light therapy, aromatherapy, sleep hygiene routines, and cognitive behaviour therapy. Unfortunately, little research has been done to provide supportive evidence for these strategies as best practice (Koch et al., 2006; Page et al., 2006). Overall, interventions should promote the maintenance of circadian rhythms and improvement of

sleep hygiene. Suggested behaviours to support sleep hygiene include limiting caffeine, smoking cessation, promoting daytime activity and exercise, avoiding prolonged napping, using the bedroom for sleep and not work, maintaining a regular sleep pattern, eating meals at regular times, and consideration of a light snack prior to sleep (Béphage, 2005). Additional strategies to promote healthy sleep patterns may include establishing a ritual prior to sleep, implementing relaxation therapy, and considering formal cognitive behaviour therapy (Gunning & Espie, 2003). Consulting other members of the health care team, such as occupational or physio-therapists can help to modify the patients' sleeping environment to remove barriers and maximize individuals' nocturnal movement potentials. Further strategies include limiting environmental stimuli, blocking patient care activities, and adjusting temperature to a comfortable level (Gunning & Espie, 2003). Unfortunately, there is a lack of clinical evidence about how non-pharmacologic sleep-symptom management strategies, other than cognitive behaviour therapy, can assist sleep disturbances in chronic illness care (Gunning & Espie, 2003; Koch, Haesler, Tiziani & Wilson, 2006; Page et al., 2006). The literature offers little evidence supporting alternative sleep management strategies in the general population or in PD, hence, this is an area that requires further investigation for this population.

Deep Brain Stimulation

Deep Brain Stimulation for PD is a relatively new surgical procedure that assists patients to gain improved motor control and decrease their reliance on medication for control of these same symptoms. DBS-PD has the highest chance of success for those who respond to dopaminergic medication (Benabid, Chabardes, Mitrofanis & Pollack, 2009). The mechanism of action of DBS is not well understood, but it is thought to work

through a combination of processes leading to inhibition of overactive neural processes due to loss of dopamine (Chang & Chou, 2006; Groiss, Wojteck, Sudermeyer & Schnitzler, 2009). These processes may include overriding the pathological activity of the basal ganglia, stimulating other dopamine producing cells in the brain, and potentially stimulating other structures in the brain that were not previously considered as part of the pathophysiological process (Moyer, Danish & Finkel, 2007).

Numerous studies have shown how the use of DBS has clearly improved quality of life secondary to improved motor function for this patient population. While consensus about the site for DBS implantation has not yet been reached, at this time, the subthalamic nucleus (STN) is generally targeted. The use of the STN is supported by research done by The Deep Brain Stimulation-PD Study Group ([DBS-PD study group], 1999). During follow-up it was found that either the STN or the globus pallidus internus (GPi) increased motor functionality ($p < .001$) but the STN site allowed for the greatest decrease in dopaminergic medication. It is important for care givers and persons living with PD to realize that DBS does not alter the progression of PD; the cognitive and physical changes of the disease will continue as time progresses (Limousin & Martinez-Torres, 2008).

Not all individuals with PD are appropriate for DBS surgery. There is consistent evidence that several patient characteristics link to poor DBS outcomes and those are poor dopamine response, advanced age, advanced stage of PD, dementia, frontal lobe dysfunction, severe anxiety, or depression. To address these issues The Core Assessment Program for Surgical Interventional Therapies in Parkinson's Disease (CAPSIT-PD) has established criteria to ensure the highest chance of successful outcomes for these

individuals (Amik & Grace, 2006; Defer, Widner, Marié et al., 1999). These criteria include:

1. A diagnosis of idiopathic Parkinson's disease established by disease duration of at least 5 years (Chang & Chou, 2006; Defer et al., 1999);
2. A positive response to levodopa (dopamine) because DBS is not effective for symptoms that are unresponsive to levodopa (e.g., speech and postural instability; Chang & Chou, 2006; Defer et al., 1999);
3. Incapacitating side-effects from levodopa therapy such as dyskinesia or rapid on/off shifting that persist despite optimal medical management (Chang & Chou, 2006; Defer et al., 1999)
4. Age less than 70 years (Chang & Chou, 2006; Defer, et al. 1999);

Neuropsychiatric testing is required during eligibility screening to evaluate for underlying dementia or other psychiatric illness that may worsen post-operatively or disallow safe and adequate intra-operative assessment (Amik & Grace, 2006; Defer et al., 1999).

Despite positive outcomes DBS surgery is not without complications. There is risk of infection, haemorrhage, equipment malfunction, and brain trauma (DBS-PD Study Group, 1999). In addition, certain cognitive-behavioural abnormalities have been known to develop following DBS. These impairments may manifest in areas such as verbal memory, fluency, visuo-spatial relations, executive function, global cognition, and worsening of depression (Amik & Grace, 2006). Should the development of one of these abnormalities occur there would be an even wider symptom complex for this population to attempt to manage (Amik & Grace, 2006; De Gaspari et al., 2006). Other side-effects related directly to brain stimulation include dystonia, confusion, paresthesia,

worsening of dyskenisa, dysarthria, double vision, cognitive changes, or behavioural change (Amik & Grace, 2006). Normally these side-effects improve with time or with adjustments to the stimulator's settings.

Overall, DBS improves PD related motor symptom management (Antonini, Landi, Mariani, DeNotaris, & Pezzoli, 2004; Cicolin, Lopiano, Cibetti et al., 2003; Rodriquez-Oroz et al., 2005) and improves quality of life (De Gaspari et al., 2006; Drapier, Raoul, Drapier et al., 2005; Lyons & Pahwa, 2005). These benefits prevent changes that may otherwise occur such as a decreased participation in activities, increased disability and potentially reduced quality of life (Askenasy, 2001; Martinez-Martin et al., 2008).

In addition to improving motor control, there is a small but growing body of literature suggesting that DBS can improve sleep disturbance or the sequelae of sleep disturbance in PD. This improvement occurs in areas such as the ability to stay asleep, feel rested upon waking, and maintain wakefulness during the day (Antonini, Landi et al., 2004; Cicolin, Lopiano et al., 2003; Hjort, Ostergard & Dupont, 2003; Iranzo et al., 2002). In a literature review, Antonini, Landi and colleagues (2004) found that DBS-STN decreased EDS and increased sleep and sleep time but that there was no improvement to either PLMD or RBD. In a small clinical trial by Iranzo and colleagues (2002; $N=11$), post DBS patients were monitored during sleep using polysomnography (PSG). The study group was used as its own control, undergoing evaluation 1 week pre-op and 6 months post-op. The DBS sleep trial was limited by its small numbers but provided evidence that there was an increase in sleep time ($p<.001$), improved sleep quality ($p<.002$), faster sleep onset ($p<.001$) and improved efficiency ($p<.001$) compared to pre-

treatment PSG values. Cicolin and colleagues (2003) undertook another small study utilizing PSG monitoring ($N=7$) in DBS-PD patients. Similar to the results produced by Iranzo, they documented significant improvements to sleep efficiency and sleep architecture such as in the areas of increased SWS and REM sleep but found non-significant improvements in daytime sleepiness. Another study of DBS-PD by Hjort, Ostergard and Dupont (2003) did not use PSG for objective measurement but instead used the subjective Parkinson's Disease Sleep Scale (PDSS) to measure potential improvements in PD sleep disruption. This clinical trial ($N=30$) compared a control ($n=10$) and intervention group ($n=20$) and found significant improvements to PDSS scores in the intervention group ($p<.022$). The areas of significant improvement were in: quality of sleep, difficulty in falling asleep, restless legs or arms, painful muscle cramps or posturing, and tremor upon waking. DBS has been reported to negatively affect sleep patterns due to imprecise electrode placement or from electrode stimulation parameters (Merello, Cavanagh, Perez-Lloret et al., 2009; Monaco et al., 2004).

Outcomes and Symptom Status

This conceptual theme combines sequential or simultaneous assessment of the management strategy on the symptom experience or the symptom experience itself. This concept includes seven outcome measures: functional status, self-care, costs, quality of life, morbidity and co-morbidity, mortality, and emotional status (Ahlberg, Ekman & Whalgren et al., 2004; Dodd et al., 2001). While this list is comprehensive, it is not exhaustive of the potential assessment criteria related to the symptom and the identified experiences of the individual. The successful evaluation of the outcomes of symptom management strategies occurs when a therapeutic relationship has been established

between health care provider and the affected individual with clearly defined outcomes (Dodd et al., 2001). When the symptom and its consequences resolve, the process of the theory is complete; otherwise, further assessment and intervention should be ongoing (Dodd et al., 2001).

Further limiting the ability to assess patient outcome and symptom response to interventions is the role adherence, “whether the intended recipient of the strategy actually received or used the strategy prescribed”, played in the scenario (Dodd et al., 2001, p. 674). Adherence is an important indicator of patient focused care and reflects the element of personal choice in the symptom management process. In the DBS-PD population adherence is impacted by the patient’s compliance with the set electrode parameters, medications, and health behaviours such as maintaining healthy sleep habits, exercise regimens, and diet. Further complicating this scenario, and apart from traditional thinking of adherence, would be the role or functioning of the DBS that could include improper electrode placement or more drastically device failure. While this is not patient adherence, it relates to the success of the surgical procedure and thus, the ability for the patient to receive the treatment. An exemplar of this scenario was presented in a case study by Monaco and colleagues (2004) when a woman post DBS experienced transient insomnia related to incorrect DBS stimulation placement and parameters.

Specific to PD, many tools can assist with establishing outcomes related to the factors identified within the theory and are commonly used in this disorder. Most commonly used in the staging of PD is the Unified Parkinson’s Disease Rating Scale (UPDRS; Goetz, et al. 2007). It is also an element of the DBS screening protocol established by CAPSIT-PD (Defer et al., 1999). The Hoehn and Yahr (H&Y) Staging

Scale (Hoehn & Yahr, 1967) is another commonly used tool used to define the stages of PD. Although the H&Y is not clinically well validated, it correlates well with other tools such as the UPDRS (Ramaker, Marinus, Stiffelbout & Hilten, 2002).

Recently, due to the increased interest in PD and sleep related disturbance, there has been the development of disease specific sleep scales. The Parkinson's Disease Sleep Scale (PDSS) was developed by Chaudhuri et al. (2002) to address the high predominance of sleep disturbance. The development of the PDSS used a multidisciplinary approach in an attempt to create a tool that would fully capture the subjective symptom experience in a quantifiable manner. This retrospective measurement tool is composed of 15 items that asks patients or their caregivers to evaluate the dimensions of quality of sleep, nocturnal non-motor symptoms, nocturnal motor symptoms, and sleep benefit. A benefit of the scale is that it allows for either the individual or caregiver to assist with completion for objective measurement supporting the TSM mandate. During psychometric testing, the PDSS tool correlated highly with the Epworth Sleepiness Scale (ESS). Tse and colleagues (2005) completed further psychometric validation of this tool and reproduced similar results. The most significant positive correlations, occurring as a result of this psychometric testing, focused on quality of sleep, difficulty staying asleep, nocturia, sleep refreshment, and daytime dozing. The researchers raised concerns about the semi-quantitative nature of the instrument and if either mean or individual item scores should be used when focusing on individuals or specific interventions. The authors also suggested expanding the PDSS to screen for comorbid sleep disorders that would influence potential therapy (Tse, Bartlen, Hälbig et al., 2005).

Further research into the development of PD sleep measurement tools has been undertaken by Martinez-Martin, Visser, Rodriguez-Blazques et al., (2008). As part of a multimodal rating scale, the Scales for Outcomes in PD (SCOPA), this team completed a comparative analysis of the Scales for Outcomes in PD Sleep Scale (SCOPA-S) and the PDSS (N=187). These two scales were strongly correlated ($r > 0.6$) and discriminated between patient perception of sleep quality related to disease severity and duration. An important result from this comparison is the substantiation that sleep disturbance progresses in relation to disease severity. The authors did distinguish that while the PDSS was more conducive to detecting nocturnal disability the SCOPA-S was better able to measure daytime sleepiness in addition to nocturnal disability.

Further work is also being done to develop general non-motor scales that look at the multi-system effects of PD. Askenasy (2001) proposed that the UPDRS be expanded to detect sleep disturbance earlier in order to detect changes from treatment and disease pathology that limits independence and decreases quality of life. The Non-motor Parkinson's Symptom Scale, developed in 2007, examines the symptom experience of PD from a multi-system approach including the aspect of sleep disturbance. The NMSS-PD has not undergone detailed psychometric evaluation but preliminary results show that it may detect sleep difficulties with reliability (Cronbach's $\alpha = 0.6$). The NMSS-PD also correlated well with quality of life scores. Limitations to this initial study include a lack of psychometric comparison and a lack of normal control subjects (Chaudhuri et al., 2007).

Summary

The spectrum of symptoms associated with Parkinson's disease is a diverse combination of motor and non-motor dysfunction. In the past, the majority of clinical care and research attention was focused on the motor symptoms. From this interest, the advent of DBS is proving to be successful in ameliorating much of the impact of the associated motor issues of this disorder, subsequently extending the treatment course and improving quality of life. Unfortunately, the non-motor symptoms of PD have not, until recently, received the same attention despite the recently demonstrated negative outcomes to health and quality of life associated with them.

It is interesting that there are claims that DBS can modify the impact of sleep disturbance secondary to PD that are supported by a small body of clinical research investigating sleep disturbance post DBS. Unfortunately, the small sample sizes used do not give complete assurance to this claim. Further limiting the claims of improved sleep benefits post DBS is a lack of replication of the evidence. Granted, this replication is difficult to do when such research is resource intensive and a stable and reliable clinical population would require a multi-centre study.

It is unfortunate that the holistic nature of sleep disturbance in this population is not documented. As the interest in the non-motor symptom of sleep disturbance in PD progresses research interest into the development and validation of new PD sleep disorders assessment tools continues. The development of quantitative subjective measurement tools will potentially be useful clinically but is hindered by a lack of replication of completed studies, small sample sizes, and unknown usefulness post DBS. Our limited understanding regarding the scope of sleep disturbance is influenced by a

lack of evidence incorporating the domains of person and environment. Therefore, the ability to gain further insight into the deeper meaning sleep disturbance has on an individual would increase our understanding of the symptom experience.

Regardless of whether or not an individual has a DBS, the pathophysiological changes of the disease will continue. A possible outcome with DBS is that the detrimental motor symptoms might increase in severity again. Additionally, the non-motor symptoms of the disease may play a greater role in future patients' symptoms experiences. If, as clinicians, we do not truly understand the breadth of the problem related to the sleep disturbances, how can appropriate planning for symptom management actualize intervention strategies? Overall, further research into this area would help to increase knowledge in order to provide the development of evidenced-based interventions, the investigation into non-pharmacologic interventions for sleep disturbance, and educational strategies for the patient and health care team

In conclusion, the lack of research supporting the patients' symptom experiences regarding sleep disruption is an area where nursing can advance the science of sleep symptom management for the DBS-PD individual. The challenge for the nursing profession will be to keep the contextual foundation of person, environment and health, and illness in mind when furthering the science of symptom management, and continuing with education and research. Ultimately, the increase in knowledge surrounding sleep disturbances of PD and potential outcomes related to DBS will improve our ability to assess this patient population and develop possible interventions and evaluations that will positively affect patient's health and quality of life.

Chapter Three: Methodology

Introduction

This chapter provides a comprehensive description of the design and methodology used in this study. Information regarding the sample, setting, measurement tools, and study procedures are included. In addition, the ethical considerations of the research are addressed.

Research Design

Study Design

The original intention of this research thesis was to undertake a pilot research study utilizing a mixed methods design with non-experimental and descriptive techniques. It was felt that this avenue would support the complexity of the sleep disturbance phenomenon in this population while supporting nursing's world view (Happ, Devito Dabbs, Tate, Hrcik & Erlen, 2006). Additionally, it was felt that this format would help to identify potential confounding variables within this phenomenon, provide justification for future research, and help to determine appropriate methods for assessing sleep disturbance in the PD-DBS population (Polit & Beck, 2008a).

Unfortunately, during the recruitment phase of this research project only two participants were recruited and completed the study protocol. Therefore, during discussion with the thesis advisory committee, an alternative approach was developed that would allow the researcher to utilize the information collected, support the participants' interest in this research, add to the literature surrounding this phenomenon, and lead to completion of the research with meaningful outcomes.

As McDonnell, James and Read acknowledged in their (2000) research paper describing the practicalities of research, the act of research is sometimes driven by pragmatic and theoretical considerations. Their belief is that, at times, there needs to be flexibility in the research process to accommodate sudden and unanticipated hurdles. To this end, the use of case study analysis was put forward as an alternative methodology and there was unanimous agreement by the standing thesis advisory committee for this amendment.

Case Study Research

Case study research is the in-depth analysis of a phenomenon or an entity that can be comprised of individuals, families or groups (Creswell, p. 73). This form of research had its early roots in the social sciences and is gaining popularity with nursing as a practical way to study complicated health care related issues (Anthony & Jack, 2009). Yin (2003) describes five key applications of this research: to explain causal link, to describe, to illustrate, to explore, and to evaluate. Yin (1981) also states that there are two distinguishing characteristics of this research strategy: that it examines a phenomenon in its real-life context and the boundaries between the phenomenon and context are unclear. Thus, this method of research is a practical approach to the complex phenomenon of sleep disturbance in the PD-DBS patient population as many of the factors influencing this area of concern remain unknown.

This method of research has been used in such areas of nursing as health status in diverse age groups, community health, health policy, and education. In addition, Anthony and Jack (2009) believe that this form of research may be an important component of mixed-methods research as both can be used as an exclusive method of study or as part of

a larger study (Anthony & Jack, 2009). In addition, this format “gives voice to the powerless voice” which is a key component to this research project (Anthony & Jack, 2009) and was identified as a gap in this population from the review of the literature.

The limitations to case study research stem from the lack of a clear definition of case study analysis and a lack of attachment to one specific research paradigm.

Researchers using this format acknowledge these limitations and the literature supports diligence to sound and meticulous research procedures in order to compensate.

Triangulation is one method used to increase the rigour of the information gathered by combining methodological strategies and simultaneously integrating qualitative and quantitative data (Creswell, Fetters & Ivankova, 2004). Yin, who is widely referenced in case study literature, states that the triangulation of data needs to begin early in the planning phase to include the choice of the case as well as the numerous forms of data that can be gathered (Yin, 1981; 2003). The multiple forms of data collected can include interviews, documents, and data collection tools (Creswell, 2007). The goal of having this diverse breadth of data is to amass converging evidence to triangulate over a given fact for completeness of data (McDonell, Jones & Read, 2000; Yin, 1999). Yin (2003) further expands on the attention to rigour by the researcher and strongly recommends that the researcher’s interpretation of the data be based upon an in-depth awareness of the study topic in order to include rival explanations of the data obtained.

The method of data analysis further adds to the rigour of case study research. The analysis can provide a case description, a sharing of thematic developments from individual analysis, or cross-case comparison that combine into a detailed analysis of the

eases (Creswell, 2007, p. 72; Yin, 2003). As well, the researcher must realize that the analysis may be iterative as new details emerge but ultimately to let the facts speak for themselves.

Numerous researchers' feel that case selection in case study research is integral to providing a sound research base and further adds to the rigour of this methodology (Creswell, 2007; McDonell, Jones & Read, 2000; Yin, 2003). Yin (1999) identifies that inadequate definition of the case leads to an inadequate representation of the findings and when multiple cases are used, they may be incomparable. Therefore, Yin (1999) and Creswell (2007) suggest developing a rationale for case selection based upon the literature and developing a framework to operationalize data collection. In summary, the sampling for case-study analysis is purposeful but based upon a strict set of criteria supported by the literature that allows for an in-depth study of the phenomena in question.

While the original intention of this research was not feasible, the modification in methods to case study analysis for this topic is supported by the literature and the accompanying literature review. The new methods are complemented by the work previously proposed and undertaken for the mixed methods paradigm. Further support comes from an extensive literature review, a clear definition of case criteria based upon inclusion and exclusion criteria that allowed for differing cases to emerge but within the representative patient population, and methods that gathered a diverse amount of data. Therefore, while the research format was required to be modified, all efforts have been made to aid in maximizing credibility of this research.

Further to the discussion of rigour is the concept of “bias”. Bias is defined as “any influence that distorts the results of a study and undermines validity” (Polit & Beck, 2008). Some examples of where bias may occur are the researcher’s pre-existing knowledge about the cases, the over-representation of a certain argument from the literature, the researcher’s preconceived ideas about the phenomenon, the subjects’ participation, or as a result of too narrow a scope of data collection methods (Creswell, 2007, p. 115; Polit & Beck, 2008, p. 197-198; Yin, 1999). In this study design, numerous ways to collect data have been proposed in order to assist in the triangulation of data regarding sleep disturbance in this population. Throughout this study, attention was paid to potentially over-represent findings supporting sleep disturbance. As well, particular attention was paid by the researcher to her role as a research instrument, any preconceived ideas about possible sleep disturbances that the researcher may have had, past clinical nursing experiences, and from the changes to the methodology. Thus, it is felt that these methods will allow for rigorous research and an intensive understanding of the patient’s experience.

Study Setting

This study was community based and restricted to Winnipeg and its close bedroom communities. Participants were recruited from the Movement Disorders Centre (MDC) located at Deer Lodge Centre (DLC) in Winnipeg, MB. This outpatient program is responsible for all DBS-PD patient care and had a population base of approximately 40 DBS-PD patients at the time of study (R. Kreck, personal communication, November 25, 2009).

Sampling

Recruitment of subjects was purposive and undertaken by using a non-probability convenience sampling method. This form of sampling would have proven useful to select cases that may have represented this phenomenon more fully considering the change in methods but the selection criteria for recruitment would have needed to be broader and not only limited to the conditions set out within the inclusion and exclusion criteria. As it stands, this method of sampling is known to be weak and prone to bias, either due to the researcher having knowledge of the study participants or by individuals self-selecting themselves due to a personal stake in the research questions (Polit & Beck, 2008b). Fortunately, for this study, the researcher had little knowledge of this small population, which decreased potential bias. Unfortunately, the proposed original sample size of 6-10 participants was not met, and the alternative sample of two based upon the revised methodology was accepted for the case study analysis.

The original timeline for recruitment was three months, from June 2010 to August 2010. Due to limited success with recruitment that was affected by the seasonal timing of recruitment and other factors, an extension for recruiting was made to the *Education and Nursing Research Ethic Board (ENREB)* affiliated with the University of Manitoba. Approval was given for this extension until October 2010 which allowed for a total recruitment period of five months. Additional recruitment strategies were implemented such as increased poster presence in the MDC clinic, further education and discussion with the MDC staff responsible for recruitment, discussion and education with the Patient Care Manager responsible for the department, an enquiry into a submission asking for participants in the Manitoba chapter of the Parkinson's Disease Society newsletter, and a

personal appearance to disseminate study information at the DBS support group.

Unfortunately, these attempts were unsuccessful in garnering further potential subjects.

Inclusion Criteria

1. Aged 40 years and older
2. English speaking
3. A willingness to participate in the study
4. The ability to provide informed consent
5. Living at home
6. Having a primary diagnosis of Parkinson's Disease
7. Minimum of six months post-operative DBS insertion

Exclusion Criteria

1. Experiencing technical difficulties with the DBS
2. PD medication change within the past month
3. An inability to activate the actigraph watch either personally or with the assistance of a caregiver
4. An inability to complete written material either personally or with the assistance of a caregiver
5. A diagnosis of major depressive disorder
6. BDI-II scores higher than 28
7. Undergoing treatment for a sleep disorder with either continuous positive airway pressure or bilevel positive airway pressure.

*Procedure**Sampling Strategies*

Data collection began following ethical approval from the *ENREB* (Appendix A) and site approval from Deer Lodge Centre as it applies to the MDC (Appendix B).

Information about the study and researcher contact information was provided from a poster on display in the clinic (see Appendix C). In addition, a personal appearance was made by the principal investigator (P.I.; T. Wells) at the DBS support group in October 2010. This presentation included an overview of the study purpose, possible benefits, and risks of the proposed research. In addition, potential interested participants were able to ask questions about the research. The P.I.'s contact information was made available to the audience from a poster handout and six copies of the consent were left with the DBS staff nurse for potentially interested participants.

Once participants had completed the process of informed consent, a brief demographic questionnaire (Appendix D) was completed as referred to in Table 3.1. Each participant declined a second visit as outlined in the proposed format and asked to have visit one and two procedures simultaneously. As both had non-significant scores on the BDI-II and the MMSE this request was granted in order to decrease the burden on their time. Participants next completed the following instruments: the PSQI, PDSS, and ESS. After visit one, the P.I. arranged a time to meet with each participant for the remainder of the study protocol, at a location of his or her convenience. At visit two, the participants were provided with an actiwatch, instructed in its use, and required to provide a competent return demonstration. At this time, each participant was provided with a sleep

log. After three nights of use the watch and sleep diary were retrieved by the P.I. at a mutually convenient pre-arranged time.

As per the protocol the UPDRS, H&Y, and S&E scores were obtained from the patient chart by the researcher with assistance from the MDC clinic's research nurse. This step was taken to ensure that patient confidentiality was maintained.

At the final visit, a short interview occurred to gather further qualitative information supporting the participant's experience. The interview was expected to take less than or equal to one hour; each ended up being completed in less than or equal to thirty minutes. Unfortunately, during the interview for Case Two technical problems occurred with the recording equipment that prevented an accurate recording of the interview; field notes were written at the time and were used for analysis. Additional benefits of this visit were that it allowed time to debrief the participant about any concerns that they may have had from the research process and to offer reassurances that they would be in receipt of research summaries.

The division of study procedures as outlined below was intended to decrease the burden on participants in order to facilitate completion of the study protocol. As well, each participant was given the opportunity to review their case presentation to make comment upon the anonymity of the information, confirm their story and amend any content. These summaries were provided to the individuals via e-mail and they responded back in kind. For DBS001 a change was made regarding whom was living in the home at the time and for DBS002 clarification was given regarding pre-DBS medication timing and her living environment. The changes for each were identified by the researcher within the case studies themselves.

Table 3.1 Instrument Administration Schedule

Study Task	Initial Meeting	Day 1	Day 2	Day 3	Participant time in minutes
Consent	✓				20
Demographic quest.	✓				10
MMSE	✓				10
BDI-II	✓				10
UPDRS/H&Y/S&E/DBS settings	✓	The gathering of these scores were consolidated into one site (MDC) visit			0
<i>Patient chart</i>					
PSQI		✓			15-20
ESS		✓			5-10
PDSS		✓			10
Sleep Log		✓	✓	✓	60
Actigraphy		✓	✓	✓	n/a
Qualitative Interview				✓	60 minutes
Interview Summary Review					1-1.5 hours

Note: MMSE= Mini Mental State Exam; UPDRS= Unified Parkinson's Disease Rating Scale, H&Y= Hoehn and Yahr Staging Scale; S&E= The Schwab and England Activities of Daily Living Scale; PSQI=Pittsburgh Sleep Quality Index, ESS=Epworth Sleepiness Scale, PDSS=Parkinson's Disease Sleep Scale, BDI-II=Beck Depression Inventory-II.

Instruments

Patient Demographic Questionnaire

The patient demographic form (Appendix D), developed by the researcher, collected information to accurately describe the sample. This information includes items such as date of birth, marital status, year or age of PD diagnosis, year or age at time of DBS implantation, and medication. In addition, this form collected items that assisted the researcher to contact the patients for planning purposes. Personal identifiers were separated from the data and each participant was assigned a study identification number.

Six variables were examined during this case study analysis. These were depression, sleep quality, excessive daytime sleepiness, sleep quantity, patient perception of sleep quality, and PD disease severity. In addition, the cognitive state of each participant was assessed as part of the screening process. The following tools supported investigation of the identified variables in the investigation of DBS-PD sleep disruption (Table 3.3).

The Beck Depression Inventory-II (BDI-II)

In order to screen for severe depression as an exclusion criteria and also provide context to the individuals' health and illness the BDI-II (Appendix E) was used. This tool is widely used and well validated. This self-administered 21 items measurement tool is used to assess the psychological and physical characteristics of depression (Beck, Steer, Ball & Ranieri, 1996; Beck, Steer & Brown, 1996; Schrag et al., 2007). Each item on the scale is rated in severity, from either 0-3 (Barroso & Sandelowski, 2001; Beck, Steer, Ball & Ranieri, 1996). The tool is straightforward and takes between 5-10 minutes to complete (Aben, Verhey, Lousberg et al., 2002; Beck, Steer & Brown, 1996).

To increase the reliability of the BDI-II in PD patients, it has been suggested that modified scoring parameters (Table 3.2) be used; similar to the scoring cut-offs recommended for insomnia patients (Carney, Ulmer, Edinger, Krystal & Knauss, 2009) and in post-stroke patients (Aben, Verhey, Lousberg et al., 2002; Schrag et al., 2007).

Table 3.2: BDI-II Scoring Guidelines

Total Score	Depression Severity
0-13*	None-Minimal
*14-19	Mild
20-28	Moderate
29-63	Severe

Note: *13/14 is suggested as consideration of potential indicators of mild depression in PD; Schrag et al., 2006

Barossa and Sandelowski (2001) have raised concerns that the BDI-II may not accurately reflect the degree of an individual's depression due to the social stigma associated with depression. In addition, they felt that there can be difficulty with participants understanding item responses when it is orally administered but other researchers have found this method reliable (Aben, Verhey Lousberg et al., 2002; Beck, Steer & Brown, 1996).

Therefore, it was felt that the BDI-II would be effective to screen for depression within the DBS-PD population but extra time be allotted if oral administration was needed (Barossa & Sandelowski, 2001). Additionally, it was expected that some element of depression may exist in the study population therefore, scores indicating severe depression (29-63) precluded individuals from participating in this study. If participants had presented with a moderate level score of depression it would have been recommended that they discuss this with their family doctor or MDS specialist. Participants with severe scores would also have been encouraged to share this information with the above mentioned health care providers. If patients had agreed that this indication of depression should have been addressed, but they or a family member were requiring assistance to make this call, the PI would have assisted with this step after gaining the participants' verbal agreement.

The Pittsburgh Sleep Quality Index (PSQI)

The PSQI (Buysse et al., 1989; Appendix F) is widely accepted as a valid and reliable retrospective measurement tool of sleep quality and patterns of a one-month period (Carpenter & Andrykowski, 1997). Devine and colleagues (2007) completed a clinical review of 22 sleep quality measurement tools and concluded that the PSQI was the only tool that consistently correlated sleep quality to the clinical sleep situation. It was shown to be reliable, valid, responsive, interpretable, and did not place undue burden on the user. The PSQI also correlates with the ESS in the identification of sleepiness (Buysse et al., 2008). In addition, numerous PD or DBS-PD studies have used the PSQI as part of protocol and concluded that the tool is valid as a clinical instrument in this population. (Iranzo, 2002; Kaynak, Kisiltan & Kaynak et al., 2005).

This 19-item measurement tool focuses on seven components of sleep that include: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The total sum of the components yields the number of significance. That is, a global PSQI score greater than five is reliable for distinguishing between good and poor sleepers ($p < .001$). A benefit of the tool is that it normally takes approximately 20 minutes to complete while the main limitation to its use relates to individuals' ability to accurately report from memory their sleep and sleep habits. Individuals' literacy levels may also provide a challenge for administration but the scale has proven to be valid with oral administration that would overcome this limitation (Smyth, 2007).

The Parkinson's Disease Sleep Scale (PDSS)

The PDSS (see Appendix G) is a self-administered scale developed in response to the high-prevalence of PD related sleep disorders (Chaudhuri, Pal, Di Marco et al., 2002). The 15-item PDSS utilizes a ten-centimetre visual analog scale to measure the dimensions of quality of sleep, nocturnal non-motor symptoms, nocturnal motor symptoms, and sleep benefit. During psychometric testing, the PDSS tool correlated highly with the Epworth Sleepiness Scale (ESS). Tse and colleagues (2005) completed further psychometric validation of this tool and reproduced similar results although two concerns were raised about the tool. The first concern was about the semi-quantitative nature of the instrument and the second, was that more significance should be given to individual item scores rather than mean scores. They also suggested expanding the PDSS to screen for co-morbid sleep disorders that would influence potential therapy (Tse, Bartlen, Hälbig et al., 2005). Overall, the authors contend that if VAS scoring is poor on items 1 (overall quality of sleep), 14 (do you feel tired and sleepy when waking in the morning), and 15 (have you fallen asleep unexpectedly during the day), then a referral for further sleep assessment may be necessary. In general, a score of less than 90 is significant or a single item score of less than six should suggest further formal sleep assessment (Chaudhuri, Martinez-Martin et al., 2004). Therefore, this tool provides screening for potential PD related sleep disturbances that may require additional investigation.

The Epworth Sleepiness Scale (ESS)

The Epworth Sleepiness Scale (ESS; Appendix H) is widely used in research for the quantification of an individual's sleepiness. Johns (1993) developed the ESS to screen

for OSA. This tool rates the propensity for an individual to fall asleep in eight scenarios, each rated in severity from either 0-3. During clinometric testing of the ESS that compared OSA and snoring, there were significant correlations between excessive daytime sleepiness and oxygen desaturation, indicative of OSA. In addition, the ESS is commonly used in the psychometric testing of other related sleep tools in the dimension of sleep propensity (Chaudhuri, Pal & DiMarco et al., 2002) and sleep quality (Buysse, Hall, Strollo et al., 2008). It has also proven effective in the identification of sleepiness in other disorders like PD (Hagell & Broman 2007; Hobson, 2003).

This self-administered tool is simple to complete and score, taking less than 10 minutes to complete and interpret. From the eight scenarios the total score is calculated, from 0-24 and provides an average score of the propensity to fall asleep during the day. Ultimately, scores higher than 10 represent excessive daytime sleepiness and need further investigation to determine the cause (Johns & Hocking, 1997). The main drawback to the scale relates to the subject's ability to remember accurately the historical situations represented in the scale (Johns, 1991).

Actigraph

The literature supports the use of actigraphy in the PD and DBS-PD patient populations contingent upon standards to ensure reliable data collection (Acebo & LeBourgeois, 2006; Littner et al., 2003). Therefore, participants in this research study wore the actigraph for 3 days on their non-dominant hand. Dr. D. McMillan, an Associate Professor at the University of Manitoba, Faculty of Nursing, and advisor to the P.I., made an actigraph watch (Actiwatch 64, Mini-Mitter) and the accompanying computer analysis software accessible to the researcher. Each participant was provided with written

instructions of how to use the actigraph (see Appendix J). When required, care-givers could be taught how to activate the actigraph watch if fine motor impairment or and underlying difficulty with fingertip sensation exists with the participant but this was not necessary for the two enrolled subjects.

Sleep Log

Supporting the recommended standards for actigraphy data collection participants completed a sleep log (see Appendix J) for the three days and nights that they wore the actigraph. The information gathered from the sleep log helped to correlate bedtimes to sleep behaviours such as SO, WASO and TST. Due to the short time span of data collection the sleep log was not effective in identifying patterns of altered nocturnal behaviours.

The Interview

To complement the quantitative data being collected, address the problem of past clinical under-appreciation of any experienced sleep disturbance, and add to the breadth of understanding surrounding this research topic, individual participant interviews were done (see Appendix K). As the literature regarding case study research outlines, the understanding of the case or phenomenon is best captured when the researcher has the ability to use more than one form of knowledge acquisition. In addition, this form of research allows researchers to work within their own paradigm of nursing. Questions regarding patient beliefs, historical perspectives, cultural perspectives, and environmental areas were asked. These interviews were audio-recorded by the researcher and took place within the participants' homes.

The Unified Parkinson's Disease Rating Scale (UPDRS)

The UPDRS (Appendix L) is a standard assessment for PD and provides individual context of illness severity related to disability. It is one of the most common and reliable tools to rate the disability associated with PD (Goetz et al., 2003; Goetz et al., 2007; Ramaker, Marinus, Stiggelbout & Hilten, 2002). Over time this scale was developed by incorporating elements from other PD disability scales in order to provide a “comprehensive but efficient and flexible means to monitor PD-related disability and impairment” (Goetz et al., 2003). The intent was that this new global scale be used in tandem with additional measures targeting the identified areas of concern (Goetz et al., 2007). The UPDRS consists of four components that assess mentation, behaviour and mood; activities of daily living; motor impairment, and complications (Goetz et al., 2003; Ramaker et al., 2002). There is a revised version of the UPDRS available now but testing occurred with the older version as per the MDC. The researcher did not have the specific clinical experience to administer the UPDRS and as a result the UPDRS score was obtained from the MDC.

The Modified Hoehn and Yahr Staging Scale (H&Y)

The H&Y (Appendix M) developed in 1967, addresses the variability of patients' presentation in order to assess the progression of the disease (Hoehn & Yahr, 1967). This simple tool assists with the staging function in PD; quantifying the functional deficits and objective signs of the disease (Goetz et al., 2004). The H&Y was originally developed as a 5-point severity scale but underwent revision in the 1990s to include 0.5 increments for some clinical trials (Goetz et al., 2004). The modified version was used in this study. The H&Y remains universally used to depict PD severity. It is quick to complete, practical,

and can be administered by a wide-variety of health care professionals. The score also relates to disease severity and can be a prognosticator of disease progression (Goetz et al., 2004).

The Schwab and England Activities of Daily Living Scale (S&E)

The S&E (Appendix N) is a standard tool in the assessment of PD where 100% represents complete independence and 0% represents a vegetative state (Schwab & England, 1968). While the S&E is widely used and accepted as valid and reliable in the assessment of PD there is little literature supporting its use (Ramaker et al., 2002). Because it is part of the assessment criteria of the MDC PD patient population it was included as part of the demographic criteria for the participants and the score was gathered from the MDC patient chart concomitantly with the H&Y and UPDRS scores. Permission to use this tool was attempted, the authors are deceased and there is no further contact information.

The Mini-Mental State Exam (MMSE)

The MMSE (Appendix O) is a short and reliable tool to assess the cognitive state of individuals and can be completed in less than 10 minutes (Folstein, Folstein & McHugh, 1975). It concentrates on the cognitive aspects of mental function but excludes questions concerning mood, abnormal mental experiences and forms of thinking. This tool is widely familiar and recommended in the assessment of cognitive state in PD (Nazem et al., 2009; Ong, Seel, Carne et al., 2005). Due to its wide acceptance this tool was deemed to be useful to ensure that individuals' cognitive state was intact for inclusion into this research study. While participants may have had a MMSE score on

their patient record, it may not have been current, and therefore, each participant was required to complete the MMSE as part of the inclusion criteria for this study.

One difficulty anticipated with the application of this tool was related to the participants' ability to complete the copy design portion of the assessment secondary to any fine motor or sensory impairment affecting the individual. This was addressed on a case by case basis within the parameters provided within the literature (Crum, Anthony, Bassett & Folstein, 1993; Folstein, Folstein & McHugh, 1975) and neither case had difficulty completing this test task.

Ethical Considerations

A thesis committee was convened that included a thesis supervisor affiliated with the Faculty of Nursing, an internal faculty member affiliated with the Faculty of Nursing, and an external member from the Faculty of Medicine, University of Manitoba, with a specialty in movement disorders. Approval from the committee to proceed with this study was granted after a thesis proposal defence and attention to recommended modifications already addressed in the above areas of the protocol. Additional permissions were given from the University of Manitoba's *Education and Nursing Ethics Review Board* (ENREB) and Deer Lodge Centre. No study procedures were undertaken until all above permissions were granted in full. Pursuant to the original approval additional approvals were given by both the committee and *ENREB* for the amended procedures.

Informed Consent and Confidentiality

A written consent (see Appendix Q) was obtained from each participant prior to data collection. Each consent was coded using a study identification number to protect the individuals' identities and a copy of this consent was provided to participants for their records.

All demographic information has been kept in a locked cabinet in the investigator's home and stored separately from the data collection tools during the time of analysis. This information has only been accessible to the researcher but parts of the data have been shared with the thesis advisor as required for learning purposes. The participant interview was transcribed using a transcriptionist whom had signed a *Personal Health Information Act (PHIA agreement)*. Personal identifiers were removed from the interviews and participants were offered the opportunity to review their interview transcripts for completeness as well as assurances that personal identifiers were removed but both declined. Each participant reviewed a copy of their case study to ensure personal identifiers were removed and for personal interest regarding their health situation. Each subject gave approval to use their respective case with minor modifications that have been previously mentioned. That being said, there may be the potential that either case may be identifiable by their health care team as this is a fairly small population and well known to the team members.

Electronic data was backed-up onto a password protected USB thumb drive. In addition, information stored on the researcher's computer is password protected. Actigraphy data was downloaded onto Dr. McMillan's computer where the relevant

analysis software resides; this data is only identifiable by study number. In addition, Dr. McMillan's computer is password protected and contained within a locked office. Data will be kept for no more than 5 years and then destroyed using a confidential waste disposal system and at that time the USB thumb drive will be destroyed. The audiotapes of the interviews will be destroyed once the research thesis has been successfully defended and they are no longer needed. Upon a successful thesis defence, Dr. McMillan will store the related study material in her locked office located at the University of Manitoba.

Participant Involvement and Potential Risks

There was no deception or coercion involved in the recruitment to the study or with the administration of study tools. Subjects were thanked for their participation with a small honorarium of a \$20.00 gift card to Safeway. It was correctly estimated that the total time for participation, excluding actigraphy, would be approximately two hours. If participants chose to review their transcripts an additional 1.5 hours would have been expected. There were no significant risks anticipated from participation in this study and the main burden may have been from wearing of the actigraph and possibly limiting participation in strenuous activity while wearing it. At all times every effort was made to provide support to the participating individuals by scheduling a phone follow-up on day one, at a preselected time, and on other days if required to answer questions.

Further support to the participant's involvement and addressing potential health concerns has been provided in regard to their study outcomes. Each participant has been provided with a copy of their case study, as previously mentioned. In addition, each was

given a copy of the study summary. This summary has identified areas of concern that would be recommended for follow-up with their respective MDC team.

Data Analysis

Since the study format changed so did the methods of analysis. To assist with data analysis and results reporting the framework of the TSM will be followed. Speziale (2003) states that the goal of data analysis in qualitative research is to provide a full understanding of the research participants' experiences and that the responsibility of the researcher is to analyze and present the data in a manner that brings life to the phenomenon in question. Unfortunately, the analysis of case-study evidence is noted as being the least developed piece of this research format (Yin, 2003). In order to support the trustworthiness of the findings of this research, four concepts were considered. These are credibility, dependability, confirmability, and transferability (Speziale, 2003).

The process of this analysis was an iterative one, working with and between the sets of data gathered. Specific to the interview and field notes, each case was individually analyzed and Case One's interview was read numerous times to see if any particular category emerged beyond those developed from the research questions. From this analysis an idea or concept developed that takes into consideration her poor sleep quality and its effects on her life did emerge. It is unfortunate that Case Two's interview was not successfully recorded to add further depth at this stage. From this analysis it could not be clearly stated that a particular concept or idea emerged regarding the phenomenon in question. During the individual analyses, in order to add to the credibility and trustworthiness of the findings, participants were able to review their case and make comment about the information shared.

The cross-case synthesis approach was then used between the two cases, keeping in mind Yin's (2003) approach of thinking about theoretical perspectives and rival explanations while developing the case description. This format tends to provide a more robust analysis than analysing a single study and is recommended when using two or more cases. It is noteworthy to remember that each case was treated individually in the analysis. Analysis was based upon the categories from the predetermined research questions but despite this predetermined agenda, there was enough information gathered from the data to help determine similarities and differences between the cases (Creswell, 2007). This method of analysis was also used when analyzing the interview data by using the predetermined research questions similar to the method of directed content analysis (Hshieh & Shannon, 2005). Reflecting back to Yin's criteria for case study analysis (2003), four of the five applications were addressed. The main application from the analysis was that descriptions of the cases and the experience were provided. In addition the phenomenon was explored and provided an illustrative example of the effects of sleep disturbance in two scenarios for this population. There was also an evaluation of the data gathered that further supported the description of the phenomenon. It cannot be said that this analysis provided a true representation of causal links of the factors affecting sleep disturbance and their outcomes, this being in part due to the complexity of the phenomenon. Further input from the thesis advisor, throughout the analysis regarding confirmation of themes and the contextual support information was done. Input from members of the thesis committee was also sought to ensure that the information imparted made sense and imparted correctly based upon their area of expertise. Overall, the

interview data provided context to the case and support while answering the research questions.

At certain points throughout the discussion, the patient perspective was included as exemplars while other information was woven among the case descriptions to provide background information and further context to situations. Had both interviews been successfully transcribed, further attention to expanding or developing the categories of interest beyond the research questions may have occurred.

Summary

This case study research explored the phenomenon of DBS-PD sleep disturbance by using a combination of subjective measures and objective data collected from actigraphy in order to contribute to the existing knowledge in this area and addressing the previously identified research objectives. By using the TSM as a framework for analysis, a complete picture of the patient experience is presented that helps to further expand the understanding of this phenomenon.

Table 3.3 Research Design Summary Incorporating the TSM

Concept	Hypothesis	Tool	Level of Measurement	TSM
Subjects	That the DBS-PD patient population recruits have a variety of societal backgrounds.	Demographic questionnaire	Nominal, interval, and descriptive	Domain of person
Parkinson's disease	That PD severity correlates to the presence and severity of sleep disturbance.	UPDRS H&Y S&E MMSE	Ratio	Domain of Health and Illness, Person.
Depression	In those with DBS-PD there is a strong likelihood of experiencing depression.	BDI-II	Ratio	Domain of Health and Illness
Sleep Quality	That the DBS-PD patients have experienced a change in the quality of their sleep since having the DBS implant.	PSQI PDSS	Interval Ratio	Symptom Perception
Daytime Sleepiness	For patients with PD and with a sleep disorder there is a strong likelihood that daytime sleepiness is experienced.	ESS	Ratio	Symptom Experience
Sleep Quantity	That the DBS-PD population is sleeping sufficient amounts.	Actigraphy	Ratio	Symptom Experience Symptom Outcome
Clinical underappreciation of sleep disturbance	Among the DBS-PD patient population there has been little appreciation of the difficulties experienced secondary to sleep disturbance.	Qualitative Interview	Descriptive	Domain of Person, Health and Illness, and Environment. Symptom experience, and symptom management

Chapter Four: Findings

The main purposes of this study were to look in-depth at sleep disturbance in the PD-DBS patient population, to identify clinically appropriate tools to assess this phenomena and to provide an avenue for the expression of the patient experience; giving a voice to the issue. This chapter will provide an analysis of each case based upon the cross-synthesis approach (Yin, 2003) and following the format of the TSM. Data collection occurred simultaneously for both participants in October of 2010.

This chapter provides a descriptive case study for each individual, summaries of the objective data and the major findings of this study. Demographic data has been presented in a manner to maintain subject anonymity.

DBS001

Nursing Domain

Person Factors. Case One (DBS001) is a female in her early to mid-fifties. She has lived with PD for close to nine years and with a DBS for just over four years at the time of data collection. She is married and a full-time homemaker. During the period of time that she was diagnosed with PD she had to leave her job in the community. In addition to herself and her husband, she has one son living at home (*personal e-mail correspondence, April 26, 2011*). Due to the nature of her husband's work she spends prolonged periods of time alone.

This subject self-identified early in our discourse that sleep disruption is a problem for her. During her interview she expressed concerns about the anxiety she felt when she felt tired and unable to keep up with her obligations or desires. In addition, she expressed insight into how her altered sleep patterns and daytime fatigue can impact

herself and those around her. She mentioned four main concerns that about the negative impact of her sleep disruption during the interview. These can be categorized as follows:

1. That her sleep disruption negatively affected her weight,

P-...and it is bad for weight too because when you are up 20 hours out of 24, I think I eat more.

R-Do you?

*P-Yes...I will snack quite a bit. If I have a nap, when I wake up I am always hungry.
Lines 243-254*

2. Concern about how her sleepiness can disrupt social occasions,

... Like I'll be in the middle, even when the kids are coming over for dinner and if we are just getting stuff ready and that and I will just say to the girls you know I have to lie down for half an hour I'll be back. They will just make the salad or do whatever and I come back and join them whenever I want you know. Lines 387-392

3. Concern about how her sleep disruption affects her husband's sleep,

... it does make it more stressful in a sense that I know I wake him up because I toss and turn a lot or I snore or whatever. He is like always like xx, roll over. You know or I will move around too much because I can't sleep. Then I will go on the couch or sometimes he will be sleeping on the couch and he will stay there and I go up. We kind of go back and forth! Lines 159-171

4. Lastly, she feels that her sleep concerns have not been given appropriate concern from her health care team providers.

R – What was their response to you [when asked about the outcome of sharing her sleep concerns]?

P- Well that is pretty much sleep with Parkinson's.... I guess like that is how it is supposed to be, so kind of just accept it... or when I used to be on Mirapex. Well for someone on Mirapex [being told], that is lots of sleep. I didn't know what that meant exactly... Lines 312-326

Her BDI-II score was potentially suggestive of mild depression (score=13). She was informed of this at the time of testing and it was suggested that she mention this to

her health care team. She did not note any change to her sleeping patterns on this tool but she did indicate that she felt a moderate loss of energy during the assessment period. No cognitive deficits were noted from the administration of the MMSE (*score=30*).

Environmental Factors. She lives outside the city limits and is a full-time homemaker. She rides a scooter within town and uses a car to get into the city. She often sleeps alone and does not wear nightclothes to bed as they are too restrictive. When her husband is home they share the bed but she sometimes feels that she needs to move to the couch in the living room because she does not want to disturb him with her sleeplessness. She prefers the room cooler and will often watch the television to fall asleep to. Other than the television, the room is dark for sleeping.

She is concerned about being overweight and focuses on eating a healthy diet. At times she finds this difficult especially in the middle of the night or when she gets up from her afternoon naps. She limits her caffeine, never having any caffeine after noon and rarely during the day.

Health and Illness Factors. This subject's PD motor symptoms are well controlled with the assistance of her DBS. This is supported by her dopaminergic equivalent medication dosage decreases (Table 4.1) and her UPDRS, S&E and H&Y scores (Table 4.6). When reviewing her scores while she is on the stimulator there is minimal negative impact upon her function. Her functional scores deteriorate significantly when off both her medication and stimulator and improve most dramatically with the stimulator in comparison to medication. Other medications that this subject takes are over the counter ibuprofen at 400mg four times a day, over the counter ranitidine at 75mg twice a day and aspirin 81mg.

This subject is also being worked up for a possible diagnosis of a familial genetic disorder. This work-up has come about in response to her long-standing complaints of pain and a recent familial diagnosis of this disorder. This disorders sentinel symptoms can include joint pain and fatigue.

Identified risk factors that may lead to sleep disruption for this subject include her diagnosis of PD, her anti-parkinsonian medications, her DBS, her stress and anxiety related to her sleep disruption, her potential co-morbid diagnosis, her weight, and altered sleep habits.

Symptom Concepts

The Symptoms Experience. During the subjective testing of daytime sleepiness this subject received a significant score on the ESS of 10 (Table 4.2). This supports her reports of daytime sleepiness and her propensity for daytime napping. Additionally, her total PSQI (Table 4.3) score of 9 is also significant for concern of poor sleep quality. The specific areas of sleep concern identified for this subject were in the area of duration, disturbance and overall quality. While her total PDSS (Table 4.4) score of 98.1 was insignificant for signifying a sleep quality or quantity issue there were specific areas of concern identified at item 14, concerning morning fatigue. As well, further concerns were raised because of her low scores (<6) in the area of sleep quality, fidgeting in bed, and nocturia.

The objective data obtained from the actigraph (Table 4.5) provided information from a 24-hour period but the actual analysis occurred according to the patient's identified sleep as indicated in her sleep log. Of note, was that on one night the subject changed her bedtime to two hours prior to her normal bed-time. The reason for this was

not commented on in the sleep log. This participant remained active during the day; her activity was clearly noticeable on the readout. She did have a period on two of the days that is noticeable for a decrease in activity mid afternoon that correlates with a nap as written on the sleep log. An analysis of daytime sleep was not part of the study protocol so no further investigation of this was undertaken. Of note, and perhaps most interesting, is the significant level of activity that she experiences during the night. This is consistent over the three nights of analysis and reflected in her sleep efficiency scores that range from 51-73% and a fragmentation index that ranges from 26-47. These numbers are particularly concerning when her averaged night's sleep from the three nights was 4.76 hours with an averaged time in bed of 5.92 hours. Overall, night-time sleep would appear to be significantly disrupted for this individual and would correlate to her complaints as evidenced by scores on her PSQI, ESS and portions of the PDSS (Table 4.6).

Symptom Management Strategies. Presently, this subject is on no medication specific for sleep; in the past she had been prescribed zopiclone but discontinued it due to unpleasant side-effects. Her medications specific for PD motor control are prescribed regularly, throughout the day, with her last dose being prior to bed. In comparison, she was on higher and more frequent dosing of her anti-parkinsonian medications prior to her DBS (Table 4.1) and overall her total levodopa equivalency scores decreased significantly by over 200% after her DBS. While she has experienced a significant reduction in the amount of medication that she takes, she remains on Sinemet® and bromocriptine for control of her PD. Both of these are known to cause sleep difficulties, with Sinemet® leading to excessive daytime sleepiness at higher doses and causing changes to sleep architecture at lower dosages. Bromocriptine, another dopaminergic

medication, is also associated with daytime sleepiness or problems falling or staying asleep (Medline plus, April 24, 2011). Additional medication that she takes includes ibuprofen to help with her pain and ranitidine for stomach upset.

DBS001 utilizes a few personal environmental strategies for attempts to improve her sleep quality. These include keeping her bedroom cool at night, avoiding caffeine, and not wearing nightclothes to bed. Conversely, her environmental risk factors for sleep disruption include her habit of falling asleep in front of the television and using the TV for comfort when she is experiencing sleeplessness. This usage could be significant due to the amount of light some televisions provide. The light emitted from some televisions can equal up to 2000 lumens (www.sony.ca/bravia, February 6, 2010). This is equivalent to the amount of light from a standard kitchen light (Brillanz Ltd., 2006) and enough perceived light by the retino-hypothalamic tract to possibly alter time of sleep onset.

The literature suggests that DBS may be a way to ameliorate or manage sleep disturbance in PD and as a technological strategy it would be this subject's primary one. She has had her deep brain stimulator for over four years and her current settings are listed in Table 4.7. She does have the independent ability to modify of the parameter of stimulation for her DBS using a handheld device and she does so throughout the day as needed. She does not believe that her sleep has been better with her DBS but she does have insight into the fact that her present health concerns may be impeding her sleep quality.

Outcomes of Symptom Status. Outcomes of symptom status refers to a array of quantifiers that include items such as functional status, self-care and quality of life. Further influencing this category is the concept of adherence, "whether or not the

intended participant actually received or used the strategy prescribed” (Dodd et al., 2001, p. 674).

Specific to DBS, this subject has limited choice but to use the stimulator but she does have control over the range or intensity of the stimulus parameters of the DBS. It is difficult to determine if she adjusts her stimulator to her symptoms as directed by the clinic staff or not. In addition, she does have control over her ability to take her medication as prescribed and through equal time intervals throughout the day. This may be difficult for her to time correctly considering her varied sleep habits. In addition, if she is taking her medication doses close together or at inappropriate times there may be the potential to either cause sleep disruption at night increasing her chances of daytime somnolence or to cause daytime somnolence alone. Also, mistiming her PD medication may impact her overall motor control and lead to difficulty moving at night, another impact to sleep quality.

The data collected would support a disrupted and poor quality sleep that leads this subject to experience daytime sleepiness, alterations in her thinking and difficulty coping:

When I don't have enough sleep I am kind of fuzzy headed, it is hard to focus at time. Days when I have had more sleep my energy level is a lot better of course...I think it affects my mood [lack of sleep]. I try not to be the b-i-t-c-h you know and I think I hold it together pretty good but some days, it depends if my pain is bad too, that is even worse, everything is kind of intolerable on those days... (lines 31-34 and 41-44).

An interesting observation regarding her health is that she does not feel that her poor sleep affects her parkinsonism but that there is a negative effect on her tolerance to pain and her ability to manage her weight.

Table 4.1 Levodopa Equivalencies

Subject	Pre-DBS PD medication	Pre levodopa equivalent total	Post DBS PD medication	Post levodopa equivalent	Change
DBS001	Mirapex 1.5mg x 4 daily = 6mg daily Sinemet CR 200/50 x 4 and at hs Levodopa 100/25 x 6 per day	1602mg	Bromocriptine 5mg x 2 Sinemet CR 200/50 (1/2 tab x4 per day) = 2 per day Sinemet 100/25 ½ tab four times per day	600mg	<i>This is a decrease of 1002mg or a 267% reduction. [1/(600/1602)]</i>
DBS002	Mirapex ½ of 1.5mg twice a day Levodopa 100/25 three times overnight (0100, 0400, 0600) Levodopa 50mg/hr throughout the day (estimate 14 doses 0800-2200)	1100.5mg	Levodopa/carbidops 100/25 ½ tab qid Amantadine 100mg twice a day	200mg	<i>This is a difference of 900.5mg or decrease of 122%.*</i>

Note: Levodopa equivalency calculation parameters: (Regular levodopa dose x 1) + (levodopa controlled release dose x 0.75) + (pramipexole dose x 67) + (ropinerole dose x 16.67) + (pergolide dose and cabergolin dose x 67) + (bromocriptine dose x 10) + {[regular levodopa dose and levodopa cCr x 0.75) x .25] if taking tolcapone or entacapone} (Gjerstad, Boeve, Wentzel-Larsen et al., 2007).

DBS002

Nursing Domain

Person Factors. Case Two is a petite female between the ages of 40-45 years. She was diagnosed with PD while in her mid-thirties but stated during the initial meeting that she first began experiencing motor control problems at the age of 15. She has had her DBS for three years; half of the time of living with the diagnosis of PD. She is married with children and also a successful businesswoman. At the time of her PD diagnosis her children were quite young and she remained their primary caregiver. She is very busy with her work and home obligations and attempting to find time with her proved challenging at times.

Upon reflection of the visits, her participation in the study appeared to have added another layer of stress for her but she continued to willingly participate. Unfortunately, her interview was not recorded due to a technical malfunction with the recording equipment and the interview was unable to be transcribed. Supplemental anecdotal information came from the field notes taken at the time immediately after the interview and from the initial meeting.

This subject felt that her doctors took her concerns regarding her sleep disruption, prior to DBS, very seriously. In order to be able to move in bed throughout the night, she was required to awaken to take levodopa once or twice to balance her nocturnal on and off periods (*personal e-mail correspondence April 26, 2011*). This led to a necessary sleep disturbance and the outcome of having difficulty managing her daytime functions. Since having the DBS implant she feels that her sleep quality is much better and that she gets a goodly amount of sleep for the time that she is in bed. This is in keeping with her personal perception of what a good sleep is, appropriate time and good quality sleep and waking feeling rested. She is quite regimented about her sleep times and tries to keep to a schedule as much as possible but she mentioned that this did limit some of her relationships and added some strain to her marriage.

Her depression score on the BDI-II was insignificant with a score of 5/63 and her cognitive function was normal (30/30) upon testing with the MMSE.

Environmental Factors. She lives in a newer two story home, with all bedrooms located on the second floor. Her bedroom was not viewed but she did state that she has a television there. In the evening she often falls asleep on the couch in the family room (*personal e-mail correspondence, April 26, 2011*). She sleeps in the same bed as her

husband. On weeknights she is in bed usually by 2200 and up by 0700 and is often asleep before her children. She stated that not sleeping well leads to irritability, difficulty keeping up with her tasks, and additional stress for her.

Health and Illness Factors. Presently, she remains healthy other than her diagnosis of PD. She does complain that approximately once per month she has a poor sleep compared to other nights; she wondered if it may be a hormonal change related to her menstrual cycle. Other risk factors that may affect her sleep are her consumption of cola beverages throughout the day and her stress level. Prior to her diagnosis of PD, she never felt that her sleep was a significant problem other than she possibly did not get enough. An interesting comment made by this subject is that she felt one of the main reasons she had her DBS for her PD so quickly was to aid her sleep and minimize the effect her need for frequent nocturnal waking caused.

She remains on medication for her PD, levodopa/carbidopa that she takes four times a day and amantadine every 12 hours. This is a significant decrease in the amount and timing of her medication previous to her DBS insertion (Table 4.1). Her UPDRS and S&Y scores show minimal impairment upon her function while she is on her stimulator and her medication. Her UPDRS scores show a functional decrease while she is off both her medication and stimulator and notable improvements when she is on both her medication and stimulator (Table 4.6). Upon review of the data there is no single one intervention that provides such dramatic improvements to function as compared to Case One and her stimulator.

Symptom Concepts

The Symptoms Experience. The objective testing of her symptom experience showed minimal difficulties with either sleep quality or quantity. Her ESS (Table 4.2) score of 3 was insignificant as was her PSQI (Table 4.3) score of 2. Her total PDSS (Table 4.4) score of 129.5 was insignificant as were the single item questions 1, 14 and 15; the only area of interest on the PDSS was that she rated her fidgetiness in bed as significant (1.5).

Subjectively, she feels that sleep is important for proper functioning and now when she does not sleep well, everything is that much harder. She did mention at her initial interview that at times sleep was difficult, but no underlying cause was mentioned or followed up on.

This subject's objective data included the actigraph (Table 4.5) for which the readouts began during the evening of watch drop-off until watch pick-up three days later. These readouts provide information from a 24 hour time-span but the actual night-time sleep analysis occurred according to the patient's sleep and wake time parameters as documented on her sleep diary. The actigraph readout shows a clear demarcation between this case's daytime and nighttime activity. While she remained very active during the day there was a consistent level of lesser movement throughout the night. An interesting note is that while her activity lessened during the night she recorded a fragmentation index that ranged from 24.4 to 33. In addition her sleep efficiency was altered, ranging from 65.3-80.7; this effect may be related to nocturnal movement but as well due to the fact that her sleep times were lower than the nine hours she estimated on the PSQI. From

actigraphy her actual sleep time ranged from 5:13hrs to 6:39hrs with an average of 6:10hrs actual sleep over the three nights.

Symptom Management Strategies. Overall, this subject uses minimal strategies for sleep. The strategies that she does employ include following a sleep routine and taking her medication regularly. It was not assessed as to her adherence to timing or dosing of her anti-parkinsonian medications and this was not indicated on her sleep diary. Her DBS can also be considered a management strategy for her PD related sleep disturbance. She had noted a significant improvement in her sleep quality after having the implant and comments that her sleep remains fairly good until this time. She does have control over the intensity of stimulation through the day but it is unclear if she manages this appropriately according to her symptoms and as taught by her PD health team. She is reliant on the controller for managing her stimulation parameters (Table 4.7) and during our initial interview she discovered that her handheld controller was malfunctioning. This caused her some distress and she immediately made note to follow-up with the clinic to address this.

She does not take medication for sleep and the only medication she was taking was her prescribed PD related medications. This subject had a significant decrease of 122% in the amount of levodopa required to control her symptoms. This decrease would suggest that the impact on her sleep or daytimes sleepiness would be decreased as levodopa at high doses is known to cause daytime somnolence. This could be considered a possibility when looking at her subjective sleep scale scores in combination with her actigraphy data.

Outcomes of Symptom Status. It would appear from discussion with this subject that since the DBS implantation this subject has experienced an improvement in sleep quality and quantity that have allowed her to maintain a job, raise her children, and function more fully throughout the day. She feels that *“Everything is easier when I have slept well”*. This improvement is supported upon analysis of the data, although it would appear that an underlying issue remains. On the PSQI she wrote that she felt she averaged 9 hours of a sleep per night and 9 hours in bed but her actigraphy data suggests that she most likely averages about 7 hours per night (range of assumed sleep 6.41-7.38 hrs; range of actual sleep 5.13-6.39 hrs). Nocturnal movement may be a problem as her fragmentation index remains elevated between 24 and 33 and sleep efficiency ranged from 65-80%. The impact of this sleep disruption appears minimal because she does not complain of significant daytime sleepiness as per her score on the ESS or a poor quality to her sleep from the PSQI. She feels that she functions well during the day but does have some frustration about the need to be so regimented with her sleep.

Table 4.2 Epworth Sleepiness Scale Scores

Use the following scale to choose the most appropriate number for each situation over the past few weeks: 0 = would <u>never</u> doze 1 = <u>slight</u> chance of dozing 2 = <u>moderate</u> chance of dozing 3 = <u>high</u> chance of dozing	DBS001	DBS002
Sitting and reading	1	1
Watching tv	3	1
Sitting, inactive in a public place	0	0
As a passenger in a car for an hour without a break	2	1
Lying down to rest in the afternoon when circumstances permit	3	0
Sitting and talking to someone	0	0
Sitting quietly after a lunch without alcohol	1	0
In a car, while stopped for a few minutes in the traffic	0	0
total	10*	3

Note: * significant result

Table 4.3 Pittsburgh Sleep Quality Index Scores

During the past month...	DBS001	DBS002
1. What time have you usually gone to bed at night?	0:00hrs	2200hrs
2. How long (in minutes) has it usually taken you to fall asleep each night?	5 to 10 minutes	0
3. What time have you usually gotten up in the morning?	6:00a.m.	0700
4. How many hours of actual sleep did you get at night?	5 to 6 hours	9
During the past month, how often have you had trouble sleeping because you...		
a) cannot get to sleep within 30 minutes Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	0	0
b) wake up in the middle of the night or early morning Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	3	1
c) have to get up to use the bathroom Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	2	0
d) cannot breath comfortably Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	0	0
e) cough or snore loudly Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	3	1
f) feel too cold Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	0	0
g) feel too hot Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	3	2

Table 4.3 PSQI cont...		
h) had bad dreams Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	1	0
i) have pain Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	3	0
j) other reasons, please describe	n/a	n/a
6. During the past month, how would you rate your sleep quality overall? Very good (0) Fairly good (1) Fairly bad (2) Very bad (3)	3	0
During the past month...		
7. How often have you taken medication to help you sleep? Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	0	0
8. How often have you had trouble staying awake while driving, eating meals, or engaging in social activity? Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	0	0
9. How much of a problem has it been to you to keep up enough enthusiasm to get things done? No problem at all (0) Only a very slight problem (1) Somewhat of a problem (2) A very big problem (3)	2	0
10. Do you have a bed partner or room mate? No bed partner or room mate (0) Partner/room mate in other room (1) Partner same room but not same bed (2) Partner in same bed (3)	3	3
If you have a roommate or partner, ask them how often in the past month you have had...		
a) loud snoring Not during the past month (0) Less than once a week (1) Once or twice a week (2) Three or more times a week (3)	3	0

Table 4.3 PSQI cont...		
b) long pauses between breaths while asleep		
Not during the past month (0)		
Less than once a week (1)	0	0
Once or twice a week (2)		
Three or more times a week (3)		
c) Legs twitching or jerking while you sleep		
Not during the past month (0)		
Less than once a week (1)	0	2
Once or twice a week (2)		
Three or more times a week (3)		
d) Episodes of disorientation or confusion during sleep		
Not during the past month (0)		
Less than once a week (1)	0	0
Once or twice a week (2)		
Three or more times a week (3)		
e) Other restlessness while you sleep: describe		
Not during the past month (0)		
Less than once a week (1)	0	2
Once or twice a week (2)		
Three or more times a week (3)		
Scoring algorithm:		
PSQIDURAT	2*	0
PSQIDISTB	2*	2*
PSQILATEN	0	0
PSQIDAYDS	1	0
PSQIHSE	1	0
PSQISLPQUAL	3	0
PSQI total	9	2

* score suggests that further investigation would be recommended by the health care team

Table 4.4 Parkinson Disease Sleep Scale Scores

Factor	DBS001	DBS002
1. The overall quality of your night's sleep is:	2.5**	8
2. Do you have difficulty falling asleep each night?	10	9
3. Do you have difficulty staying asleep?	0	7
4. Do you have restlessness of legs or arms at night or in the evening causing disruption of sleep?	9	8.5
5. Do you fidget in bed?	5.1*	1.5*
6. Do you suffer from distressing dreams at night?	9.5	10
7. Do you suffer from distressing hallucinations at night?	10	10
8. Do you get up to pass urine?	1*	9.5
9. Do you have incontinence of urine because you are unable to move due to "off" symptoms?	10	10
10. Do you experience numbness or tingling of your arms or legs which wake you from sleep at night?	10	9
11. Do you have painful muscle cramps in your arms or legs which wake you from sleep at night?	0*	10
12. Do you wake early in the morning with painful posturing of arms or legs?	10	10
13. On waking do you experience tremor?	9	10
14. Do you feel tired and sleepy after waking in the morning?	2**	7.5
15. Have you unexpectedly fallen asleep during the day?	10	9.5
Total scores	98.1	129.5

Note: * significant results <6 that require further inquiry; ** are the responses for 1, 14 and 15 that if <6 should be referred for PSG by the health care team

Table 4.5 Actigraphy Summary

	Actual sleep (hrs & min.)	Sleep %	Actual wake (hrs & min.)	Sleep efficiency (%)	No. of sleep bouts	No. of wake bouts	Sleep latency (hrs & min.)	Mean activity score	Fragmentation index
DBS001									
Night 1	3:46	76.5	1:10	73.8	44	43	00:10	21.96	47.3
Night 2	4:19	83	0:53	51.6	43	42	2:22	18.61	26.2
Night 3	6:09	71	2:31	65.3	69	69	00:24	32.81	42.9
DBS002									
Night 1	6:39	87.2	00:58	80.7	56	55	00:21	7.91	24.4
Night 2	5:13	78.2	1:27	65.3	72	72	00:23	14.02	33.5
Night 3	6:27	85.5	1:05	70.5	71	70	00:36	8.58	33.0

Table 4.6 Patient Comparisons of PD Severity and Actigraphy Data

	UPDRS n	S&E on both/off	H&Y on both/off	Actual sleep (hrs & min.)	Sleep %	Actual wake (hrs & min.)	Sleep efficiency (%)	Fragmenta tion index	PDSS	ESS	PSQI
DBS001											
Night 1	1/17 (3yrs post DBS)	100 on both 75 off both	1%/4%	3:46	76.5	1:10	73.8	47.3	98.1	10*	9*
Night 2				4:19	83	0:53	51.6	26.2			
Night 3				6:09	71	2:31	65.3	42.9			
DBS002											
Night 1	1/4 (one year post DBS)	100 on both 80 off both	No data	6:39	87.2	00:58	80.7	24.4	129.5	3	2
Night 2				5:13	78.2	1:27	65.3	33.5			
Night 3				6:27	85.5	1:05	70.5	33.0			

*this data represent being on both the stimulator and medications compared to scores being off both medication and stimulator

Table 4.7 DBS Stimulator Settings

Subject	Range	Amplitude	Pulse width	Current	Rate	Impedence
DBS001						
Left channel	+6 to 2-	3.3v	60us	26uA	130Hz	964
Right channel	+7 to 6-	2.2v	60us	26uA	130Hz	636
DBS002						
Left channel	+2 to 1-	2.1v	150us	63uA	145Hz	693
Right channel	+2 to 1-	3.4v	90us	32uA	145Hz	1360

Summary

Both cases were analyzed in a similar fashion using the TSM as a template for data representation. With the exception of a missing interview for DBS002 the data collection was as per protocol. The benefit of simultaneous case analysis has helped to show that the differences represented, taken together, provide a more in-depth picture of the symptoms experience on sleep disturbance in DBS.

Chapter 5: Discussion

The non-motor symptom of PD related sleep disturbance is well documented to affect a staggering number of individuals with PD. This phenomenon is estimated to impact more than 50% of this population (Dhawan et al., 2006; Gerstad, Wentzel-Larsen, Aarsland & Larsen, 2007) and the literature references it as being one of the top five most distressing non-motor symptoms (Backer, 2006). The result of prolonged sleep disruption is known to cause difficulties in areas such cognition, behaviour, socialization, and health maintenance for example (Culebras, 2002; Hodgson, 1991; Lee, 2003). While the literature surrounding the area of PD related sleep disruption continues to grow there are still areas that require attention, specifically to address the holistic patient experience. Increased knowledge surrounding the phenomenon of sleep disturbance in PD will aid in providing improved patient care management strategies to maintain their health and regulate sleep-wake patterns.

The recent literature investigating sleep disturbance in PD has been focusing on the utility of DBS as a possible sleep disturbance management tool in addition to the benefits it provides for motor symptoms (Antonini et al., 2004; Cicolin et al., 2003). While this claim may be valid, early evidence is inconclusive as to why this improvement may occur. Therefore, this chapter will discuss the data as it applies to the research questions, the implications to nursing practice, the strengths and limitations of the study and where gaps in knowledge remain for potential further research.

Research Questions

1. *Does DBS provide a symptom management strategy for sleep disturbance in the Parkinson's disease patient population?*

The literature suggests that DBS proves beneficial to the management of sleep disturbance in PD. The mechanism of action for these benefits remains complex and can be related to a number of factors such as medication reduction, stimulating other areas of the brain that may be involved in sleep that leads to a rebalancing of the neurochemical matrix within the brain. These neurotransmitters may include dopamine, hypocretin, serotonin and melatonin, all known to play a role in sleep. Conversely, the literature also suggests that the stimulator itself may be a cause of sleep disruption for some individuals related to either the position within the STN or the parameters of the stimulation such as reported by Merello et al., 2009 or Monaco et al., 2004. Monaco and colleagues (2004) have reported that in studies of cats and humans with certain subthalamic lesions, interrupting the reticular activating system's waking activity can be inhibited that subsequently leads to the inhibition of sleep. This is similar to the theoretical perspective of the homeostatic sleep drive. These trials also detected that with certain lateral hypothalamic lesions the secretion of the two neuropeptides hypocretin and leptin played a role alterations of waking behaviour. Hypocretin is partially responsible for sleep and leptin is partially responsible for the feeling of satiety. When these two neuropeptides were altered in an experiment by Monaco et al. (2004) the result was an increase in food intake and motor activity in mammals. This change subsequently leads to alterations in the body's rhythms and therefore can cause sleep disturbance.

It is apparent, that for both subjects, the stimulator has provided an exceptional intervention for the control of their PD related motor symptoms as evidenced by significant improvements in the UPDRS and S&E scores. This improvement has subsequently decreased their reliance on large doses of dopaminergic medication and has improved their motor symptoms experience related to wearing off. Despite these improvements in motor function, it is unclear from the data if DBS is a tool for symptom management specific to PD related sleep disturbance. During the comparison of subjective responses from the ESS, PSQI and ESS, Case One continues to express significant problems with her sleep in the domains of quantity, quality, daytime sleepiness and impact to daytime function. In contrast, Case Two appears to have little difficulty in the domains of sleep quality or quantity but there is a suggestion of concern in the domain of sleep disturbance related to nocturnal movement. These subjective findings are further supported for both subjects with the objective data from the actigraph that showed an increased fragmentation index for each, with Case One having the larger index score. Overall from the data gathered and analyzed it would suggest that the cases selected were able to provide different standpoints to some of the potential sleep disturbances experienced in this population.

The phenomenon of sleep disruption is a multi-faceted problem for Case One. An area of concern arises from her complaints of pain from either her PD or her potential comorbid diagnosis. Secondly, there are specific areas of difference between the two cases when comparing stimulator settings that would benefit from further consideration. Individual stimulators are programmed specifically to the requirements and responses of the person but upon comparison of the two there is a notable increase in range of

stimulation from Case One to Case Two. Given that Case One has significant problems with sleep disruption and complaints of difficulty with weight management, it could be proposed that her DBS is stimulating areas of the hypothalamus and reticular activating system leading to sleep disruption and weight management difficulties.

The literature suggests that significant reductions in dopaminergic medication are to be expected after DBS. In a study of 18 patients post DBS-PD followed for 12 months post-operatively by Thobois and colleagues (2002) their study population experienced an average reduction of 65.5% of dopaminergic medication. This reduction remained stable at a 12 month follow-up. Benabid and colleagues (2009) conducted a literature review of this issue and suggested that at five years post DBS patients remained having a dosing decrease on average of 67%. This finding from the general population has been noted within this study's population. It is very interesting as to the extreme reductions in dopaminergic medication for each case comparing pre and present day dosing. Case One has experienced a 267% reduction and Case Two a 122% reduction as calculated using levodopa equivalencies. These dosage reductions have led to the simplification of dosing regimens and as the literature reflects, decreases the effect that these medication play on sleep and daytime sleepiness (Schweitzer, 2005).

It appears that for these two individuals DBS has not shown itself as the singular symptom management strategy for PD related sleep disturbance. However, from the information gathered there is the suggestion that DBS has a role in managing this symptom that may be a combined factor of significant improved motor symptom control that allows easier movement throughout the night, decreasing possible sleep side-effects caused by higher doses of anti-parkinsonian medication and potential changes to the

brain's underlying sleep physiology. Further controlled study is needed looking at pre and post DBS factors such as medication regimens, sleep function, and co-morbidity with a larger study population.

2. *Do the measurements captured by the Pittsburgh Sleep Quality Index (PSQI), the Parkinson's disease Sleep Scale (PDSS), the Epworth Sleepiness Scale, and actigraphy relate to the patient perspective of their sleep and possible sleep disturbance?*

Actigraphy is accepted as a tool for sleep assessment in numerous populations including PD (Cuellar et al., 2007; Koch et al., 2006) but it has not been widely used in the DBS-PD population. Therefore, it was felt that the use of actigraphy in conjunction with the ESS, PSQI and PDSS would provide valuable information about this complex phenomenon.

As was predicted, the use of actigraphy proved beneficial by adding information that correlated with the individuals' perceptions. Both subjects identified "difficulty with sleep disturbance" on the PSQI and "fidgetiness in bed" on the PDSS. These complaints correlated with their elevated fragmentation indexes and decreased sleep efficiencies. For Case One, the average time in bed was 7.65 hours with an actual sleep time average of 4.76 hrs. In comparison, Case Two averaged an actual sleep time of 7 hours per night from approximately 8.5 hrs in bed.

The interest in sleep fragmentation, the brief arousals that can occur throughout the night, is garnering more attention in the literature for in the general population and for PD (Haba-Rubio, Ibanez, Sforza, 2004; Stepanski, 2002; Trenkwalder, 2004).

Trenkwalder(2004) estimates that patients with PD can spend between 30-40% of their

night experiencing an arousal. When viewing the data generated by both cases, each had an elevated fragmentation index, suggestive of arousals.

Case One has two causes for her fragmentation index to be elevated. She complains of an inability to sleep throughout the night that was corroborated by her accompanying sleep diary and from her interview. Secondly, for the time that she is in bed she appears to be quite active based upon her actigraphy tracings. Case Two did not complain of difficulty with sleep or sleep disturbance but she, as well, showed a significant amount of movement throughout the night that led to a decrease in her sleep efficiency. For both subjects over the three nights there was no specific pattern to their movements that would be attributable to the wearing off phenomenon. Further study using more detailed sleep diaries and longer actigraphy periods would be needed to assess this possibility.

In summary, Case One had the highest sleep fragmentation and poorest sleep efficiency that correlated to clinically significant scores on the PSQI, the ESS and portions of the PDSS. Case Two also had a higher than expected fragmentation index and lower sleep efficiency from the actigraphy data gathered when compared to her perceptions about her sleep. What is of interest is that the only notable areas of concern from the subjective tools were on single item scores for this subject in the area of sleep disturbance on the PSQI and for fidgetiness at night on the PDSS. This would suggest that while the screening tools provide insight into sleep disturbance for this population, unless single item scores are noted as significant, this disturbance may go undetected. As well, it is felt that the actigraphy data provides enough information to identify a concern

but the collateral information from the tools used, in addition to patient complaints, provides the greatest sense of the problem.

3. *How do the DBS-PD patients describe the experience of living with and managing the phenomena of disease related sleep-disturbance throughout their illness?*

The lived experience of dealing with sleep disturbance in the diagnosis of PD with or without DBS is different for both individuals and offers a unique perspective missing from the literature. Case One continues to feel that her sleep issues and the impact on her health remain underappreciated by her clinical health team that is supported from the literature by Backer (2006) and Chaudhuri et al. (2006). There is an underlying stress that negatively affects her ability to manage her daily functions in a manner that she sees fit.

In comparison, Case Two has shared that she has experienced significant improvements to her sleep quality that have made her abilities to perform her activities of daily living easier. She does have remaining concern regarding her vigilance about her sleep habits and she continues to often be the first one asleep at night. Despite these concerns she continues to be very active with her family and work activities and did not express concern that sleep disruption was affecting her life any further.

4. *What factors do patients identify as influencing their sleep?*

There are a multitude of factors beyond PD that have influenced the two individuals' sleep (Table 5.1) that range from stress, health, family obligations, and sleep habits. In addition, there are other factors that were identified from the case analysis, supported by the literature review, that are summarized in Table 5.1.

5. *What are the patients' perceptions of how the factors influencing sleep have affected their quality of life?*

Both individuals reported that quality of life is affected when their sleep is disrupted. This is similar to study findings of chronic illness patients with sleep disturbance as reported by Yngman-Uhlin and Edéll-Gustafson (2005) and Bröström, Strömberg, and colleagues (2004; Table 5.1). For Case One, this impact on quality of life continues and is felt to be caused by the negative effects of sleep disturbance. These negative impacts on her quality of life stem from changes with her ability to participate fully within her family and community leading to stress and anxiety (Culebras, 2002; Lee, 2003). Case Two has been quite satisfied with her outcomes regarding sleep and her quality of life but she does express concern about the vigilance that she is required to keep about her sleep habits in order to maintain the quality of life she is now accustomed to.

Table 5.1 Summary of Case Identified TSM Concept Characteristics

Case Combined Patient Sleep Disturbance Risk Factors	Case Combined Patient Responses and Outcomes to Sleep Disturbance	Case Combined Symptom Management Strategies for Sleep Disturbance
Age (Ancoli-Israel, 2005; Collop et al., 2008; Vitello, 2006)	Stress (McCance et al., 2008)	DBS (Antonini et al., 2004; Cicolin et al., 2003; Hjort et al., 2003)
Stress (Lee, 2003)	Anxiety (Hodgson, 1991; Lee, 2003)	PD Medication dosing (Freedom, 2005; Schweitzer, 2005; Ancoli-Israel, 2005)
DBS (Merello et al., 2009; Monaco et al., 2004)	Altered thinking (Hodgson, 1991; Lee, 2003)	PD Medication adherence (Freedom, 2005; Schweitzer, 2005; Ancoli-Israel, 2005)
Medication (Ancoli-Israel, 2005; Comella et al., 2005; Romigi et al., 2005; Schwietzer, 2005)	Difficulty managing co-morbid conditions (Hodgson, 1991; Lee, 2003; Patel, 2006; Stepanski, 2002)	DBS adherence (Amik & Grace; Dodd et al., 2001)
Sleep environment (Béphage, 2003; Gunnie & Espie, 2003)	Altered social relationships (Culebras, 2002; Lee, 2003)	Sleep hygiene (Béphage, 2003; Gunnie & Espie, 2003; Koch et al., 2006)
Other co-morbidity (Jankovic, 2008; Yngman-Uhlin & Edell, Gustafson, 2005)	Role stress (Lee, 2003)	
Sleep hygiene habits (Lee, 2003)	Decreased sleep efficiency (Haba-Rubio et al., 2004; Stepanski, 2002; Trenkwalder, 2004)	
Ambient light (Jones, 2005; Richardson, 2005)	Increased fragmentation index (Haba-Rubio et al., 2004; Stepanski, 2002; Trenkwalder, 2004)	
Being alone (Adler & Thorpy, 2005)	Nocturnal awakenings (Haba-Rubio et al., 2004; Stepanski, 2002; Trenkwalder, 2004)	
Study participation (Yngman-Uhlin & Edell-Gustafson, 2005)	Altered sleep hygiene habits (Béphage, 2003; Gunnie & Espie, 2003; Koch et al., 2006)	
Gender (Berg, 2009; Bliwise, 2005; Krishnan & Collop, 2006)		

Clinical Implications

Nursing

Overall, from this case study analysis there are areas of concern that are relevant to both participants and, therefore, transferable to this population. Firstly, both participants are experiencing decreased sleep efficiency that may in part be related to nocturnal movement as evidenced by their increased fragmentation indices. Also, the participants' underlying sleep habits may play a role with this disturbance; that is going to bed before actually being sleepy, prolonged daytime napping, and staying in bed when not actually sleeping. Secondly, the role of the pharmacology for PD may also play a role in experienced sleep disturbance despite significant dose reductions. As the literature suggests, the use of dopaminergic medication is key in assisting with motor control throughout the day and night for this population (Groiss, 2009). The literature also suggests that higher doses of the pharmacological agents used to treat PD can lead to daytime somnolence but overall these medications continue to cause changes to sleep architecture despite dose reductions (Comella et al., 2005; Schweitzer, 2005). Thus for this population, DBS allows for improved motor control and medication dosage reductions helping to balance the pros and cons of this necessary therapeutic treatment. Although clinically its impact to sleep improvement has been anecdotal for these two subjects. Therefore, the use of the PSQI and the PDSS as subjective measures allows for the identification of areas that may require further clinical attention. Further to these identifiable areas, actigraphy showed significant value for objectively quantifying subjective concerns and also proves valuable as a clinical tool.

The first step for an individual describing a sleep disturbance is a thorough assessment of the person's experience, the person, the environmental factors, and the health factors that may be playing a role in this problem, regardless of the interventions to be undertaken. This information will help identify potential environmental and personal factors that may be confounding the situation (Béphage, 2005; Hodgson 1991; Lamm et al., 2008). Specifically to the DBS-PD population, particular attention should be given to the motor symptoms they are experiencing; the pharmacology used to treat these symptoms that includes dosing and timing of medication; the physical environment they are sleeping in; the sleep habits that they partake in; and the specific complaints that they are experiencing. A complementary physical exam of motor and cognitive function may also provide further insight into confounding variables such as decreased motor function, a DBS malfunction, or even additional underlying pathophysiological causes such as depression, pain, or a sleep disturbance associated with PD (i.e., RLS, PLMD). This history and physical should be complemented by objective measures for establishing baseline parameters of concern and possible benefits once an intervention is identified.

From the two cases analysed the use of actigraphy provided a clear picture of increased nocturnal activity that as the literature suggests is very suggestive of sleep fragmentation. In the general population, prolonged sleep fragmentation leads to a cumulative sleep deprivation that has negative effects towards health (Lee, 2003; Stepanski, 2002). While the three night period was useful as a screening period, the use of a seven night measurement period would have assisted in determining sleep-wake habits and may have clarified Case One's situation further. When considering the use of actigraphy as a clinical assessment tool the pros for use include its accessibility, ease of

use and relative ease of analysis. The cons to actigraphy usage are that while in comparison to PSG the cost and resources are significantly less, the priority for funding allocation is often beyond the control of the clinician and resource accessibility to qualified sleep clinicians trained for actigraphy can be limited. Lastly, participants need to be able to understand how to use the watch and be able to add a minimum of information to the sleep diary.

The use of pen and paper measurement tools can be just as accessible to the clinician and provide reliable data to guide care. From the tools used in this case study analysis the ESS (Johns, 1993), the PSQI (Buysse et al., 1989) and the PDSS (Chaudhuri et al., 2002) proved that they were able to identify areas of concern. From these tools, the ESS was the simplest to administer and score but was only able to differentiate between the severities of the sleep disruption to daytime sleepiness between the two cases. Both the PSQI and PDSS identified areas of concern that were reflected in the actigraphy data as well. From the two tools used, the PSQI would appear to be more sensitive for many domains affecting sleep quality but the PDSS proved to corroborate subjective concerns on single item scores for disease specific sleep items. Therefore, from the data gathered and the increased understanding of this problem, regardless of their treatment regimen patients should regularly be screened for sleep disturbance using the ESS and either the PSQI or the PDSS. This will provide a consistent format for understanding the symptom experience and further follow-up.

When accessible, actigraphy proves to be able to detect nocturnal movements and sleep quality for this population (Comella et al., 2004; Katayama, 2001; Nass & Nass, 2009). Actigraphy may have proven more sensitive if used to assess sleep disturbance

before and after DBS and may have a place to determine the effects of stimulator parameters and the effect of sleep maintenance as the literature suggests.

Nursing interventions should support, as much as possible, a return to healthy or what would be considered normal sleep-wake patterns; that is sleeping during the night for an appropriate amount of time and wakefulness during the day. This would be evidenced by improvements in sleep fragmentation and sleep efficiency. These interventions could include a combination of non-pharmacologic and pharmacological modifications with the goal being the adoption of and maintenance of healthy circadian rhythms and improvement of sleep hygiene (Béphage, 2003; Gunning and Espie, 2003). From the two cases studies presented, Case One requires immediate attention in numerous realms that should include further sleep assessment using PSG, consideration of non-pharmacologic interventions such as CBT to address issues surrounding her insomnia (Koch et al., 2006), exercise to promote daytime activity, the establishment of sleep hygiene habits, and attention to her underlying pain. Attention to these areas of concern would help to promote a healthier sleep-wake cycle (Béphage, 2003; Gunning and Espie, 2003).

Factors to consider prior to initiating pharmacologic therapy for sleep disturbance include the aetiology of the sleep-wake disturbance, current PD medications (Page, Berger, & Johnson, 2006), and what medication patients may be already using to promote sleep. These non-prescribed sleep aids may cause negative effects to the sleep-wake cycle (Gonneratne et al., 2011). Both participants still require dopaminergic medication, in addition to their DBS, for management of parkinsonism symptoms, therefore, this still requires attention from the clinician in the areas of dose timing. Other pharmacologic

interventions can be considered, but must be weighed against potential side effects and safety concerns when taking any sedating medication (Ancoli-Israel, 2005).

Pharmacologic treatment strategies of insomnia could include the addition of one of the newer benzodiazepine receptor agonists (i.e., zopiclone, zolpidem). These newer options appear to be a relatively safe option for treatment of sleep disturbance in adults (Ancoli-Israel, 2005; B  phage, 2005). Ultimately, these medications are recommended for short-term therapy and consideration of continuation of this therapy needs to be based upon the patient's symptoms outcomes. Also consideration of adjunct cognitive behavioural therapy for sleep hygiene would increase the potential of returning to a healthier sleep pattern (Page, 2006).

Because both participants had significant nocturnal movements and RLS may be common in this population, the treatment of RLS should potentially be considered. This would include the correction of underlying iron deficient anemia with iron supplementation (Lee, 2003). For the treatment of PLMD and ongoing symptoms of RLS, additional pharmacotherapy, such as changes in dopaminergic medications or dosing could be recommended (Montplaisir et al., 2005). As well further pharmacotherapy, such as Gabapentin, an anticonvulsant that is traditionally used to treat seizure disorders and neuropathic pain, can be considered to treat the symptoms of RLS in PD (Freedom, 2009).

In addition to the above recommended pharmacological sleep aids, Cesamet   a man-made cannabinoid, has proven to aid in pain management, management of chemotherapy induced nausea and vomiting, and sleep maintenance in populations with cancer, chronic neuropathic pain, post-traumatic stress disorder and fibromyalgia (Davis,

Maida, Daennick & Pergolissi, 2007; Fraser 2009; Berlach, Shir & Ware, 2006). With the PD population facing many of the same issues as the above patient populations such as pain and sleep disturbances, the addition of this medication may assist with managing the non-motor symptoms of this disease and assist functioning of this patient population although this has not yet been explored.

Education

Education into the benefits of healthy sleep-wake patterns begins with health care providers and extends to patients and their families. Therefore, health care providers must be educated regarding the assessment strategies available to them, the significance of sleep-wake pattern maintenance to health and well-being, and the roles of the many facets of PD that may play a part in this phenomena. This holistic educational approach, supported by the TSM will also ensure that patients and their caregivers have the tools necessary to advocate for optimal care. This approach, which should include the spouse, home care supports, and the entire health care team in the development and implementation of interventions, is ultimately beneficial to the patient (Béphage, 2005; Koch et al., 2006).

Expanding the clinical knowledge base in the arena of sleep and having the ability to share this with patients and their families will ensure that patient choices regarding sleep hygiene, sleep-wake pattern maintenance, and pharmacological adherence are based on research-based evidence or best practice guidelines. Lastly, the attention to education will ensure that the health care team recognizes the importance of sleep to health.

Research

With developments in pharmacotherapy leading to increased options for tailoring patient care with respect to balancing outcomes and side-effects and the increased interest in complementary therapies many individuals may look for *natural* ways to manage their health care concerns. Clinicians need to be aware of these developments to understand the potential influences on care. With the development of nutraceuticals there may be a role for further research into this area; specifically to PD. As an example, there is beginning interest in the use of cherry juice to improve insomnia. Pigeon, Carr, Gorman and Perlis (2009) undertook a pilot study of 15 older adults with complaints of insomnia. The factors of interest included sleep onset, WASO, TST and SE. While significant improvements were found in the study group, when compared to placebo the only significant improvement was in WASO. While this research is very preliminary, it is out of the box thinking and addresses the need for research into the alternative and complementary management strategies that people seek and an increased awareness on the part of the clinician.

Further to the attention being given to alternative or complementary therapies is consideration of melatonin. A clinical review of melatonin use for sleep disorders, by Arendt, Someren, Appleton, Skene and Akerstedt (2009) found there was little clinical evidence about the efficacy of melatonin for aiding sleep disturbance. On the other hand Garfinkel, Laudon, Nof and Zisapel (1995) conducted a randomized, double blind crossover study in an elderly population (N=12) with chronic health problems and complaints of insomnia that compared melatonin to placebo. Laudon (1995) noted that

while the TST did not improve there were improvements in sleep efficiency and WASO. Thus, this may be another area for further clinical research in the PD population.

Additional research in the areas of measuring sleep disturbance from the period prior to and post DBS still warrants attention. While this case study provided an in-depth look at this phenomenon post DBS, further information regarding quality of life in combination with measureable sleep quality measures throughout this diseases trajectory would be beneficial. This information may lead to possibly including sleep disturbance severity and impact as a criterion for implantation.

While the pre and post DBS-PD sleep disturbance scenario is one area to investigate, further research into valid sleep measurement tools for this population must be considered. The PSQI has proven valid in this population (Iranzo, 2002; Kaynak, 2005) as had the PDSS (Chaudhuri, 2007) but neither seems to consistently be used as the one reliable tool. Due to the increase in attention to the non-motor symptoms impact of this disease having one simple and reliable tool would benefit this population.

Lastly, research into the social impacts of this phenomenon would provide valuable information about the extent of this problem on the patient and their social support group. This could include research into what health care providers for this population feel are the fundamentals of healthy sleep-wake patterns and the misconceptions or awareness they possess. In addition, there is a paucity of literature surrounding the impact on caregivers of this population and the effect this disease has on their sleep-wake patterns. Having increased knowledge of the challenges care-givers face, either at home or in an inpatient care setting, may assist with tailoring interventions to the

individual, aid in disseminating relevant information, and decrease care-giver burden especially when a clearer understanding of the health care teams' beliefs is known.

Limitations

There were several limitations to this research study, the first being the limited recruitment of subjects that required a significant change in methodology. Case study analysis works best when the case selection is clear and well-defined in order to provide an adequate representation of the phenomena in question (Creswell, 2007; Jones & Read, 2000; Yin, 1999). These two cases were not chosen specifically for their representation of different facets of the problem but they were chosen from a strict set of criteria (i.e. inclusion and exclusion criteria) that allowed for a broad potential pool of participants representing the population in question. From the literature it is clear that these two cases represent a facet of the general DBS-PD population. Lastly, this study may have been stronger with an additional case or cases and longer actigraphy data collection. The additional case could have provided another experience that would have enhanced thematic development. The longer collection period may have helped to control for sleep disruption related to participant hypervigilance to sleep habits secondary to participation in this study.

Early in the development of this research study much effort went into providing an extensive literature review with a breadth that increased the researcher's awareness of this situation and ultimately aided in supporting the change in methods. Should this situation have turned out differently, and planning for the case study approach been the primary focus of this research, I would recommend the following changes. First off, I would recommend that the research begin with one broad question that may have been

“what is the patient experience of sleep disturbance in Parkinson’s disease before and after DBS implantation?” Secondly, it is important that the cases be purposefully chosen to represent different facets of the disease process. Thirdly, using a subsequent follow-up interview, that built upon initial conversations may have provided a clearer and deeper depiction of the cases. Finally, it would be helpful if the interview itself was more general in nature in order to support thematic development and support the iterative nature of qualitative research. These changes may provide the opportunity to look further at the phenomenon of sleep disturbance in PD and the use of DBS as a relevant symptom management strategy. In addition, any researcher bias from the original format would have been lessened and the credibility of the final product strengthened.

Conclusion

The TSM proved to be an ideal organizing framework to develop research methods investigating the phenomena of sleep disturbance of the DBS-PD population. It also enabled the dissection of a symptom into all its facets that allowed for increasing the understanding of the problem for the clinician that ultimately allows for appropriate planning of care and reassessment. The underlying assumptions aided in driving the direction of the research questions and aided in supporting that the patients’ experiences with PD sleep disruption are complex. Having the ability to gather information from different perspectives offers a more comprehensive approach to understanding the symptoms and symptom management strategies experiences and outcomes for patients with PD-DBS.

Additionally, the case study analysis format proved useful for developing a clearer understanding of the phenomena of sleep disturbance in the DBS-PD population.

It is clear that this phenomenon is an outcome of many factors in the individuals' illness trajectory that includes the pathophysiology of the disease, pharmacotherapy, DBS, improved nocturnal motor symptom control, and behavioural changes. Much of the literature supported the outcomes of the data collected but question still remains as to the impact of DBS on sleep disturbance. While there were numerous limitations to this study it would appear that an increase in clinical attention to this phenomenon is warranted both pre and post DBS. Overall, this population faces a challenging future and every effort should be made toward supporting healthy sleep-wake patterns to support their health and social well-being for optimal quality of life.

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Appendix A

Education and Nursing Research Ethics Board Application and Approval

April 20, 2010

Ms. M. Bowman
Coordinator - Human Ethics
CTC Building
208 - 194 Dafoe Road
(204) 474-7122
(204) 269-7173 (fax)

Dear Ms. Bowman:

**Re: Factors Associated with Sleep Disturbance in the Parkinson's Disease
Patient Post Deep Brain Stimulation**

Please find attached my submission to the Education and Nursing Research and Ethics Board for expedited review. This research protocol is being submitted in accordance with my obligations for graduation as completion of my Master of Nursing. I have enclosed the required number of copies including the original for your records.

As part of this research process, once I have received approval from ENREB to proceed I will be applying to the Deer Lodge Centre for site access to the Movement Disorders Centre. Dr. Hobson, the medical director of this program, is aware of my intention and I will be seeking a letter of support regarding the site access portion of this process. Once I am in possession of this letter, I will forward a copy to you for your records as they apply to this submission.

I look forward to hearing back from yourself and Dr. Guse in the future.

Regards,

Tamara Wells

Enclosures: original submission plus three copies.



UNIVERSITY

OF MANITOBA

Fort Garry Campus Research Ethics Boards
CTC Building, 208 - 194 Dafoe Road
Winnipeg, MB R3T 2N2
Phone: (204) 474-7122

Protocol # _____
(Assigned by HES Admin.)

FORT GARRY CAMPUS RESEARCH ETHICS BOARD SUBMISSION FORM

Psychology/Sociology REB ☐

Education/Nursing REB ☐

Joint-Faculty REB ☐

Check the appropriate REB for the Faculty or Department of the Principal Researcher. This form, attached research protocol, and all supporting documents, must be sent **in quadruplicate** (original plus 3 copies), to the Human Ethics Coordinator, CTC Building, 208 - 194 Dafoe Road, 474-7122.

Principal Researcher(s): Tamara Wells RN

Status of Principal Researcher(s): (please check): Faculty ☐ Post-Doc ☐ Student: Graduate ☒
Undergraduate ☐ WRHA Affiliate ☐ Other ☐ Specify: _____

Address (to receive Approval Certificate): 85 Pinehurst Cres. Wpg., MB, R3K 1Y8

Phone: 799-7067 Fax: _____ Email: tamwells@shaw.ca

Project Title: Factors Associated with Sleep Disturbance in Parkinson's Disease Patients Post Deep Brain Stimulation

Start date: May 2010 Planned period of research (if less than one year): until August 2010

Type of research (Please check):

Faculty Research

Self-funded ☒ Sponsored ☐

(Agency) _____

Administrative Research

Central ☐

Unit-based ☐

Student Research

Thesis ☒ Class Project ☐

Course Number: _____

Note: While this research project is self-funded at this time opportunities may present for the researcher to gain funding. Should this be the case then ENREB would be duly notified of this occurrence.

Signature(s) of Principal Researcher(s): _____

For student research: This project is approved by department/thesis committee. The advisor has reviewed and approved the protocol.

Name of Thesis Advisor: Dr. D. McMillan **Signature** _____
(Required if thesis research)

Name of Course Instructor: _____ **Signature** _____
(Required if class project)

Persons signing assure responsibility that all procedures performed under the protocol will be conducted by individuals responsibly entitled to do so, and that any deviation from the protocol will be submitted to the REB for its approval prior to implementation. Signature of the thesis advisor/course instructor indicates that student researchers have been instructed on the principles of ethics policy, on the importance of adherence to the ethical conduct of the research according to the submitted protocol (and of the necessity to report any deviations from the protocol to their advisor/instructor).

Ethics Protocol Submission Form (Basic Questions about the Project)

The questions on this form are of a general nature, designed to collect pertinent information about potential problems of an ethical nature that could arise with the proposed research project. In addition to answering the questions below, the researcher is expected to append pages (and any other necessary documents) to a submission detailing the required information about the research protocol (see page 4).

1. Will the subjects in your study be UNAWARE that they are subjects? ___ Yes ☒ No
2. Will information about the subjects be obtained from sources other than the subjects themselves? ___ ☒ Yes ___ No

Information will be gathered from consenting individuals from their Deer Lodge Centre-Movement Disorders (DLC-MDC) chart. This is anticipated to occur one to two times as a direct result of participant accrual. In preparation for gathering this chart information the DLC-MDC research nurse will pull up the electronic health record of the consenting individuals so the P.I. (T.Wells) can access the following information: the UPDRS, H&Y, S&E scores, DBS settings, and the levodopa equivalency medication prior to DBS. The P.I. (T.Wells) is PHIA authorized through her work with the WRHA as is the MDC research nurse. It is felt that this solution for data access (i.e. one or two visits to the DLC-MDC) maximizes efficiency and decreases the potential burden upon the DLC-MDC staff.

3. Are you and/or members of your research team in a position of power vis-a-vis the subjects? If yes, clarify the position of power and how it will be addressed. ___ Yes ☒ No

The P.I. has no clinical involvement with the proposed study population. The medical director of the DLC-MDC, Dr. Doug Hobson, is the external member of the researcher's thesis committee. His name does not appear on the consent or other study information given to potential participant. Dr. Hobson will not be notified of who has consented to be in this proposed research study. He will be presented with aggregate and anonymized data only.

4. Is any inducement or coercion used to obtain the subject's participation? ___ Yes ☒ No

Participants will be offered a small honorarium (\$20.00 Sobeys gift card) to thank them for their time and commitment for participating in this research study.

5. Do subjects identify themselves by name directly, or by other means that allows you or anyone else to identify data with specific subjects? If yes, indicate how confidentiality will be maintained. What precautions are to be undertaken in storing data and in its eventual destruction/disposition. ___ ☒ Yes ___ No

It is necessary that the participants will meet face to face with the PI for the consent process and data collection. The consent form will contain the participants' full name and a mailing address. The demographic collection form also collects names and other personal identifiers for the process of completing study process. To ensure participant confidentiality, names will be removed from study documents and participants will only be identified with an assigned study code. The corresponding master list of participants (demographic face page and corresponding consent) and their study codes will be kept separate from the study documents in a locked file within the researcher's office. Any computerized data will be stored on a password protected USB drive. All persons involved in any way with this study will have an understanding and completion of PHIA (i.e. the P.I., thesis advisor, DLC-MDC research nurse, the statistician, and the transcriptionist). The data will be reported in aggregate format only. Data will be destroyed after a period of seven years. At the end of seven years paper documentation will be shredded and treated as confidential while any electronic data will be erased/deleted.

6. If subjects are identifiable by name, do you intend to recruit them for future studies? If yes, indicate why this is necessary and how you plan to recruit these subjects for future studies.

___ Yes ☒ ___ No

7. Could dissemination of findings compromise confidentiality?

___ Yes ☒ ___ No

Dissemination of data will not compromise confidentiality because all data will be presented in aggregate format and qualitative data will be removed of all personal identifiers.

8. Does the study involve physical or emotional stress, or the subject's expectation thereof, such as might result from conditions in the study design?

___ Yes ☒ ___ No

There is the potential that participants may find the data collection process fatiguing. Every effort will be made to ensure individuals comfort. Furthermore some of the data collection procedures may reveal scores that are concerning for the PI and the participants regarding their emotional well-being. This specifically refers to the Beck Depression Inventory-II and the Mini-Mental State Exam. If these scores raise concern for the researcher and meet exclusion criteria (BDI-II > 28; MMSE < 23) the potential participants will not be enrolled and it will be strongly suggested to them or their caregiver that these results and concerns be shared with their health care providers. Should the participant feel that they are unable to make this call on their own but agree that the health care provider should be contacted; the PI will assist the participant with that if the participant verbally agrees. In addition patients who are claiming that they feel that they shall harm themselves will be given crisis numbers to call in addition to the above steps.

9. Is there any threat to the personal safety of subjects?

___ Yes ☒ ___ No

10. Does the study involve subjects who are not legally or practically able to give their valid consent to participate (e.g., children, or persons with mental health problems and/or cognitive impairment)?
If yes, indicate how informed consent will be obtained from subjects and those authorized to speak for subjects.

___ Yes ☒ ___ No

Cognitive impairment is a possibility for those living with PD. In order to ensure that participants are cognitively intact a screening tool will be used (MMSE). Participants who score low on this tool (<23) will be excluded. They will be encouraged to share this information with their health care provider.

11. Is deception involved (i.e., will subjects be intentionally misled about the purpose of the study, their own performance, or other features of the study)?

___ Yes ☒ ___ No

12. Is there a possibility that abuse of children or persons in care might be discovered in the course of the study?
If yes, current laws require that certain offenses against children and persons in care be reported to legal authorities. Indicate the provisions that have been made for complying with the law.

___ Yes ☒ ___ No

13. (a) Does the study include the use of personal health information? The Manitoba Personal Health Information Act (PHIA) outlines

responsibilities of researchers to ensure safeguards that will protect personal health information. If yes, indicate provisions that will be made to comply with this Act (see document for guidance - <http://www.gov.mb.ca/health/phia/index.html>).

☒ Yes ☐ No

This study includes the use of personal health information. Specifically, participant demographic, medication history, PD staging tools, dates surrounding PD diagnosis and DBS implantation, complications, and personal information regarding sleep history. Participants will be made aware of what information regarding their health history is to be included during the consent process, making the sharing of this information voluntary. The PI and the thesis advisor have both completed PHIA as will have the transcriptionist, the DLC-MDC research nurse, and the statistician. All information will be kept in a secure area, accessible to the researcher only. Required personal information will be kept separate from the study data and study data will be assigned study codes. Any presentation of the data will be in aggregate format with the exception of potential exemplars from the qualitative interviews that will have all personal identifiers removed. Should this data be presented in the future there will be no personal information or identifiers included.

13. (b) PHIA requires that all employees, students, or agents who handle or are exposed to personal health information take PHIA Orientation and sign a pledge of confidentiality that acknowledges that they are bound by written policy and procedures.

Has PHIA Orientation and pledge-signing been completed by all employees, students, and agents? ☒ Yes ☐ No
If "No," the Principal Investigator should contact UM Access & Privacy Coordinator's Office to make arrangements, fippa@umanitoba.ca

Where individuals have not completed PHIA Orientation and signed a pledge, and for the purpose of ensuring that they do, Principal Investigator's contact information will be provided to the University Access & Privacy Coordinator's Office.

Provide additional details pertaining to any of the questions above for which you responded "yes", excluding question 13 (b). Attach additional pages, if necessary.

____/____/____
dd mm yr

Signature of Principal Researcher

Ethics Protocol Submission Form

Page 4

(Required Information about the Research Protocol)

Each application for ethics approval should include the following information and be presented in the following order, using these headings:

1. **Summary of Project:** Attach a detailed but concise (one typed page) outline of the **purpose** and **methodology** of the study describing precisely the procedures in which subjects will be asked to participate.
2. **Research Instruments:** Attach copies of **all** materials (e.g., questionnaires, tests, interview schedules, etc.) to be given to subjects and/or third parties.
3. **Study Subjects:** Describe the number of subjects, and how they will be recruited for this study. Are there any special characteristics of the subjects that make them especially vulnerable or require extra measures?
4. **Informed Consent:** Will consent in writing be obtained? If so, attach a copy of the consent form. (see guidelines on informed consent). If written consent is not to be obtained, indicate why not and the manner by which subjects' consent (verbally) or assent to participate in the study will be obtained. How will the nature of the study and subjects' participation in the study be explained to them before they agree to participate. How will consent be obtained from guardians of subjects from vulnerable populations? If confidential records will be consulted, indicate the nature of the records, and how subjects' consent is to be obtained. If it is essential to the research, indicate why subjects are not to be made aware of their records being consulted.
5. **Deception:** Deception refers to the deliberate withholding of essential information or the provision of deliberately misleading information about the research or its purposes. If the research involves deception, the researcher must provide detailed information on the extent and nature of deception and why the research could not be conducted without it. This description must be sufficient to justify a waiver of informed consent.
6. **Feedback/Debriefing:** Describe the feedback that will be given to subjects about the research after they have completed their participation. How will the feedback be provided and by whom? If feedback will not be given, please explain why feedback is not planned. If deception is employed, debriefing is mandatory. Describe in detail the nature of the post-deception feedback, and when and how it will be given.
7. **Risks and Benefits:** Is there any risk to the subjects, or to a third party? If yes, provide a description of the risks and the counterbalancing benefits of the proposed study. Indicate the precautions taken by the researcher under these circumstances.
8. **Anonymity and Confidentiality:** Describe the procedures for preserving anonymity and confidentiality. If confidentiality is not an issue in this research, please explain why. Will confidential records be consulted? If yes, indicate what precautions will be taken to ensure subjects' confidentiality. How will the data be stored to ensure confidentiality? Will the data be destroyed, if so, when?
9. **Compensation:** Will subjects be compensated for their participation? Compensation may reasonably provide subjects with assistance to defray the costs associated with study participation.

Ethics Protocol Submission Form

Page 5

Review your submission according to this:

Checklist

Principal Researcher: _____

T	Item from the Ethics Protocol Submission Form
	All information requested on the first page completed in legible format (typed or printed).
	Signatures of the principal researcher (and faculty advisor, or course instructor if student research).
	Answers to all 13 questions on pages 2-3 of Ethics Protocol Submission form, INCLUDING ANY QUESTIONS FOR WHICH YOUR RESPONSE WAS "YES".
	Detailed information requested on page 4 of the Ethics Protocol Submission Form in the numbered order and with the headings indicated.
	Ethics Protocol Submission Form in quadruplicate (Original plus 3 copies).
	Research instruments: 4 copies of all instruments and other supplementary material to be given to subjects.
	Copy of this checklist.

NOTE: For ease of reviewing it would be much appreciated if you could number the pages of your submission (handwriting the numbers is quite acceptable).

Summary of Project:

In Canada, there are approximately 100,000 people living with PD, with a significant portion being over the age of 65 (Canadian Brain & Nerve Health Coalition, 2007). Traditionally, the motor symptoms associated with this disorder receive a significant amount of clinical attention, but there are also many debilitating non-motor symptoms associated with this disease. Despite the myriad of potential and complex non-motor symptoms associated with this disorder, there has historically been an under-appreciation of the patient's experiences with these non-motor symptoms (Backer, 2006; Chaudhuri Martinez-Martin, Brown, et al., 2007; Chaudhuri, Healy & Schapira, 2006; Jankovic, 2008). Of these non-motor symptoms sleep disturbance is predominant, affecting a staggering number of individuals (60-98%) with PD (Dhawan, Healy, Pal, & Chaudhuri, 2006; Gjerstad, Wentzel-Larsen, Aarsland, & Larsen, 2007).

The information regarding patients' long-term responses to sleep pattern disruption in PD is limited but there is a body of evidence supporting general negative impacts of sleep loss. It is recognized that the long term effects of sleep disturbances and sleep loss cause pathophysiological responses (i.e. altered immune, metabolic and endocrine function, and the development of co-morbidities); cognitive behavioural changes (i.e. fatigue, memory impairment, difficulties with problem solving (Hodgson, 1991; Lee, 2003); emotional impairments, and social dysfunction (Culebras, 2002; Lee, 2003).

Treatment for PD has traditionally relied upon pharmacotherapy but select PD patients can receive a biomedical option for control of their debilitating motor symptoms. Deep brain stimulation (DBS) for PD (DBS-PD) is the surgical implantation of electrodes most commonly into the sub-thalamic nucleus. An additional benefit of DBS may be improvement to PD related sleep disturbances (Ancoli-Israel, 2005) and the development and application of disease specific measurement tools (Chaudhuri Pal, Di Marco, et al., 2002; Chaudhuri et al., 2007; Tse et al., 2005). While it is important to measure the potential improvements in this group's sleep patterns, key information regarding about the patient's perspective about which specific improvements are needed are absent from the literature.

Thus, the main purpose of this mixed methods research study will be to explore the phenomena of DBS-PD sleep disturbance from a holistic perspective. The goal of this study is to address the knowledge gaps surrounding potential sleep benefits from this surgery and investigate the patients' experiences as it pertains to sleep health with readily accessible clinical tools. Addressing these goals will assist in drawing attention to the significant clinical and quality of life challenges that sleep disturbances pose for this group. The study findings may also contribute to the development of DBS-PD patient assessment strategies, sleep interventions, and support PD research as a whole.

Research Methods:

A summary of the research protocol is attached (see Appendix O). This proposed study will be community based and restricted to the urban Winnipeg area. Participants will be recruited from the Movement Disorders Centre (MDC) located at Deer Lodge Centre (DLC). This outpatient program is responsible for all DBS-PD patient care and has a population base of 40 DBS-PD patients (R. Krcek, personal communication, November 25, 2009).

Data collection will begin following ethical approval from the *Education and Nursing Ethics Review Board*, affiliated with the University of Manitoba and site access from Deer Lodge Centre as it applies to the MDC.

Once participants have completed the process of informed consent, a brief demographic form will be completed (see Appendix A). In addition, patient eligibility tools will be administered and scored (The BDI-II and the MMSE) to ensure that inclusion/exclusion criteria are met. The P.I. will arrange a time to meet with participants in their homes or if the participant wishes, another suitable venue for the second step of data collection. At visit two participants will complete the following instruments: the PSQI, the PDSS, and the ESS. After completion of these instruments the participants will be provided with an actiwatch and instructed in the use of the actiwatch and sleep log. A time will be arranged by the P.I. to check in the next day by phone to trouble shoot any potential difficulties with the actiwatch or sleep log. After three nights of use the watch and sleep diary will be retrieved by the P.I. at a mutually convenient pre-arranged time. At this third and final visit, a short interview will occur to gather the qualitative aspect of the MMR program. The interview is expected to take less than or equal to one hour. An additional benefit of this visit is that it will allow time to debrief the participant, if needed. The division of study procedures as outlined above has been proposed to decrease the burden on participants and facilitate completion of the study protocol.

The P.I. will have participants indicate on their consent form if they are interested in reviewing their transcripts and if so, a time will need to be arranged to deliver and pick up the transcript. Additionally, the researcher will clarify on the consent if telephone contact can be initiated after the interview in order to clarify information gathered.

After the process of informed consent by the participants one or two visits will be required to the DLC-MDC to gather information from the electronic patient record. This information includes the UPDRS, H&Y staging score, the S&E activities of daily living score, DBS settings, and levodopa dosage equivalencies. Only the consented patient records will be accessed by the MDC research nurse for the researcher to gather the above information. It is believed that this format for gathering information will minimize any burden on the MDC staff and ensure strictest confidentiality of patients' health information.

Research Instruments:

Patient Demographic Form

The patient demographic form (see Appendix A) was developed by the researcher to collect information to accurately describe the sample. This information includes items such as date of birth, marital status, year or age of PD diagnosis, year or age at time of DBS implantation, and medication. In addition, this form will be used to collect items that will assist the researcher to contact the patients and plan for implementation of the study tools. Personal identifiers will be separated from the data and the participants will be referred to with a study identification number.

The Mini-Mental State Exam (MMSE)

The MMSE (see Appendix B) is a well validated tool that quickly assesses an individual's cognitive state and it is well used in the assessment of cognition in PD (Nazem et al.,

2009) All patients will complete this tool at visit one to screen for potential cognitive impairment. Scores of less than 23 indicate cognitive impairment and these individuals will be excluded from the study (Crum, Anthony, Bassett & Folstein, 1993). It is anticipated to take 20 minutes for completion and scoring.

The Beck Depression Inventory-II (BDI-II)

In order to screen for severe depression as an exclusion criteria and provide context to the individuals' health and illness the BDI-II (see Appendix C) will be used. The BDI-II is a widely used, well validated, self-administered tool consisting of 21 items that assess the psychological and physical characteristics of depression (Beck, Steer & Brown, 1996; Beck, Steer, Ball & Ranieri, 1996; Schrag, et al., 2007). Each item on the scale is rated in severity from 0-3 (Barroso & Sandelowski, 2001; Beck, Steer, Ball & Ranieri, 1996). Despite concerns that the BDI-II may not accurately reflect the degree of an individual's depression due to the social stigma of depression (Barossa and Sandelowski, 2001) it is felt that the BDI-II will be effective to screen for depression within the DBS-PD population. An additional benefit is that oral administration is also reliable (Aben, Verhey, Lousberg, et al., 2002; Beck, Steer & Brown, 1996). The tool is straightforward and takes approximately 5-10 minutes to complete (Aben, et al., 2002; Beck, Steer & Brown, 1996). Scores indicating severe depression (29-63) would preclude the individual from participating in this study for their own well-being.

The Unified Parkinson's Disease Rating Scale (UPDRS)

The UPDRS (see Appendix D) is standard in the tool kit for the assessment and treatment of PD and provides an individual context of illness severity related to disability. It is referenced as one of the most common and reliable tools to rate the disability associated with PD (Goetz, et al., 2003; Goetz, et al., 2007; Ramaker, Marinus, Stiggelbout & Hilten, 2002) and is used consistently in the staging of the DLC-MDC DBS-PD patient population. The UPDRS consists of four components that assess: mentation; behaviour and mood; activities of daily living; motor impairment; and complications (Goetz, et al., 2003; Ramaker et al., 2002). A drawback to the scale is that it requires a trained expert to administer and in addition, it is strongly suggested, that video recording be undertaken at the time of administration for inter-rater reliability. Therefore, due to these limitations, the UPDRS score will be obtained from the DLC-MDC patient chart to provide context of patient illness severity.

The Hoehn & Yahr Staging Scale (H&Y)

The H&Y (see Appendix E) assesses the variability of PD presentation in order to assess the progression of the disease (Hoehn & Yahr, 1967). This simple tool assists with the staging of clinical function in PD by quantifying the functional deficits and objective signs of the disease (Goetz et al., 2004). The H&Y remains universally used to depict PD severity and is routinely done at the DLC-MDC for their PD population. It is quick to complete, practical, and able to be applied by a wide-variety of health care professionals. The level of score is also related to disease severity and progression and can be a prognosticator of disease progression (Goetz et al., 2004). This score will be accessed from the participants MDC chart once informed consent has been obtained and inclusion/exclusion criteria are met. This will be done while gathering participant's UPDRS and S&E scores in order to diminish any burden upon the clinical facility.

The Schwab and England-Activities of Daily Living Scale (S&E)

The S&E (see Appendix F) is a standard tool in the assessment of PD where 100% represents complete independence while 0% represents a vegetative state related to PD progression (Schwab & England, 1968). While the S&E is widely used and accepted as valid and reliable in the assessment of PD there is little literature supporting its use (Ramaker et al., 2002). Because it is part of the assessment criteria of the DLC-MDC PD patient population either with or without DBS the S&E will be included as part of the demographic information for the participants. This score will be gathered from the MDC patient chart concomitantly with the H&Y and UPDRS scores.

The Pittsburgh Sleep Quality Index (PSQI)

The PSQI (Buysse et al., 1989; Appendix G) is widely accepted as a valid and reliable measurement tool of sleep quality and patterns over a one month period (Carpenter & Andrykowski, 1997). This 19-item tool focuses on seven components of subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The total sum of the components yields the number of significance. That is, a global PSQI score greater than five is reliable for distinguishing between good and poor sleepers ($p < .001$). The tool should take approximately 20 minutes to complete. Limitations to the use of the PSQI relate to individuals' abilities to accurately report from memory their sleep and sleep habits. Individual's literacy levels may also provide a challenge for administration but the scale has proven to be valid with oral administration (Smyth, 2007).

The Parkinson's Disease Sleep Scale (PDSS)

The PDSS (see Appendix H) is a self-administered scale that developed in response to the high-prevalence of PD sleep disorders (Chaudhuri, et al., 2002). The 15-item PDSS utilizes a ten-centimetre visual analog scale to measure the dimensions of quality of sleep, nocturnal non-motor symptoms, nocturnal motor symptoms, and sleep benefit.

During psychometric testing by Tse and colleagues (2005) certain modifications were suggested that included paying closer clinical attentions to certain test variables. Overall, the authors contend that if VAS scoring is poor on items 1 (overall quality of sleep, 14 (do you feel tired and sleep when waking in the morning), and 15 (have you fallen asleep unexpectedly during the day), then a referral for further sleep assessment may be necessary. In general, a total score of less than 90 is significant or a single item score of less than six should suggest further formal sleep assessment (Chaudhuri, Martinez-Martin, et al., 2004). Therefore, this tool provides screening for potential sleep disturbances that may require additional investigation.

The Epworth Sleepiness Scale (ESS)

The Epworth Sleepiness Scale (ESS; see Appendix I) is widely used in research for the quantification of an individual's sleepiness. In addition, the ESS is commonly used in the psychometric testing of other related sleep tools in the dimension of sleep propensity (Chaudhuri, et al. 2002) and sleep quality (Buysse, Hall, Strollo et al., 2008). It has also proven effective in the identification of sleepiness in other disorders like PD (Hagell & Broman 2007; Hobson, 2003). This self-administered tool is simple to complete and score, taking less than 10 minutes to complete and interpret. The total score from the

eight scenarios is calculated, from 0-24. This provides an average score of the propensity to fall asleep during the day. Therefore, scores higher than 10 represent excessive daytime sleepiness and need further investigation to determine the cause (Johns & Hocking, 1997).

Actigraphy

The literature supports the use of actigraphy in the PD and DBS-PD patient populations contingent upon certain standards to ensure reliable data collection (Acebo & LeBourgeois, 2006; Littner et al., 2007). Therefore, participants in this research study will wear the actigraph for 3 days on the non-dominant hand. Dr. D. McMillan, an Associate Professor at the University of Manitoba, Faculty of Nursing, and advisor to the P.I., has made an actigraph watch (Actiwatch 64, Mini-Mitter) and the accompanying computer analysis software accessible to the researcher. Each participant will be provided with an education support kit (see Appendix J). When required, care-givers will be taught how to activate the actigraph watch if fine motor impairment or and underlying difficulty with fingertip sensation exists with the participant.

Sleep Log

Supporting the recommended standards for actigraphy data collection participants will be asked to complete a sleep log (see Appendix K) for the three days and nights that they are wearing the actigraph. The information gathered from the sleep log will help correlate bedtimes to sleep behaviours. In addition, caregivers will be asked to record the specified information when participants have difficulty with writing secondary to impairment of fine motor finger movements.

The Interview

The interview (see Appendix L) will address the areas not covered by the quantitative method aspect of this study and add to the breadth of understanding surrounding this research topic. Questions regarding patient beliefs, historical perspectives, cultural perspectives and environmental areas will be addressed. These interviews will be audiotaped or digitally recorded by the researcher and preferably take place within the participants' homes but if participants wish, this can be completed at an alternate but suitable pre-arranged location.

Study Subjects:

Recruitment of subjects will be undertaken using non-probability convenience sampling methods to meet a quota between 6-10 participants. The timeline for recruitment will be over a two month period in order to reach a broader patient sample and allow for further recruiting should previously interested subjects not be eligible. Potential participants will be recruited from the Movement Disorders Clinic at Deer Lodge Centre (MDC-DLC) once ethical approval is given from the University of Manitoba and site access permission from DLC is granted. Patients will be informed about the study and researcher contact information from a poster that will be on display in the clinic (see Appendix M). A second opportunity for recruitment may be possible via the DBS support group that meets on a monthly basis from September to June. Pending approval this venue will receive a brief presentation from the P.I. that will include an overview of the study purpose and the possible benefits, risks and stressors of the proposed research.

Investigator contact information will be made available by handout at the MDC-DLC. It will be the responsibility of interested patients to contact the researcher from the information provided to them on the poster.

Inclusion Criteria

1. Aged 40 and older
2. English speaking
3. A willingness to participate in the study
4. The ability to provide informed consent
5. Living at home
6. Having a primary diagnosis of Parkinson's Disease
7. Six months post-operative DBS insertion

Exclusion Criteria

1. Experiencing technical difficulties with the DBS
2. PD medication change within the past month
3. An inability to activate the actigraph watch either personally or with the assistance of a caregiver
4. An inability to complete written material either personally or with the assistance of a caregiver
5. A diagnosis of major depressive disorder
6. BDI-II scores higher than 28
7. MMSE scores less than
8. Undergoing treatment for a sleep disorder with either continuous positive airway pressure or bilevel positive airway pressure.
9. Permission not granted to access the individual's DLC-MDC electronic record.

Informed Consent:

A written consent (see Appendix N) will be obtained from each participant prior to data collection. They will be coded with a study identification number to protect the individuals' identities. A copy of the consent will be provided to each participant for their records.

Deception:

There is no deception in this study. Dr. Hobson, the medical director of the DLC-MDC is aware of this study and is the external member of the researcher's thesis committee. He will not be made aware of whom is enrolled in the study, has not been asked to assist with recruitment of this study and will be presented with aggregate data only upon completion of this study. All protocol items are outlined within the consent and with this submission.

Feedback/Debriefing:

Patients will be given the opportunity to review their transcripts for accuracy and completeness once completed. This is not a requirement of the study. In addition, once the research has been completed participants will be given the opportunity to receive a summary of the project. Both these options will be indicated on the consent.

Risks and Benefits:

There will be no deception or coercion involved in either recruitment to the study or with the administration of study tools. It is estimated the total time, excluding actigraphy, for the participants will be approximately three hours. This is not taking into account the potential for participants to review their interviews. Should participants choose to review their transcripts an additional 1.5 hours is anticipated. Other than the wearing of the actigraph and possibly limiting participation in strenuous activity while wearing the actigraph, there are no significant risks anticipated. At all times every effort will be made to provide support to the individuals participating by scheduling a phone follow-up on day one, at a preselected time, and on other days if required to answer questions.

If during the screening process or during the collection of study materials it becomes apparent that the patient is experiencing significant distress suitable measures will be put into place to address the patients safety. If BDI-II scores are higher than 29 participants will be encouraged to inform either their family doctor or their movement disorders physician about their depressive symptoms and this score. If they do not feel that they are able to make this call on their own but want assistance and if it is agreed, the PI will assist with this call. If a patient is claiming to be suicidal crisis numbers, in addition to the above actions, will be provided. If significant psychological or physical distress arises for participants during the study they will be supported but withdrawn from the study. Similar steps shall be taken should significant cognitive impairment be uncovered (score<23) on the MMSE.

Anonymity and Confidentiality:

All demographic information will be kept in a locked cabinet in the investigator's office and stored separately from the data collection tools. This information will only be accessible to the researcher but data may be shared with the thesis advisor as required.

Interviews will be transcribed using a transcriptionist whom has signed *Personal Health Information Act (PHIA)*. Personal identifiers will be removed from the interviews and participants will be offered the opportunity to review their transcript for completeness as well as assurances that personal identifiers were removed. Coded study data will be backed-up onto a password protected USB thumb drive. In addition, information processed on the researcher's computer will be password protected. Actigraphy data will be downloaded onto Dr. McMillan's computer that owns the relevant analysis software. This data will only be identified using a study number. This computer is password protected and contained within a locked office. Data will be kept for seven years and then destroyed using a confidential waste disposal system. The stored but study coded electronic data will be deleted/erased.

The information gathered from the patient record will be completed by the PI. Consented participants electronic records will be accessed by the PD research nurse affiliated with the DLC-MDC. There will be no electronic transmission of data.

Compensation:

Participants will receive no compensation for their participation in this study. A small honorarium (\$20.00 gift certificate) will be provided to each participant to thank them for the time they have committed to this study.

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Appendix O: Outline of Study Protocol

Study Task	Initial Meeting	Day 1	Day 2	Day 3	Participant time in minutes
Consent	✓				20
Demographic quest.	✓				10
MMSE	✓				10
BDI-II	✓				10
UPDRS/H&Y/S&E/DBS settings <i>Patient chart</i>	✓	The gathering of these scores will be consolidated into one site (MDC) visit			0
PSQI		✓			15-20
ESS		✓			5-10
PDSS		✓			10
Sleep Diary		✓	✓	✓	60
Actigraphy		✓	✓	✓	n/a
Qualitative Interview				✓	60 minutes
Interview Summary Review					1-1.5 hours

Appendix P: Permissions

Below is a table of permissions granted and those pending. Once approval has been given for the outstanding items, a copy will be forwarded to ENREB to accompany this file submission.

Tool	Outcome
The BDI-II	Permission pending
The PSQI	Permission granted
The MMSE	Permission granted
The PDSS	Permission granted
The ESS	Permission pending
The UPDRS (not being administered only collected)	Permission granted
The H&Y (not being administered only collected)	Permission granted
The S&E (not being administered only collected)	Permission pending

Appendix B

Deer Lodge Centre Access Application and Approval

June 14, 2010

Mr. Michael Kaan
Manager, Research Program
Deer Lodge Centre
2109 Portage Avenue
Winnipeg, Manitoba
R3J 0L3
Tel: (204) 831-3422 Fax: (204) 831-3421

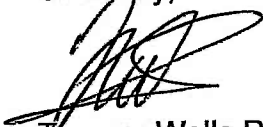
Dear Mr. Kaan:

Re: Research Access Application Master of Nursing Thesis Research

Please find attached my research access application for Deer Lodge Centre's Movement Disorder Clinic and their associated patient population. I would sincerely appreciate the Centre's consideration to allow me access to the Movement Disorder Clinic in order to pursue my research into sleep disturbance in the Parkinson's Disease patient with deep brain stimulation. This research is in support of my Masters of Nursing Degree with the University of Manitoba.

I have appended my research protocol, the accompanying correspondence between myself and the Ethics and research Board (ENREB), and my ethic approval certificate from the University of Manitoba. Should there be any questions or concerns I would look forward to having the opportunity to discuss these with you or the interested parties.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tamara Wells', with a stylized flourish at the end.

Tamara Wells RNB
Master of Nursing Student

April 22, 2010

Michael Kaan
Manager, Research Program
Deer Lodge Centre
2109 Portage Avenue
Winnipeg, Manitoba
R3J 0L3
Tel: (204) 831-3422 Fax: (204) 831-3421
E-mail: research@deerlodge.mb.ca

Dear Mr. Kaan:

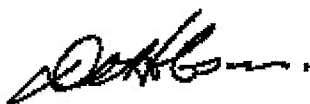
Re: Access Application for Tamara Wells

I am aware of Ms. Wells interest in performing research towards her Master of Nursing regarding *Factors Associated with Sleep Disturbance in the Parkinson's Disease Patient Post Deep Brain Stimulation* and am the external member of her thesis committee. I have had the opportunity to review Ms. Wells supportive background literature surrounding this problem and methodology would appropriately investigate this situation and as such contribute to knowledge in this field.

We have had the opportunity to discuss the actual process of recruitment within the clinic and I do not believe that this will place undue burden on the staff. Recruitment will be done via posters without direct contact with the clinic staff. In addition, Tamara is requiring certain background information of the consented population that includes Parkinson's disease staging scores, DBS settings and medication pre DBS implantation for levodopa equivalencies. This chart access would be facilitated in one or two visits, dependent on how enrolment accrues, with our MDC research nurse, Ms. S. Hobson.

I am not anticipating difficulties with this small research project and am looking forward to the information gained.

Sincerely,



Doug Hobson BSc, MD, FRCP(C)

DEER LODGE CENTRE

REQUEST FOR RESEARCH ACCESS

I. Identification: Please print or type

Complete Box A

A. Title of Study: Factors Associated with Sleep Disturbance in the Parkinson's Disease Patient Post Deep Brain Stimulation

Principal Investigator:

Tamara Wells RNB, MN student,

University of Manitoba

Address: 85 Pinehurst Crescent

Winnipeg, MB

Postal Code: R3K 1Y9

Telephone: Home: 888-5546

Cell: 799-7067

Email: tamwells@shaw.ca

Other Members of Team:

Name: Dr. D. McMillan (Thesis Advisor and Committee Chair) University of Manitoba
Faculty of Nursing

Name: Dr. M. Edwards (Internal Member) University of Manitoba Faculty of Nursing

Name: Dr. D. Hobson (External Member) Medical Director Movement Disorders Clinic

Complete Box B, C or D as appropriate

B. Student

Student: Tamara Wells RN,BN

Name

Signature

Phone No.

Faculty Advisor: Dr. D. McMillan

Name

Signature

Phone No.

Educational Institution: University of Manitoba Graduate Studies, Master of Nursing Program

Faculty/Dept. & Address: Helen Glass Centre for Nursing

Course For Which Research Required: Thesis completion as required by the Master of Nursing Program.

Thus, the main purpose of this mixed methods research study will be to explore the phenomena of DBS-PD sleep disturbance from a holistic perspective. The goal of this study is to address the knowledge gaps surrounding potential sleep benefits from this surgery and investigate the patients' experiences' as it pertains to sleep health with readily accessible clinical tools. Addressing these goals will assist in drawing attention to the significant clinical and quality of life challenges that sleep disturbances pose for this group. The study findings may also contribute to the development of DBS-PD patient assessment strategies, sleep interventions, and support PD research as a whole. This is pertinent to the Deer Lodge patient population as they are involved with the only centre in Manitoba able to manage their care with a health care team that is renowned for their clinical abilities in this area. Therefore, additional information supporting the care of this population is beneficial.

IV. Resource Requirements

- 1. What contacts will be required with staff? (List staff members with title and amount of time required.**

The only anticipated contact with the staff will be when the researcher arrives to put up or distribute the attached recruitment poster and subsequently after enrollment begins with the MDC research nurse, Ms. Hobson RN. Information will be gathered from consenting individuals from their Deer Lodge Centre-Movement Disorders (DLC-MDC) chart. This is anticipated to occur one to two times as a direct result of participant accrual. In preparation for gathering this chart information the DLC-MDC research nurse will pull up the electronic health record of the consenting individuals so the P.I. (T.Wells) can access the following information: the UPDRS, H&Y, S&E scores, DBS settings, and the levodopa equivalency medication prior to DBS. It is felt that this will be about 10minutes per chart for a total time between 60-100 minutes. The P.I. (T.Wells) is PHIA authorized through her work with the WRHA as is the MDC research nurse. It is felt that this solution for data access (i.e. one or two visits to the DLC-MDC) maximizes efficiency and decreases the potential burden upon the DLC-MDC staff.

- 2. List Centre supplies and equipment that may be required. Describe plans to cover expenses.**

There are no requirements from the centre regarding supplies or equipment.

- 3. List space requirements.**

I would need access to an area to post the recruitment poster. This may require a subsequent visit if there is significant patient interest in the study. In addition I would need to use a computer to access the patient record. There is a research office within the clinic where this could happen without disruption to clinic flow.

- 4. Is access to resident charts, records or other personal health information required as part of this research? Please describe how compliance with the Personal Health Information Act will be ensured.**

It is necessary that the participants will meet face to face with the PI for the consent process and data collection. The consent form will contain the participants' full name and a mailing address. The demographic collection form also collects names and other personal identifiers for the process of completing study process. To ensure participant confidentiality, names will be removed from study documents and participants will only be identified with an assigned study code. The corresponding master list of participants (demographic face page and corresponding consent) and their study codes will be kept separate from the study documents in a locked file within the researcher's office. Any computerized data will be stored on a password protected USB drive. All persons involved in any way with this study will have an understanding and completion of PHIA (i.e. the P.I., thesis advisor, DLC-MDC research nurse, the statistician, and the transcriptionist). The data will be reported in aggregate format only.

Data will be destroyed after a period of seven years. At the end of seven years paper documentation will be shredded and treated as confidential while any electronic data will be erased/deleted This study

includes the use of personal health information. Specifically, participant demographic, medication history, PD staging tools, dates surrounding PD diagnosis and DBS implantation, complications, and personal information regarding sleep history. Participants will be made aware of what information regarding their health history is to be included during the consent process, making the sharing of this information voluntary. The PI and the thesis advisor have both completed PHIA as will have the transcriptionist, the DLC-MDC research nurse, and the statistician. All information will be kept in a secure area, accessible to the researcher only. Required personal information will be kept separate from the study data and study data will be assigned study codes. Any presentation of the data will be in aggregate format with the exception of potential exemplars from the qualitative interviews that will have all personal identifiers removed. Should this data be presented in the future there will be no personal information or identifiers included.

Add additional page(s) as required.

Research protocol is appended. Ethics approval and accompanying correspondence is also appended.

TO BE COMPLETED BY DEER LODGE CENTRE:

Date

Research Program Manager

Date

Faculty Advisor (Students only)

see front page.

June 14/10

Date

[Signature]

Signature of Applicant

Date

Deer Lodge Centre Administration Approval

Date

Deer Lodge Centre PHIA Commissioner
Approval (if required)

The completed Request for Research Access Form, a copy of the research proposal and evidence of ethics approval, should be submitted to:

*Michael Kaan
Manager, Research Program
Deer Lodge Centre
2109 Portage Avenue
Winnipeg, Manitoba
R3J 0L3
Tel: (204) 831-3422 Fax: (204) 831-3421
E-mail: research@deerlodge.mb.ca*



DEER LODGE CENTRE

Making Lives better

2400 Portage Avenue
Winnipeg, Manitoba R3H 0L3
www.deerlodgecentre.ca

August 3, 2011

Ms. Tamara Wells
85 Pinehurst Crescent
Winnipeg, MB
R3K 1Y8

Dear Ms Wells:

Please be advised that your study, "Factors Associated with Sleep Disturbance in the Parkinson's Disease patient after Deep Brain Stimulation", has been approved for Deer Lodge Centre at the Movement Disorders Clinic. Your site contact will be Doug Furness. If you have additional questions about the research process at DLC, please contact Michael Kaan at 831-3422.

Thank you for your interest in DLC as a research site.

Real Cloutier
Chief Operating Officer, WRHA
WRHA Vice President, Long Term Care and Community Health Services
WRHA Chief Allied Health Officer
Chief Operating Officer, Deer Lodge Centre

resent copy.
TW

Appendix C

Recruitment Poster

Exploring Sleep in Parkinson's Disease Patients with Deep Brain Stimulation

I am a Master of Nursing student at the University of Manitoba and am doing research looking at sleep disturbances in Parkinson's disease patients with a deep brain stimulator.

I am looking for people to take part in this study. All potential participants will be asked screening questions related to their mood and cognitive health to determine eligibility. The study itself would involve approximately three hours of your time over three visits to your home. At these visits questionnaires will be completed that will ask about your mood, cognitive state, and how you are sleeping. You will also be asked to wear a special activity recording watch for three nights. At the last visit you will be asked to participate in an interview asking more information regarding how you feel about your sleep and the effects sleep and sleep problems have on your life.

In addition to your above participation, I will be asking your permission to look at your patient record at the Movement Disorders Clinic. This will be done so that I can collect your PD staging scores (the UPDRS, Schwab and England, and Hoehn and Yahr) as well as the amount of dopamine like medication you were on before you had your stimulator.

If you are over the age of 40, have PD with a deep brain stimulator (DBS), and live in Winnipeg or in the immediate surrounding area, you may be suitable to participate. If you would like to know more about this study please call me at 799-7067 or e-mail me at tamwells@shaw.ca. I would be very pleased to speak with you in more detail about your participation, and answer any questions that you may have.

Sincerely,
Tamara Wells RNB
Master of Nursing Student
University of Manitoba

Appendix D

Demographic Questionnaire

Patient Demographic Form

Name:

Study I.D.

Address:

Phone Number:

Alternate Phone or contact number:

Consent completed

Best time of day to call:

Study ID _____

Please circle the number of the item that relates to you.

1. **Age:**

Stated and DOB: _____

2. **Age or year of PD diagnosis** _____3. **Age or year of DBS implantation** _____.

DBS settings:

4. **Marital Status**

1.	Living with a spouse or spouse equivalent
2.	Living alone
3.	Living with another family member or equivalent (i.e., a friend or caregiver)

5. **Gender**

1.	male
2.	female

6. **UPDRS scores (from the chart):**

On _____ off _____ date of assessment _____

MMSE score: _____

H&Y score _____ (date)

Schwab and England score: _____ (date)

7. **Are you able to read and complete forms on your own or do you need assistance?**

(e.g., a magnifier, larger print, assistance from a spouse or caregiver, non-english speaking, literacy, etc.) Who will provide the assistance?

Notes re same and plans to address the above.

Study ID _____

Medication list:

Name of medication	Dosing	Route	Timing

Previous medication and dosing

Name of medication	Dosing	Route	Timing

Levodopa equivalencies:

Appendix E

The Beck Depression Inventory-II

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

- 0 I do not feel sad.
- 1 I feel sad much of the time.
- 2 I am sad all the time.
- 3 I am so sad or unhappy that I can't stand it.

*copy***2. Pessimism**

- 0 I am not discouraged about my future.
- 1 I feel more discouraged about my future than I used to be.
- 2 I do not expect things to work out for me.
- 3 I feel my future is hopeless and will only get worse.

3. Past Failure

- 0 I do not feel like a failure.
- 1 I have failed more than I should have.
- 2 As I look back, I see a lot of failures.
- 3 I feel I am a total failure as a person.

4. Loss of Pleasure

- 0 I get as much pleasure as I ever did from the things I enjoy.
- 1 I don't enjoy things as much as I used to.
- 2 I get very little pleasure from the things I used to enjoy.
- 3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

- 0 I don't feel particularly guilty.
- 1 I feel guilty over many things I have done or should have done.
- 2 I feel quite guilty most of the time.
- 3 I feel guilty all of the time.

6. Punishment Feelings

- 0 I don't feel I am being punished.
- 1 I feel I may be punished.
- 2 I expect to be punished.
- 3 I feel I am being punished.

7. Self-Dislike

- 0 I feel the same about myself as ever.
- 1 I have lost confidence in myself.
- 2 I am disappointed in myself.
- 3 I dislike myself.

8. Self-Criticalness

- 0 I don't criticize or blame myself more than usual.
- 1 I am more critical of myself than I used to be.
- 2 I criticize myself for all of my faults.
- 3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

- 0 I don't have any thoughts of killing myself.
- 1 I have thoughts of killing myself, but I would not carry them out.
- 2 I would like to kill myself.
- 3 I would kill myself if I had the chance.

10. Crying

- 0 I don't cry any more than I used to.
- 1 I cry more than I used to.
- 2 I cry over every little thing.
- 3 I feel like crying, but I can't.

Subtotal Page 1

Continued on Back**PEARSON**

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PsychCorp

11. Agitation

- 0 I am no more restless or wound up than usual.
- 1 I feel more restless or wound up than usual.
- 2 I am so restless or agitated that it's hard to stay still.
- 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people or activities.
- 1 I am less interested in other people or things than before.
- 2 I have lost most of my interest in other people or things.
- 3 It's hard to get interested in anything.

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have much greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- 0 I have not experienced any change in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 I have not experienced any change in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than usual.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19. Concentration Difficulty

- 0 I can concentrate as well as ever.
- 1 I can't concentrate as well as usual.
- 2 It's hard to keep my mind on anything for very long.
- 3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of the things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

Subtotal Page 2

Subtotal Page 1

Total Score

Appendix F

The Pittsburgh Sleep Quality Index

Subject's Initials _____ ID# _____ Date _____ Time _____ AM
PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

- a) Cannot get to sleep within 30 minutes

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

- b) Wake up in the middle of the night or early morning

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

- c) Have to get up to use the bathroom

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

d) Cannot breathe comfortably

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

e) Cough or snore loudly

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

f) Feel too cold

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

g) Feel too hot

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

h) Had bad dreams

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

i) Have pain

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

j) Other reason(s), please describe _____

How often during the past month have you had trouble sleeping because of this?

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

- a) Loud snoring

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

- b) Long pauses between breaths while asleep

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

- c) Legs twitching or jerking while you sleep

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

d) Episodes of disorientation or confusion during sleep

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

e) Other restlessness while you sleep; please describe _____

Not during the past month _____	Less than once a week _____	Once or twice a week _____	Three or more times a week _____
------------------------------------	--------------------------------	-------------------------------	-------------------------------------

Appendix G

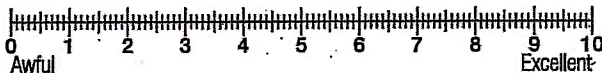
The Parkinson's Disease Sleep Scale

Parkinson's Disease Sleep Scale (PDSS)



How would you rate the following, based on your experience during the past week.
(Place a cross at the appropriate point on the line)

1. The overall quality of your night's sleep is:



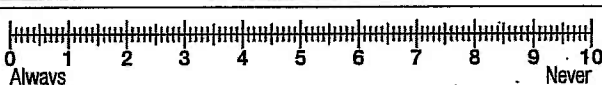
2. Do you have difficulty falling asleep each night?



3. Do you have difficulty staying asleep?



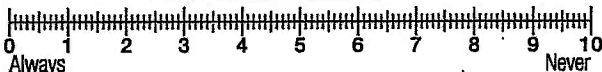
4. Do you have restlessness of legs or arms at night or in the evening causing disruption of sleep?



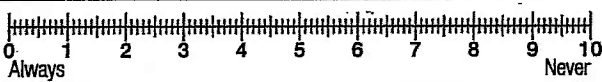
5. Do you fidget in bed?



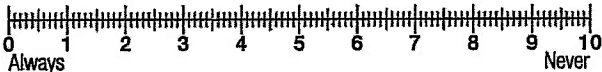
6. Do you suffer from distressing dreams at night?



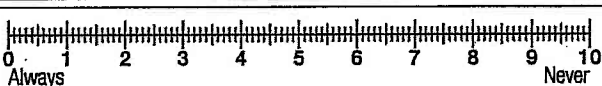
7. Do you suffer from distressing hallucinations at night (seeing or hearing things that you are told do not exist)?



8. Do you get up at night to pass urine?



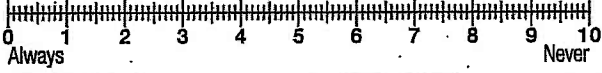
9. Do you have incontinence of urine because you are unable to move due to "off" symptoms?



10. Do you experience numbness or tingling of your arms or legs which wake you from sleep at night?



11. Do you have painful muscle cramps in your arms or legs which wake you from sleep at night?



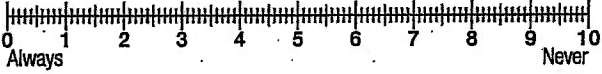
12. Do you wake early in the morning with painful posturing of arms or legs?



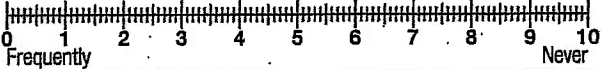
13. On waking do you experience tremor?



14. Do you feel tired and sleepy after waking in the morning?



15. Have you unexpectedly fallen asleep during the day?



Appendix H

The Epworth Sleepiness Scale

Epworth Sleepiness Scale

Name: _____

Date: _____

Your age: (Yr) _____ Your sex: ☐ Male ☐ Female

How likely are you to doze off or fall asleep in the situations described below, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the most appropriate number for each situation:-

- 0 = would never doze
 1 = Slight chance of dozing
 2 = Moderate chance of dozing
 3 = High chance of dozing

Situation	Chance of dozing
Sitting and reading	
Watching TV	
Sitting, inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	
Total	

Score:

0-10 Normal range
 10-12 Borderline
 12-24 Abnormal

Appendix I

Written Patient Actigraphy Instructions

The watch you are wearing is called an Actiwatch®. This watch will be recording your movement and rest periods over the next _____ days.

Why am I wearing it?

Wearing the Actiwatch will help us measure your activity and rest patterns which will help us see how you may be sleeping. It will also give us an idea about how active you may be during the day.

What you need to know.

1. The Actiwatch is **worn on your non-dominant hand**. That means if you are right-handed you wear the watch on your left wrist. If you are left-handed you wear the watch on your right wrist.
2. Press the event button on the front of the watch **3 times when you are going to sleep**. If you go to bed but don't go to sleep right away because you are reading etc., don't press the button until you are going to sleep. If you forget to press the button do not worry the information will still be there.
3. When you **wake up** in the morning, press the event button **3 times again**. If you forget to press the button do not worry, the information will still be there.
4. You should take the watch off for bathing, swimming or sports where the watch could get banged up. Put the watch back on when you are done.
5. Remember to fill out the sleep diary with the times that you go to sleep and the times that you wake up. Keeping this close to your bed may help you remember to write this down.

If you have any questions, please call:

Appendix J

Sleep Log

Sleep Diary:

Keeping a sleep diary can help you avoid activities that worsen your chances of restful sleep. It will also help your doctor decide if drug therapy would help and to choose the best method of treatment. It is important that you complete this chart on a daily basis.

IN THE COLUMNS BELOW, MARK THE DIARY AS FOLLOWS**A** = Time of wake-up alarm**C** = Caffeinated drink**D** = Alcoholic drink**E** = Exercise**M** = Meal**S** = Snack**N** = Noise disturbing sleep**B** = Bathroom use during sleep-time**Z** = Sleeping pill**I** = Each time you get into bed**↑** = Each time you get out of bed**—** = Beginning/end of sleep — join the lines to indicate sleep periods

WEEK OF	SUN	MON	TUE	WED	THU	FRI	SAT
01:00							
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23:30							
24:00							
Total sleep hours							

EXAMPLE:

WEEK OF	SUN	MON	TUE	WED	THU	FRI	SAT
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23:30							
24:00							
Total sleep hours							

Appendix K:**Patient Interview Script**

The purpose of this interview is to allow you the chance to share your experiences with your sleep since your diagnosis with PD including the time since your DBS implantation. I am hoping that the information gathered from our conversation adds to the information that I have already collected from you. It also gives you the chance to share your experiences, especially ones that may have not been included with the forms that you filled out.

This interview should take no longer than one hour. If at anytime you need to take a break, please let me know. At the end of the interview you will have the opportunity to clarify anything that you have mentioned and ask questions.

Your information will be treated as confidential and any names or personal identifiers will be removed during the transcription process. Should you happen to share with me, information about thoughts of harming yourself or others I will need to report that. If at any time speaking about these items' is distressing for you, we will halt the interview and discuss what to do next and you may be encouraged to share certain information with your doctor.

Are you ready to begin?

1. Tell me about sleep?

Probes: Do you feel that sleep is important? To health, socialization, work, etc.

2. Tell me about your sleep?

Probes: bedtimes, waketimes, feelings upon waking,

Probes: Tell me about what getting a good night's sleep means to you?

Probes: does it refer to the length of time in bed, does it refer to how you feel upon waking, sleep hygiene habits.

3. When you look back over time do you think that you have been what is often called a good sleeper?

Probes: Have you had time when you didn't get enough sleep or didn't sleep well, shift work, child-rearing, health problems, social issues.

4. Tell me about how does not sleeping well at night affects you?

- Are you missing things during the day, has your mood changed, are you not able to concentrate as well as you should, do you think it has affected your health, what changes do you need to make during the day or night because of this.

5. Tell me about how you felt about the questions you were asked in the tools that you were asked to complete about your sleep?
- Do you think your story was told? Do you think that we would understand what you are going through with your sleep from these forms? Did they ask you to identify problems you have experienced with your sleep now or in the past.

6. Have you ever shared with your doctors or specialists the fact that you haven't been sleeping well? What was their response?

Probes: If you did not tell them were you ever asked? What was done about it? Did they follow-up with this? What did they ask you?

7. I would like to talk specifically about your sleep and Parkinson's disease. How do you feel that your sleep patterns or ability have changed since then? Prior to having your DBS did need to take medication throughout the night?

Probes: What kinds of things wake you up, worries, mobility, pain, etc.

8. How do you feel that you are sleeping better since having a DBS? How is it better; how is it worse? Do you still have cramps, stiffness, do you still need to void frequently at night, take medication throughout the night? Etc.

Have I addressed functional status, self-care, costs, quality of life, cost emotional status and overall health. Double check before you end the interview.

Is there anything else you would like to add or to clarify because we are done? Do you have any questions?

Appendix L**Unified Parkinson's Disease Rating Scale****UNIFIED PARKINSON'S DISEASE RATING SCALE (UPDRS)*****I. MENTATION, BEHAVIOR AND MOOD*****1. Intellectual Impairment**

0 = None.

1 = Mild. Consistent forgetfulness with partial recollection of events and no other difficulties.

2 = Moderate memory loss, with disorientation and moderate difficulty handling complex problems. Mild but definite impairment of function at home with need of occasional prompting.

3 = Severe memory loss with disorientation for time and often to place.

Severe impairment in handling problems.

4 = Severe memory loss with orientation preserved to person only. Unable to make judgements or solve problems. Requires much help with personal care. Cannot be left alone at all.

2. Thought Disorder (Due to dementia or drug intoxication)

0 = None.

1 = Vivid dreaming.

2 = "Benign" hallucinations with insight retained.

3 = Occasional to frequent hallucinations or delusions; without insight; could interfere with daily activities.

4 = Persistent hallucinations, delusions, or florid psychosis. Not able to care for self.

3. Depression

0 = None.

1 = Periods of sadness or guilt greater than normal, never sustained for days or weeks.

2 = Sustained depression (1 week or more).

3 = Sustained depression with vegetative symptoms (insomnia, anorexia, weight loss, loss of interest).

4 = Sustained depression with vegetative symptoms and suicidal thoughts or intent.

4. Motivation/Initiative

0 = Normal.

1 = Less assertive than usual; more passive.

2 = Loss of initiative or disinterest in elective (nonroutine) activities.

3 = Loss of initiative or disinterest in day to day (routine) activities.

4 = Withdrawn, complete loss of motivation.

II. ACTIVITIES OF DAILY LIVING (for both "on" and "off")**5. Speech**

0 = Normal.

1 = Mildly affected. No difficulty being understood.

2 = Moderately affected. Sometimes asked to repeat statements.

3 = Severely affected. Frequently asked to repeat statements.

4 = Unintelligible most of the time.

6. Salivation

0 = Normal.

1 = Slight but definite excess of saliva in mouth; may have nighttime drooling.

2 = Moderately excessive saliva; may have minimal drooling.

3 = Marked excess of saliva with some drooling.

4 = Marked drooling, requires constant tissue or handkerchief.

7. Swallowing

0 = Normal.

1 = Rare choking.

2 = Occasional choking.

3 = Requires soft food.

4 = Requires NG tube or gastrostomy feeding.

8. Handwriting

- 0 = Normal.
- 1 = Slightly slow or small.
- 2 = Moderately slow or small; all words are legible.
- 3 = Severely affected; not all words are legible.
- 4 = The majority of words are not legible.

9. Cutting food and handling utensils

- 0 = Normal.
- 1 = Somewhat slow and clumsy, but no help needed.
- 2 = Can cut most foods, although clumsy and slow; some help needed.
- 3 = Food must be cut by someone, but can still feed slowly.
- 4 = Needs to be fed.

10. Dressing

- 0 = Normal.
- 1 = Somewhat slow, but no help needed.
- 2 = Occasional assistance with buttoning, getting arms in sleeves.
- 3 = Considerable help required, but can do some things alone.
- 4 = Helpless.

11. Hygiene

- 0 = Normal.
- 1 = Somewhat slow, but no help needed.
- 2 = Needs help to shower or bathe; or very slow in hygienic care.
- 3 = Requires assistance for washing, brushing teeth, combing hair, going to bathroom.
- 4 = Foley catheter or other mechanical aids.

12. Turning in bed and adjusting bed clothes

- 0 = Normal.
- 1 = Somewhat slow and clumsy, but no help needed.
- 2 = Can turn alone or adjust sheets, but with great difficulty.
- 3 = Can initiate, but not turn or adjust sheets alone.
- 4 = Helpless.

13. Falling (unrelated to freezing)

- 0 = None.
- 1 = Rare falling.
- 2 = Occasionally falls, less than once per day.
- 3 = Falls an average of once daily.
- 4 = Falls more than once daily.

14. Freezing when walking

- 0 = None.
- 1 = Rare freezing when walking; may have starthetisation.
- 2 = Occasional freezing when walking.
- 3 = Frequent freezing. Occasionally falls from freezing.
- 4 = Frequent falls from freezing.

15. Walking

- 0 = Normal.
- 1 = Mild difficulty. May not swing arms or may tend to drag leg.
- 2 = Moderate difficulty, but requires little or no assistance.
- 3 = Severe disturbance of walking, requiring assistance.
- 4 = Cannot walk at all, even with assistance.

16. Tremor (Symptomatic complaint of tremor in any part of body.)

- 0 = Absent.
- 1 = Slight and infrequently present.
- 2 = Moderate; bothersome to patient.
- 3 = Severe; interferes with many activities.
- 4 = Marked; interferes with most activities.

17. Sensory complaints related to parkinsonism

0 = None.

1 = Occasionally has numbness, tingling, or mild aching.

2 = Frequently has numbness, tingling, or aching; not distressing.

3 = Frequent painful sensations.

4 = Excruciating pain.

III. MOTOR EXAMINATION**18. Speech**

0 = Normal.

1 = Slight loss of expression, diction and/or volume.

2 = Monotone, slurred but understandable; moderately impaired.

3 = Marked impairment, difficult to understand.

4 = Unintelligible.

19. Facial Expression

0 = Normal.

1 = Minimal hypomimia, could be normal "Poker Face".

2 = Slight but definitely abnormal diminution of facial expression.

3 = Moderate hypomimia; lips parted some of the time.

4 = Masked or fixed facies with severe or complete loss of facial expression; lips parted 1/4 inch or more.

20. Tremor at rest (head, upper and lower extremities)

0 = Absent.

1 = Slight and infrequently present.

2 = Mild in amplitude and persistent. Or moderate in amplitude, but only intermittently present.

3 = Moderate in amplitude and present most of the time.

4 = Marked in amplitude and present most of the time.

21. Action or Postural Tremor of hands

0 = Absent.

1 = Slight; present with action.

2 = Moderate in amplitude, present with action.

3 = Moderate in amplitude with posture holding as well as action.

4 = Marked in amplitude; interferes with feeding.

22. Rigidity (Judged on passive movement of major joints with patient relaxed in sitting position. Cogwheeling to be ignored.)

0 = Absent.

1 = Slight or detectable only when activated by mirror or other movements.

2 = Mild to moderate.

3 = Marked, but full range of motion easily achieved.

4 = Severe, range of motion achieved with difficulty.

23. Finger Taps (Patient taps thumb with index finger in rapid succession.)

0 = Normal.

1 = Mild slowing and/or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

24. Hand Movements (Patient opens and closes hands in rapid succession.)

0 = Normal.

1 = Mild slowing and/or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

25. Rapid Alternating Movements of Hands (Pronation-supination movements of hands, vertically and horizontally, with as large an amplitude as possible, both hands simultaneously.)

0 = Normal.

1 = Mild slowing and/or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

26. Leg Agility (Patient taps heel on the ground in rapid succession picking up entire leg. Amplitude should be at least 3 inches.)

0 = Normal.

1 = Mild slowing and/or reduction in amplitude.

2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.

3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.

4 = Can barely perform the task.

27. Arising from Chair

(Patient attempts to rise from a straightbacked chair, with arms folded across chest.)

0 = Normal.

1 = Slow; or may need more than one attempt.

2 = Pushes self up from arms of seat.

3 = Tends to fall back and may have to try more than one time, but can get up without help.

4 = Unable to arise without help.

28. Posture

0 = Normal erect.

1 = Not quite erect, slightly stooped posture; could be normal for older person.

2 = Moderately stooped posture, definitely abnormal; can be slightly leaning to one side.

3 = Severely stooped posture with kyphosis; can be moderately leaning to one side.

4 = Marked flexion with extreme abnormality of posture.

29. Gait

0 = Normal.

1 = Walks slowly, may shuffle with short steps, but no festination (hastening steps) or propulsion.

2 = Walks with difficulty, but requires little or no assistance; may have some festination, short steps, or propulsion.

3 = Severe disturbance of gait, requiring assistance.

4 = Cannot walk at all, even with assistance.

30. Postural Stability (Response to sudden, strong posterior displacement produced by pull on shoulders while patient erect with eyes open and feet slightly apart. Patient is prepared.)

0 = Normal.

1 = Retropulsion, but recovers unaided.

2 = Absence of postural response; would fall if not caught by examiner.

3 = Very unstable, tends to lose balance spontaneously.

4 = Unable to stand without assistance.

31. Body Bradykinesia and Hypokinesia (Combining slowness, hesitancy, decreased arm swing, small amplitude, and poverty of movement in general.)

0 = None.

1 = Minimal slowness, giving movement a deliberate character; could be normal for some persons. Possibly reduced amplitude.

2 = Mild degree of slowness and poverty of movement which is definitely abnormal.

Alternatively, some reduced amplitude.

3 = Moderate slowness, poverty or small amplitude of movement.

4 = Marked slowness, poverty or small amplitude of movement.

IV. COMPLICATIONS OF THERAPY (In the past week)

A. DYSKINESIAS

32. Duration: What proportion of the waking day are dyskinesias present?

(Historical information.)

0 = None

1 = 1-25% of day.

2 = 26-50% of day.

3 = 51-75% of day.

4 = 76-100% of day.

33. Disability: How disabling are the dyskinesias?

(Historical information; may be modified by office examination.)

- 0 = Not disabling.
- 1 = Mildly disabling.
- 2 = Moderately disabling.
- 3 = Severely disabling.
- 4 = Completely disabled.

34. Painful Dyskinesias: How painful are the dyskinesias?

- 0 = No painful dyskinesias.
- 1 = Slight.
- 2 = Moderate.
- 3 = Severe.
- 4 = Marked.

35. Presence of Early Morning Dystonia (Historical information.)

- 0 = No
- 1 = Yes

B. CLINICAL FLUCTUATIONS**36. Are "off" periods predictable?**

- 0 = No
- 1 = Yes

37. Are "off" periods unpredictable?

- 0 = No
- 1 = Yes

38. Do "off" periods come on suddenly, within a few seconds?

- 0 = No
- 1 = Yes

39. What proportion of the waking day is the patient "off" on average?

- 0 = None
- 1 = 1-25% of day.
- 2 = 26-50% of day.
- 3 = 51-75% of day.
- 4 = 76-100% of day.

C. OTHER COMPLICATIONS**40. Does the patient have anorexia, nausea, or vomiting?**

- 0 = No
- 1 = Yes

41. Any sleep disturbances, such as insomnia or hypersomnolence?

- 0 = No
- 1 = Yes

42. Does the patient have symptomatic orthostasis?

(Record the patient's blood pressure, height and weight on the scoring form)

- 0 = No
- 1 = Yes

Appendix M**The Modified Hoehn and Yahr Staging Scale**

Stage 0: no signs of disease

Stage 1: symptoms are very mild and appear only on one side of the body

Stage 1.5: symptoms appear only on one side of the body but with axial involvement

Stage 2: symptoms appear on both sides without impairment of balance

Stage 2.5: symptoms appear on both sides and still mild, with recovery on pull test

Stage 3: symptoms are mild to moderate, some postural instability occurs, but patients are physically independent

Stage 4: symptoms are severe; the patient is severely debilitated and needs some assistance, but can still walk or stand unassisted

Stage 5: symptoms are very severe; the patient is typically wheelchair-bound or confined to a bed, unless aided

Appendix N**The Schwab and England Activities of Daily Living Scale**

- 100% Completely independent. Able to do all chores w/o slowness, difficulty, or impairment.
- 90% Completely independent. Able to do all chores with some slowness, difficulty, or impairment. May take twice as long.
- 80% Independent in most chores. Takes twice as long. Conscious of difficulty and slowing.
- 70% Not completely independent. More difficulty with chores. 3 to 4X along on chores for some. May take large part of day for chores.
- 60% Some dependency. Can do most chores, but very slowly and with much effort. Errors, some impossible.
- 50% More dependant. Help with half of chores. Difficulty with everything.
- 40% Very dependant. Can assist with all chores but few alone.
- 30% With effort, now and then does a few chores alone or begins alone. Much help needed.
- 20% Nothing alone. Can do some slight help with some chores. Severe invalid.
- 10% Totally dependant, helpless.
- 0% Vegetative functions such as swallowing, bladder and bowel function are not functioning. Bedridden.

Appendix O

The Mini-Mental State Exam



Date of Examination _____/_____/_____ Examiner _____

Name _____ Age _____ Years of School Completed _____

Instructions: Words in boldface type should be read aloud clearly and slowly to the examinee. Item substitutions appear in parentheses. Administration should be conducted privately and in the examinee's primary language.

Circle 0 if the response is incorrect, or 1 if the response is correct. Begin by asking the following two questions:

Do you have any trouble with your memory?

May I ask you some questions about your memory?

ORIENTATION TO TIME

RESPONSE

SCORE (circle one)

What is the... year?	_____	0	1
season?	_____	0	1
month of the year?	_____	0	1
day of the week?	_____	0	1
date?	_____	0	1

ORIENTATION TO PLACE*

Where are we now? What is the...

state (province)?	_____	0	1
county (or city/town)?	_____	0	1
city/town (or part of city/neighborhood)?	_____	0	1
building (name or type)?	_____	0	1
floor of the building (room number or address)?	_____	0	1

*Alternative place words that are appropriate for the setting and increasingly precise may be substituted and noted.

REGISTRATION*

Listen carefully. I am going to say three words. You say them back after I stop. Ready?

Here they are... APPLE [pause], PENNY [pause], TABLE [pause]. Now repeat those words back to me.

[Repeat up to 5 times, but score only the first trial.]

APPLE	_____	0	1
PENNY	_____	0	1
TABLE	_____	0	1

Now keep those words in mind. I am going to ask you to say them again in a few minutes.

*Alternative word sets (e.g., PONY, QUARTER, ORANGE) may be substituted and noted when retesting an examinee.

ATTENTION AND CALCULATION [Serial 7s]*

Now I'd like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I tell you to stop.

What is 100 take away 7?	[93]	_____	0	1
<i>If needed, say: Keep going.</i>	[86]	_____	0	1
<i>If needed, say: Keep going.</i>	[79]	_____	0	1
<i>If needed, say: Keep going.</i>	[72]	_____	0	1
<i>If needed, say: Keep going.</i>	[65]	_____	0	1

*Alternative item (WORLD backward) should only be administered if the examinee refuses to perform the Serial 7s task. →

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9876

Reorder #RO-4740

Printed in the U.S.A.

WARNING! PHOTOCOPYING OR DUPLICATION OF THIS FORM WITHOUT PERMISSION IS A VIOLATION OF COPYRIGHT LAWS.

Substitute and score this item only if the examinee refuses to perform the Serial 7s task.

Spell WORLD forward, then backward.

Correct forward spelling if misspelled,
but score only the backward spelling.

(D = 1) (L = 1) (R = 1) (O = 1) (W = 1) _____
(0 to 5)

RECALL

RESPONSE

SCORE
(circle one)

What were those three words I asked you to remember? [Do not offer any hints.]

APPLE	_____	0	1
PENNY	_____	0	1
TABLE	_____	0	1

NAMING*

What is this? [Point to a pencil or pen.]

_____ 0 1

What is this? [Point to a watch.]

_____ 0 1

*Alternative common objects (e.g., eyeglasses, chair, keys) may be substituted and noted.

REPETITION

Now I am going to ask you to repeat what I say. Ready? "NO IFS, ANDS, OR BUTS." Now you say that.
[Repeat up to 5 times, but score only the first trial.]

NO IFS, ANDS, OR BUTS. _____ 0 1

Detach the next page along the lengthwise perforation, and then tear it in half along the horizontal perforation. Use the upper half of the page (blank) for the Comprehension, Writing, and Drawing items that follow. Use the lower half of the page as a stimulus form for the Reading ("CLOSE YOUR EYES") and Drawing (intersecting pentagons) items.

COMPREHENSION

Listen carefully because I am going to ask you to do something.

Take this paper in your right hand [pause], fold it in half [pause], and put it on the floor (or table).

TAKE IN RIGHT HAND	_____	0	1
FOLD IN HALF	_____	0	1
PUT ON FLOOR (or TABLE)	_____	0	1

READING

Please read this and do what it says. [Show examinee the words on the stimulus form.]

CLOSE YOUR EYES _____ 0 1

WRITING

Please write a sentence. [If examinee does not respond, say: Write about the weather.]

0 1

Place the blank piece of paper (unfolded) in front of the examinee and provide a pen or pencil. Score 1 point if the sentence is comprehensible and contains a subject and a verb. Ignore errors in grammar or spelling.

DRAWING

Please copy this design. [Display the intersecting pentagons on the stimulus form.]

0 1

Score 1 point if the drawing consists of two 5-sided figures that intersect to form a 4-sided figure.

Assessment of level of consciousness.

Total Score = _____
(Sum all item scores.) (30 points max.)

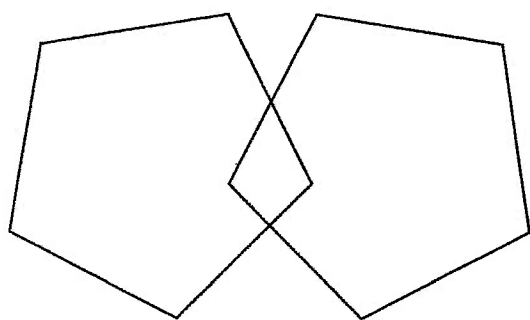
Alert/
Responsive

Drowsy

Stuporous

Comatose/
Unresponsive

CLOSE YOUR EYES



Appendix P

**Education and Nursing Research Ethics Board Protocol Amendment Requests and
Approvals**



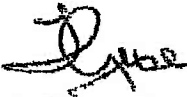
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May 13, 2010

TO: Tamara Wells
Principal Investigator

FROM: Lorna Guse, Chair 
Education/Nursing Research Ethics Board (ENREB)

Re: Protocol #E2010:064
"Factors Associated with Sleep Disturbance in Parkinson's Disease
Patients Post Deep Brain Stimulation"

Your above noted protocol was reviewed by members of the Education/Nursing Research Ethics Board. A few concerns were noted and are listed below:

- i) Data collection: The protocol requires study participants to complete a significant number of questionnaires and assessment tools, some of which appear to overlap in terms of the criteria they are designed to measure. The large number of tools/questionnaires to be completed seems potentially onerous for participants. The protocol does not provide a clear rationale for the use of all of these tools, or an indication of how all of the data collected will be used to inform the study results. It is unclear whether the MMSE and BDI are used for screening purposes only or whether this information will also be used in the study itself. All of this needs to be discussed and explained in more detail. Similarly it is unclear how the information being collected from participant's charts will be used. The detailed data being collected, coupled with the small sample size would seem to have the potential to identify participants depending upon how the data is analysed and presented.
- ii) Permission to use/reproduce tools: The majority of tools being proposed for use in this study are copyrighted. Have permissions been obtained for their use?

- iii) Poster: The poster should be revised to provide more information regarding the nature of the study – i.e. that participants would i) receive three visits from the researcher during which they would complete questionnaires and interviews to gather demographic information, and information about their sleep and activities and that ii) they would allow the researcher to access their health records to collect information about their medication history and PD staging scores.
- iv) Exclusion criteria: The consent form and the poster should more clearly explain that participants may potentially be excluded and why. This would best be placed at the beginning of the consent form, perhaps under a "Who can participate" heading that reiterates that potential participants must be over 40, have a diagnosis of Parkinson's Disease, and have had a Deep Brain Stimulator implanted more than six months ago. It should then indicate that those who have initially consented to participate in the study will be screened through the MMSE and BDI to ensure that there are no cognitive or psychiatric issues that would make it difficult for them to complete the study, and that if these scores indicate that there may be health issues that require further investigation that they will be advised of this, excluded from study participation, and with their permission referred or connected with the appropriate supports.
- v) Consent form:
- Must indicate that participation is voluntary
 - Must clearly describe the process for withdrawal i.e. by telling or e-mailing the researcher and indicate that should they decide to withdraw, any data collected to that point will be deleted from the study and disposed of confidentially.
 - Must indicate when, where and how visits will be scheduled
 - The check boxes related to agreeing to future contact and reviewing interview transcripts are placed in the middle of the consent form, before the potential participant has actually decided to participate. Additionally, these are decisions that participants can more intelligently make after they have completed the interviews. This would be better dealt with by simply stating that the researcher may contact you to clarify the information you provided during your interview to ensure that it is accurate, and will provide you with a transcript of your interview to check for errors and omissions. If the researcher is not prepared to use data if clarification is not received if requested or member checking is not done this should be explained at the point that these requests to participants are made.
- vi) Data storage – will audiotapes be erased as soon as they are transcribed? If not, how will they be stored/disposed of?

- vii) Recruitment via support group – A script or outline of the presentation to be given at the support group meeting should be provided.

Approval is pending your response to the above items. Your written response, **including a cover letter which addresses each of the above items, and includes any revised forms (with revisions highlighted, if possible)**, should be sent to Margaret (Maggie) Bowman, Human Ethics Coordinator, Room 208 – 194 Dafoe Road (CTC Building), or by e-mail to Margaret_bowman@umanitoba.ca. **(Please note that there is no need to re-submit the entire submission, just those pertinent sections.)** If you have any questions you may contact me directly at 474-8113.

June 7, 2010

Dr. L. Guse
Chair, Education/Nursing Research Ethics Board
University of Manitoba
CTC Building
208-194 Dafoe Rd.
Winnipeg, MB
R3T 2N2

Dear Dr. Guse:

RE: Protocol #E2010:064: Factors Associated with Sleep Disturbance in the Parkinson's Disease Patient After Deep Brain Stimulation.

I would like to thank for the constructive feedback provided from ENREB as it applies to my proposed nursing research study. I will address the concerns brought forward from the review in the order that they have been brought to my attention.

Concern 1: Data collection and justification for the number of tools being used.

The concern was raised that the number of assessment tools that participants will be required to complete may be onerous to them. This point is well taken and was discussed in depth by my committee from which I will provide further rationale. The study is aiming to gain a comprehensive understanding of the sleep and sleep disturbance experience of individuals with PD, which to date has not been adequately addressed in the literature. For this reason, a mixed methods approach was proposed. Study tools fall into five major categories: 1) Screening tools (MMSE, BDI); 2) Chart-based data (not completed by participant during the study); 3) Study Questionnaires (PSQI, ESS, PDSS, BDI*); 4) Actigraphic data (Actigraphy and Sleep Diary); and 5) Semi-structured Interview

1. Screening Tools: The Mini-Mental State Exam (MMSE) and the Beck Depression Inventory (BDI) will both be used for screening purposes as both cognitive impairment and depression are common co-morbid conditions of Parkinson's Disease. If either or both impairment are significant I cannot ensure that consent is valid. In addition, severe depression may put potential participants at risk for further stress and the likelihood of severe sleep issues is great which would be difficult to control for in my data analysis. Only the enrolled participants' BDI* scores will be included in further data analysis to determine if the presence of mild to moderate depression impacts sleep disturbance in this population despite deep brain stimulation (DBS). The BDI is not routinely done at the MDC so will need to be completed for all.

The MMSE will have been collected at some point during the patients' care at the Movement Disorders Centre (MDC) but in discussion with the Centre's medical director, the timeliness of this tool cannot be guaranteed to ensure that it reflects the patient's current status. That is, for the purpose of this research it is felt that the MMSE must be current within a six-month timeframe from the date of enrolment into this study. The MMSE is widely familiar and recommended for the assessment of cognitive state in PD (Nazem et al., 2009; Ong, Seel, Carne, et al., 2005). In comparison to the MMSE, the Neuropsychiatric Inventory (NPI; Cummings, J. et al., 1994), which is endorsed by the Movement Disorders Society to assess psychological and cognitive fitness in dementia related illness, requires a longer time to administer, extensive involvement of caregivers, and training to administer. In addition, there is a paucity of references regarding this tool in the literature specific to the use in PD. Thus, the MMSE is one of the briefest (approximately 10 minutes) and most widely accepted and referenced tools for

the assessment of cognitive state in PD (Arnulf et al., 2002; Backer, 2006; Gjerstad, Boeve, et al., 2007).

The BDI is similarly referenced as being brief and valid for assessing depression in PD. The tool is straightforward and takes approximately 5-10 minutes to complete (Aben, Verhey, Lousberg, et al., 2002; Beck, Steer & Brown, 1996). This was discussed with the thesis committee and felt to have a reasonable timeline for administration that will not cause undue burden for the participant. In addition, as it will be administered after the MMSE, potential burden of cognitive impairment will preclude this test being done as per the exclusion criteria.

2. Chart based data: The specific patient information regarding the Unified Parkinsons Disease Rating Scale (UPDRS), the Hoehn & Yahr (H&Y), the Schwab & England (S&E), and dopamine equivalencies being collected from the MDC patient records will provide further demographic clues as to individual's disease state and how their ranked disease profile may impact potential sleep disturbance. This data is important to provide a complete picture of the study sample for comparison of disease severity to potential sleep disturbance. This collection of this information has been recommended by the medical director of the MDC to ensure that the information gathered is in keeping with the standards of other relevant studies (Arnulf, et al., 2002; Gjerstad, Boeve et al., 2007; Gjerstad, Wentzel-Larson, 2007; Hobson, et al., 2002).
3. Study Questionnaires: The Pittsburgh Sleep Quality Index (PSQI), is anticipated to be the most time consuming tool to complete (approximately 20 minutes) for the patient. However, it is considered to be a 'standard' subjective sleep assessment tool, and it will help to more comprehensively assess sleep disturbance and its impact in the target population. While it may appear redundant, the Epworth Sleepiness Scale (ESS) and the Parkinson's Disease Scale (PDSS) are valuable additional components of this assessment. Firstly, it is important to note that the ESS is a measure of daytime sleepiness which is related but not equivalent to sleep disturbance; daytime sleepiness is notoriously known in this population to be underestimated by the patient with PD (Hobson, 2003). Secondly, the PDSS was developed specifically for the purposes of use with PD patients. While it lacks the generalizability of the PSQI, it may offer a unique dimension and insight into the sleep problems of this group. At this stage of development of the PDSS, the committee felt that both lent value and unique insight into this investigation.
4. Actigraphic/Sleep Diary Data: The literature supports the use of actigraphy as an objective data source in the PD and DBS-PD patient populations contingent upon certain standards to ensure reliable data collection (Acebo & LeBourgeois, 2006; Littner et al., 2003). These standards include the use of a sleep diary that will help correlate bedtimes to sleep behaviours such as SO, WASO and TST. It will also identify when the watch has been removed. The Pittsburgh Sleep Quality Index, the Parkinson's Disease Sleep Scale, sleep diary and the Epworth Sleepiness Scale will help to support the actigraphy data being acquired when used to compare recorded rest times and patients' perceptions of their sleep and its quality.
5. Semi-Structured Interview: The interview is required for completeness of the mixed methods protocol and is estimated to last a maximum of one hour. It is important to include this aspect of data-collection to support the patients' voice surrounding the phenomena of sleep disturbance in this population as it is sorely lacking from the literature. Therefore, it is felt that this combination of tools will best determine the patients' sleep situation and identify potential clinical screening tools.
6. Participant Identification: The researcher and advisor are aware of the sensitive nature of the data and the need to ensure participant confidentiality. As indicated previously, data

will be presented in aggregate format only. Interview data will also be carefully selected and presented so that the use of any quotes to support themes will be gender anonymous in addition to individually anonymized. As well no demographic information that determines working roles or physical characteristics will be collected. I personally have no awareness of this patient population. It is felt that these precautions will minimize the potential risk of participants potentially being identified.

Concern 2: Permission to use/reproduce tools:

As per the reviewers comments, the majority of tool being proposed for use in this study are copyrighted. I have amended Appendix P that outlines permissions obtained and attached it below. The only remaining outstanding permission is the S & E, which is based on data collected from the chart (see note). I would appreciate guidance as to how I should proceed in this point. Any further correspondence in this matter will be forwarded to you updating you to status.

Appendix P:

Tool	Outcome
The BDI-II	Permission granted and tool purchased as required
The PSQI	Permission granted
The MMSE	Permission granted and tool purchased as required
The PDSS	Permission granted
The ESS	Permission granted
The UPDRS (not being administered only collected)	Permission granted
The H&Y (not being administered only collected)	Permission granted
The S&E (not being administered only collected)	Permission pending (I have been unable to locate a way to gain permission to reference this tool in my protocol and have discussed this with Dr. Hobson, he has had similar difficulty but continues to use this tool. I have been unable to locate contacts for this tool, those that I have located are deceased)

Concern 3: Clarified and Expanded Poster Information:

It was suggested that the poster provide more in-depth information regarding the nature of the study. I have amended the poster to include more detailed information about the study as specified to me in the review letter. This includes mention of the three visits from the researcher, the manner of the questionnaires involved, as well as requesting access to potential participants' medical file. I have enclosed the poster with this letter for your review.

Concern 4: Clarification of the Participant Explanation of Exclusion Criteria

1. The reviewers mention in the next point of exclusion criteria that I should provide more information about who may be excluded from the study and why. I have mentioned the screening component but left the details of this off the revised poster as I feel that may be too much information for potential participants to understand from a poster. I would prefer that they telephone or e-mail me, and this point can be discussed when answering questions that they may have about the study and prior to setting up potential times to review the consent at visit one. This would still ensure that they will be informed about the screening for cognition and depression prior to meeting to discuss participation in the study at visits one. I believe that the script below addresses your concerns.
 - That they would receive three visits from me at their home or if they prefer another suitable location to be arranged by phone or through e-mail.

- "If you are interested in participating in this study you will be given the Mini-Mental State Exam (MMSE) and the Beck Depression Inventory (BDI-II) prior to enrolment in the study to ensure that there are no cognitive or psychiatric issues that would make it difficult for you to complete the study." If these scores indicate that there may be health issues that require further investigation you will be advised of this, and excluded from study participation. If you agree you can be referred or connected with the appropriate supports, such as your family doctor, your PD health team, or a crisis number.
 - "That access to your patient record at the Movement Disorders Centre is needed to collect information regarding your UPDRS score, your Hoehn and Yahr, and Schwab and England staging scores. Your levodopa type medication amounts prior to DBS will also be recorded to compare to your present PD medication regimen. This information is needed to help with the data analysis in investigating potential contributing factors to sleep disturbance in this population.
 - This is the only data that will be gathered from your chart.
2. I have amended the consent form addressing the exclusion criteria under the section *Who Can Participate* as per the recommendation.

Patients who are over 40 years of age with PD and have had their DBS for more than six months are able to participate in this study. For those who agree to participate in this study they will be screened using the Mini-Mental State Exam (MMSE) and the Beck Depression Inventory (BDI-II) to ensure that there are no cognitive or psychiatric issues that would make it difficult for them to complete the study. If these scores indicate that there may be health issues that require further investigation they will be advised of this, and excluded from study participation. If patients agree they will be referred or connected with the appropriate supports. (page 1 of the consent)

Concern 5: Consent form revisions:

I have amended the consent form on the following points; the revised copy is attached for your review and consideration.

1. Addressed that participation is voluntary.

Your participation in this study is voluntary. page.1

2. Outlined the process for withdrawal.

You are free to withdraw from the study at any time, and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. Should you wish to withdraw you need to only contact the researcher by phone or e-mail to express this to us. If you choose to withdraw from the study any data or information collected will be deleted from the study and disposed of confidentially. page 3

3. Clarified how the visits will be scheduled and where they will occur.

Visits will be arranged by phone or e-mail and will occur in your home unless you wish to have them at another suitable location. Daytime and evening visits will be offered and every effort will be made to ensure that these times are convenient to you. page 2

4. The check boxes have all been moved to a separate page at the end of the consent. I have amended the wording regarding future contact for information clarification and transcription review as per your suggestion.

The researcher may contact you once the information from the interview has been collected to clarify information that you have provided to ensure that it is accurate. You will also be offered the opportunity to check your completed transcript for errors and omissions. Neither of these steps are required of you but are offered as a courtesy to ensure that your experience is represented as fully as possible. Regardless, your data will still be included in the study. page 2

5. Exclusion criteria re: who can participate? Please see concern 4 point 2.

Concern 6: Data Maintenance and Storage:

The audiotapes will not be destroyed as soon as they are transcribed. They will need to be available to the researcher to listen to in order to check the accuracy of transcription and allow for the researcher to double check the information gathered and gain further insight into the interviews if required. They will be disposed of once the study is completed and the thesis successfully defended. They will be erased and destroyed by taking the tape out of the cassettes after erasure.

Concern 7: Recruitment via support group:

I have provided an outline of the presentation should it be required.

1. Introduction to the researcher
 - *Graduate Nursing student with the University of Manitoba*
 - *Interested in chronic illness and sleep*
 - *A handout of the researcher contact information will be left behind for those who may be interested*
2. The Nature and Purpose of the Study
 - *The prevalence of sleep disturbance in PD*
 - *The potential modification of this disturbance with DBS*
 - *How the exploration of these factors may help provide direction for health care teams with their assessment and treatments of this patient concern.*
3. What am I consenting for?
 - *The study procedures*
 - *Time involved*
 - *How contact will be made*
 - *Exclusion criteria and associated screening*
 - *Where visits will occur*
4. The Risks and Benefits
 - *Discuss the numerous forms involved*
 - *The time commitment of actigraphy*
 - *Should other health issues arise such as cognitive impairment or severe depression be noted how will be communicated to them and how to connect with the appropriate supports*
5. Confidentiality of Information
 - *Data storage procedure*
 - *Data destruction procedure*
 - *How presentation of the data will be handled*
6. Process of withdrawal

I look forward to hearing back from you and would like to express my appreciation again for the helpful feedback regarding my submission.

Sincerely,

Tamara Wells RNB

cc: Dr. D. McMillan
 enc: consent form
 recruitment poster

References:

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Ethics

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APPROVAL CERTIFICATE

June 11, 2010

TO: Tamara Wells
Principal Investigator

Diana McMillan

FROM: Lorna Guse, Chair
Education/Nursing Research Ethics Board (ENREB)

Re: Protocol #E2010:064
"Factors Associated with Sleep Disturbance in Parkinson's Disease
Patients Post Deep Brain Stimulation"

Please be advised that your above-referenced protocol has received human ethics approval by the **Education/Nursing Research Ethics Board**, which is organized and operates according to the Tri-Council Policy Statement. This approval is valid for one year only.

Any significant changes of the protocol and/or informed consent form should be reported to the Human Ethics Secretariat in advance of implementation of such changes.

Please note:

- if you have funds pending human ethics approval, the auditor requires that you submit a copy of this Approval Certificate to Eveline Saurette in the Office of Research Services, (e-mail eveline_saurette@umanitoba.ca, or fax 261-0325), including the Sponsor name, before your account can be opened.
- if you have received multi-year funding for this research, responsibility lies with you to apply for and obtain Renewal Approval at the expiry of the initial one-year approval; otherwise the account will be locked.

The Research Ethics Board requests a final report for your study (available at: http://umanitoba.ca/research/ors/ethics/ors_ethics_human_REB_forms_guidelines.html) in order to be in compliance with Tri-Council Guidelines.

Appendix Q

Participant Consent Form



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Participant Consent Form

Factors Associated with Sleep Disturbance in the Parkinson's Disease Patient after Deep Brain Stimulation.

Researcher: Tamara Wells RN
Graduate Student
Faculty of Nursing

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information. Your potential participation in this study is voluntary on your part.

Nature and Purpose of the Study:

Parkinson's disease is very complex with a combination of motor and non-motor symptoms. One of the most common non-motor symptoms of PD is sleep disturbance. It is known that Deep Brain Stimulation (DBS) is helpful for managing the motor symptoms of PD but in addition there is the suggestion that it may also help with the related sleep disturbance. This research study, as part of a graduate nursing thesis, will explore factors associated with the phenomenon of sleep disturbance in the Parkinson's disease deep brain stimulation (DBS-PD) population.

Who can participate?

Patients who are over 40 years of age with PD and have had their DBS for more than six months are able to participate in this study. For those who agree to participate in this study they will be screened using the Mini-Mental State Exam (MMSE) and the Beck Depression Inventory (BDI-II) to ensure that there are no cognitive or psychiatric issues that would make it difficult for them to complete the study. If these scores indicate that there may be health issues that require further investigation they will be advised of this, excluded from study participation. If patients agree they will be referred or connected with the appropriate supports.

What am I consenting to?

If you agree and consent to take part in this research study you are agreeing to complete six questionnaires, undergo an interview that will take about one hour or less and to wear a special activity monitoring watch for 3 days and nights. In addition, you are agreeing

that the researcher can access your health care file to gather information regarding your most recent PD staging scores and your past PD medications.

Visits will be arranged by phone or e-mail and will occur in your home unless you wish to have them at another suitable location. Daytime and evening visits will be offered and every effort will be made to ensure that these times are convenient to you.

The research plans are divided into three visits. *The first visit* will involve reviewing this consent, signing the consent form if you agree to participate, and completing three of the questionnaires to assess your eligibility. It is anticipated that this **first visit will take less than or equal to one hour**. Also, if you agree and qualify to participate we will need to arrange for a time to deliver the actiwatch, teach you how to use it, and complete the remaining questionnaires.

At *visit two*, you will be asked to complete three scales related to your sleep. You will be given an actiwatch-64 to wear for three days and nights. This special watch will record your movements that will allow the researcher to identify your sleep and wake times. You and your caregiver will be taught how to use this simple device. You will also be given a sleep diary to complete while you are wearing the watch. A mutually agreeable time will be set for the researcher to pick up the watch and conduct your interview, after three days. In addition the researcher, (T. Wells) will arrange a time to call you the next day to ensure that there was no difficulty understanding how to use the watch the night before. It is anticipated that this **second visit will take less than or equal to one hour**.

At *visit three* the watch will be picked up and you will be asked to participate in an interview regarding your sleep. This interview is expected to **take no more than one hour** and will be audiotaped/digitally recorded by the researcher. At this time the researcher may also take notes about what is happening during the interview for their own reference. After this visit the researcher may contact you to clarify any information that was given during the interview.

The researcher may contact you once the information from the interview has been collected to clarify information that you have provided to ensure that it is accurate. You will also be offered the opportunity to check your completed transcript for errors and omissions. Neither of these steps are required of you but are offered as a courtesy to ensure that your experience is represented as fully as possible. Regardless, your data will still be included in the study.

Risks and Benefits

There is no immediate benefit from you participation in this study. It is hoped that with your participation that the results are found to be beneficial for the care of patients with PD and sleep disturbance in the future.

There is no anticipated harm to you should you decide to participate in this study. There are quite a few forms that you will need to complete with the researcher. You may find

Initials: _____

this tiring. If you do have difficulty completing these forms your caregiver may assist you or they can be read to you by the researcher. You may also find that talking during the interview is tiring. Every effort will be made to ensure your comfort during these visits.

Due to the information some of the questionnaires gather there may be the identification of other emotional issues. Should this occur the researcher will discuss your ability to participate in the study. In addition, it will be suggested to you and your caregiver that your health care team is made aware of these scores and the situation. If you agree that there may be emotional issues affecting you and you agree that your health care team should be notified but you are unable to do this, the researcher can assist you with this call if you agree. Should at anytime you admit that you feel you may harm yourself, the researcher will provide crisis numbers to you in addition to taking the above steps.

Confidentiality of Information

Your personal information will be removed from study documents and you will be given a study code. Any personal identifiers from the interview will be removed. For example, all names will be replaced with pseudonyms or deleted.

Your interview will be audio-recorded/digitally recorded in order to have the interview transcribed for the researcher. The information from this recording will be transcribed using an individual who understands and has signed a *personal health information agreement* (PHIA).

The information gathered during this study will be kept locked in the researcher's home and accessible only to the primary researcher. Names will be separated from the general study data. Only the researcher will know the names of those who are participating in this study. Only the researcher, her thesis advisor, and possibly a statistician will have access to the data from the questionnaires. If this is necessary only study coded data will be presented to them. Study data will be kept for seven years and then destroyed and treated as confidential waste.

The information from this study may be published or presented at relevant scientific meetings. If this should occur, at no time will you be identified by name. All information will be presented as group findings rather than individual responses.

Your voluntary participation in this study is greatly appreciated. While there is no monetary compensation provided to you for your participation a small honorarium, to thank you for your time, will be provided to you in the form of a gift card (\$20.00) from Safeway.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time, and/or refrain from answering any questions you

Initials: _____

prefer to omit, without prejudice or consequence. Should you wish to withdraw you need to only contact the researcher by phone or e-mail to express this to us. If you choose to withdraw from the study any data or information collected will be deleted from the study and disposed of confidentially. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Should you have any questions or concerns you may contact the Principal Investigator

Tamara Wells RN at 799-7067 (tamwells@shaw.ca)

Or

Dr. Diana McMillan at 474-7295

This research has been approved by the *Education and Nursing Research Ethics Board*. If you have any concerns or complaints about this project you may contact any of the above-named persons or the Human Ethics Secretariat at 474-7122. A copy of this consent form has been given to you to keep for your records and reference.

-----Provide for Signatures as Required-----

Participant's Signature _____ Date _____

Researcher's Signature _____ Date _____

Would you like a summary of this research study once it has been completed?

YES _____ NO _____

Name of the person to which the study results should be sent including mailing address.

Initials: _____