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**Understanding Expectations of, and Satisfaction with,
Deep Brain Stimulation of the Subthalamic Nucleus:
Patient and carer perspectives in Parkinson's disease**

Submitted for the Doctorate in Clinical Psychology, University of Sheffield

Alan M Gray

August 2010

Declaration

I declare that this thesis is the result of my own work.

It has not been submitted to any other institution or for any other qualification.

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Summary

This thesis is concerned with understanding the challenges faced by individuals living with Parkinson's disease. The first section comprises a literature review of 26 studies examining the predictive relationship between patients' symptoms and the level of burden reported by caregivers. Analysis of results suggests that whilst patient's motor, psychiatric and cognitive symptoms are associated with caregiver burden, there is less evidence of a direct predictive relationship. A critique of studies' methodologies highlights inconsistent measurement of caregiver burden and participant recruitment strategies that question the ecological validity of results. Clinical implications and directions for future research are addressed. The second section presents a qualitative study examining patient and caregiver perceptions of a neurosurgical procedure (deep brain stimulation) which aims to alleviate Parkinsonian motor symptoms. Through semi-structured interviews, this longitudinal study explores 8 patients' and 6 respective caregivers' expectations of surgery and their subsequent evaluations of its impact. Using Template Analysis, the study investigates whether participants' evaluations of surgery overlap with themes deemed salient prior to surgery, and whether patients and carers differ in their accounts. Findings suggest some consistency in pre- and post-surgical discussions, with change in motor symptoms and quality of life deemed important. However, unanticipated difficulties with fluctuating symptom change and side effects impacted on satisfaction. Participants also evaluated the manner in which treatment was delivered. Patients and caregivers did not differ substantially in the themes discussed. Clinical implications of these findings are discussed as well as a critique of the study's methodology, with directions for future research proposed.

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The Role of Motor, Psychiatric and Cognitive
Symptoms in Predicting Caregiver Burden in
Parkinson's Disease:

A Review of the Literature

Abstract

Parkinson's disease is characterised by not only motor impairments, but also cognitive and psychiatric disturbance. High levels of caregiver burden (CB) have been found in those providing informal support for sufferers, and researchers have examined the relationship between patient symptoms and CB. The aim of this literature review was to examine the quality of this research and assess the impact of the different components of the Parkinsonian symptom profile on CB. A systematic search of databases (PsycINFO, Web of Science, OVID Medline, British Nursing Index, CINAHL) revealed 26 studies of relevance. Analysis of study findings indicated that whilst motor, psychiatric, and cognitive impairments were associated with CB, the extent to which these symptoms independently predicted CB after controlling for covariates was limited. In many cases, level of patient disability was found to be a better predictor and was sometimes found to mediate the relationship between symptoms and CB. The only symptom that appeared to independently predict CB was the presence of psychosis. The comparison of results across studies is limited by heterogeneous use of conceptually varied burden measures. Biases in sampling strategies may mean that results lack ecological validity. Additional methodological weaknesses are addressed, and clinical implications and directions for future research discussed.

Introduction

Informal caregiving is “the act of providing assistance to an individual with whom the caregiver has a personal relationship” (Kasuya et al, 2000, p.119). In the UK almost six million people provide unpaid healthcare assistance to others (Buckner & Yeandle, 2007). Yet the provision of informal support can have significant consequences for caregivers. The term ‘caregiver burden’ (CB) refers to the impact of caregiving on the carer’s ability to meet their own basic needs (Braithwaite, 1996). It is commonly seen as a multidimensional concept involving the impact on caregivers’ physical and emotional health, social functioning, and financial well-being (Zarit, 1980; 1986).

Parkinson’s disease (PD) is a chronic neurodegenerative movement disorder, primarily characterised by three cardinal motor symptoms: bradykinesia (i.e. slowed movement), rigidity, and resting tremor. Additional axial symptoms include postural instability and gait disturbance. Whilst medication can reduce the severity of motor symptoms, its effectiveness diminishes over time. In addition, its side effects include periods of dyskinesia (uncontrollable movements) which can fluctuate unpredictably to states of akinesia (loss of movement). PD is also associated with significant psychiatric and cognitive disturbance. An estimated 30-40% of sufferers present with clinical depression (Dooneief et al, 1992) and a similar percentage present with anxiety (Aarsland et al, 2009). Around 15-25% develop symptoms of psychosis, and up to 50% experience benign hallucinations (Aarsland et al, 1999; Hanagasi & Emre, 2005). The neurological basis of the disorder results in cognitive sequelae varying from relatively subtle impairments in memory retrieval, executive functioning, and visuomotor construction (Cooper et al, 1991; Taylor & Saint-Cyr, 1995), through to Parkinson’s Disease Dementia which involves severe impairment in multiple cognitive modalities

and is akin to a dysexecutive syndrome (Marder & Jacobs, 2008). These non-motor symptoms often present from the earliest stages of the illness, suggesting that they are as central to the Parkinsonian symptom profile as more traditional conceptualisations around motor impairment.

Over a third of PD sufferers receive support from an informal caregiver, with this number increasing as the disease progresses (Whetten-Goldstein, 1997). Research has accumulated demonstrating the impact on PD caregivers. Around 40% feel their health has suffered through caregiving (Schrag et al, 2006). Levels of emotional distress are higher than in other caregiver groups (Parrish et al, 2003) and consistently higher than the general population (Dura et al, 1990; O'Reilly et al, 1996). The financial burden of PD results largely from the impact of lost earnings, both in the sufferer and the caregiver. A third of working age PD caregivers take early retirement or are on sick leave to meet the sufferer's needs (Lökk, 2008), with lost earnings estimated to be in the region of \$12000 per year (Whetten-Goldstein et al, 1997). Socially, PD carers tend to have smaller social networks and a more restricted range of social contacts (Miller et al, 1996). Most feel their social life has suffered through caregiving whilst 25% report a negative impact on their relationships with other family members (Schrag et al, 2006).

This literature review is concerned with evaluating those studies that have examined the impact of PD symptoms (motor, psychiatric, and cognitive) on CB. The past 15 years has seen a steady growth of this literature base, yet to date there has been no attempt to review these findings. Our understanding of this area is important for a number of reasons. Firstly, understanding the predictors of CB allows services to direct limited funding towards areas where caregivers require assistance. Seventy percent of PD caregivers report requiring additional support (Parrish et al, 2003) and the NHS is

pledged to support caregivers of patients with long-term neurological conditions (Department of Health, 2005). Enabling caregivers to continue in their role reduces the likelihood of nursing home placements for the patient, which in turn has been linked to better health outcomes (Zarit et al, 1986).

Secondly, understanding how symptoms affect CB potentially increases our understanding of how various PD treatments will affect caregivers. Current treatments have a differential impact across the Parkinsonian symptom profile. Levodopa medication, whilst effective in reducing the severity of some motor symptoms, can lead to additional motor impairments and neuropsychiatric symptoms (Molho, 2008). Neurosurgical treatments for PD, specifically deep brain stimulation of the subthalamic nucleus (STN-DBS), can improve levodopa-responsive motor symptoms and reduce medication use and dysknetic side-effects (Limousin & Martinez-Torres, 2008). Yet it has little impact on motor symptoms unresponsive to levodopa, cognition and mood, with some studies showing exacerbation of cognitive and emotional impairments following surgery (Berney et al, 2002; Temel et al, 2006). Interestingly a recent study found the majority of caregivers to be disappointed with the results of STN-DBS (Schüpbach et al, 2006). It could therefore be proposed that non-targeted symptoms place a more significant strain on the caregiver. As Carter et al (2008) highlight: “before the impact of new PD medical and surgical therapies on caregivers can be evaluated, we must first understand how much variation in caregiver strain and depression is actually explained by symptoms of the disease” (p. 1211).

This literature review aims to address the following:

1. The role of patients' motor, psychiatric and cognitive symptoms in predicting caregiver burden
2. The most significant predictors of caregiver burden

In order to address these aims effectively, this paper will first outline limitations in the studies' designs relating to participant recruitment strategies, the measurement of CB, and a reliance on cross-sectional methodology. This is necessary to understand subsequent findings.

Search Method

Relevant studies were retrieved through systematic searches (Appendix 3) in the databases of PsycINFO (1806 – February 2010), Web of Science (1900 – February 2010), OVID Medline (1950 – February 2010), British Nursing Index (1985 – February 2010) and CINAHL – Cumulative Index to Nursing and Allied Health Literature (1982 – February 2010). The key term PARKINSON'S DISEASE was entered and paired with each of the following key terms:

- * CAREGIVER BURDEN
- * CAREGIVER DISTRESS
- * CAREGIVER STRAIN
- * CAREGIVING
- * CAREGIVER STRESS
- * CAREGIVER QUALITY OF LIFE

* CAREGIVER WELL-BEING

Examination of the titles and abstracts of resulting papers took place. Only papers published in English and in peer reviewed journals were included. Papers were required to include a detailed description of their methodology and results, thus allowing a critique of their findings. Short articles and abstracts from conference presentations were therefore excluded. Since this review was concerned with idiopathic PD, papers including other forms of Parkinsonism were excluded. Papers were required to examine at least one aspect of the care-recipient's motor, cognitive, or psychiatric symptom profile and assess its impact on caregiver burden. Studies had to provide some measurement of the negative impact of caregiving. Twenty-six studies met these inclusion criteria. Table 1 provides details of these studies including the areas of patient symptomatology examined.

Table 1 – Patient Symptomatology Examined in Reviewed Papers

Study	MOTOR SYMPTOMS				PSYCHIATRIC SYMPTOMS			COGNITIVE SYMPTOMS		
	Disease stage	Extent of motor symptoms	Medication-induced motor symptoms	Individual symptoms	Depression	Anxiety	Psychosis	Global cognitive functioning	Role of dementia	Specific cognitive modalities
Caap-Ahlgren & Dehlin (2002)	*				*					
Carter et al (1998)	*									
Carter et al (2008)					*					*
D’Amelio et al (2009)	*	*			*			*		
Fernandez et al (2001)	*	*			*		*	*		

Goldsworthy & Knowles (2008)								*		
Happe & Berger (2002)		*			*					
Kim et al (2007)	*									
Lyons et al (2009)	*									
Marsh et al (2004)		*			*		*	*		
Martínez-Martín et al (2003)	*	*								
Martínez-Martín et al (2005)	*	*	*		*	*		*		
Martínez-Martín et al (2007)	*				*					
Martínez-Martín et al (2008)	*	*	*		*	*		*		
Meara et al (1999)		*			*			*		
Miller et al (1996)	*	*			*	*				*
Parrish et al (2003)					*					
Reading et al (2001)							*	*		
Schrag et al (2006)	*			*	*		*			

Speer et al (1993)					*					
Stella et al (2009)	*				*				*	
Takeda et al (2005)	*			*	*			*		
Tanji et al (2008)	*			*				*		
Thommessen et al (2002)					*			*		
Wallhagen & Brod (1997)		*								
Washio et al (2002)									*	

* Areas that studies have addressed

Results

1.0 BIASES IN PARTICIPANT RECRUITMENT STRATEGIES

Prior to examining the relationship between symptoms and CB, it is necessary to consider the inclusion/exclusion criteria for participation in the reviewed studies. As will be outlined, such recruitment biases may result in samples unrepresentative of the wider PD caregiver/receiver population. In addition, inconsistent recruitment criteria for caregivers means comparisons of results may be confounded since extent of caregiving may vary between samples.

A number of studies excluded patients at the extreme ends of the age spectrum. Younger patients were excluded to minimise the inclusion of atypical forms of PD (Martinez-Martin et al, 2005; 2008; Wallhagen & Brod, 1997), whilst older patients were excluded to minimise the risk of additional health problems confounding the results (Martinez-Martin et al, 2008; Miller et al, 1996). Related to this, some studies excluded patients with comorbid dementia (Happe & Berger, 2002; Meara et al, 1999; Reading et al, 2001; Wallhagen & Brod, 1997), whilst others were less specific and excluded patients with “comorbid difficulties seen to impair assessment” (Martinez-Martin et al, 2003; 2005; 2008). Whilst these exclusion criteria give the reader more confidence that any effect on CB is mediated by PD symptoms, it reduces the ecological validity of the results since many sufferers do experience additional health problems and global cognitive decline. It is also likely to limit the participation of older sufferers who are more likely to experience such comorbidities (Hughes et al, 2000). Exclusion of older sufferers is also likely to reduce the number of participants with more advanced PD symptoms.

In terms of inclusion/exclusion criteria for caregivers, nine studies stipulated that this must be the patient's spouse (Carter et al, 1998; 2008; D'Amelio et al, 2009; Fernandez et al, 2001; Happe & Berger, 2002; Lyons et al, 2009; Speer et al, 1993; Thommessen et al, 2002; Wallhagen & Brod, 1997). A further seven stated it must be someone living with the patient, thereby biasing recruitment towards spouses (Martinez-Martin et al, 2005; 2007; 2008; Meara et al, 1999; Miller et al, 1996; Reading et al, 2001; Tanji et al, 2008). Results may therefore be less reflective of other caregiver/receiver relationships. It also means that PD patients without spouses are automatically excluded from studies. A third difficulty is that studies that recruited spouses assumed that these individuals were the primary caregivers, with little attempt to examine whether they identified with the 'caregiver' role or measure the amount of care provided. Only four studies provided a working definition of 'caregiver' which stipulated that this person must provide direct care and be directly affected by care-recipient health problems (Caap-Ahlgren & Dehlin, 2002; Martinez-Martin et al, 2005; 2007; 2008). Therefore most studies may have included some caregivers who were either not the primary caregivers or provided a limited amount of care and thus might be inappropriate in relation to examining the impact of care-recipient symptoms.

2.0 THE MEASUREMENT OF CAREGIVER BURDEN

In order to understand the relationship between patient symptoms and caregiver burden, it is important to consider the aspects of burden that have been examined. It is also important to examine the integrity of the measures used to assess this dimension. Table 2 displays the various measures used by studies.

Table 2 – Measures of Caregiver Burden

Study	No. of participants (patient/caregiver dyads)	Generic burden measure	Emotional well-being measure	Social well-being measure	Financial well-being measure	Health functioning measure
Caap-Ahlgren & Dehlin (2002)	65	CBS	GDS-15			
Carter et al (1998)	219	FCI	CES-D			
Carter et al (2008)	380	FCI				
D’Amelio et al (2009)	40	CBI				
Fernandez et al (2001)	45		HAM-D			
Goldsworthy & Knowles	136	1) CBI	Rosenberg Self-	RAS		

(2008)		2) SQLC	Esteem Scale			
Happe & Berger (2002)	101		CES-D			Sleep problems
Kim et al (2007)	68	Montgomery Burden Scale				
Lyons et al (2009)	255	FCI				
Marsh et al (2004)	50	ZBI				
Martínez-Martín et al (2003)	60	SQLC				
Martínez-Martín et al (2005)	62	SQLC				
Martínez-Martín et al (2007)	80	ZBI	HADS			1) SF-36 2) EuroQoL
Martínez-Martín et al	286	ZBI	HADS			EuroQoL

(2008)						
Meara et al (1999)	79		GDS-15			
Miller et al (1996)	54	MSS	1) GHQ 2) BDI 3) GDS-15			
Parrish et al (2003)	324		1) CES-D 2) Reports of distress for various patient symptoms			
Reading et al (2001)	12		NPI – distress scale			
Schrag et al (2006)	91	1) CBI 2) SQLC	BDI			
Speer et al (1993)	26	CCI	GDS-15	ISEL		1)Duke-North

						2) Health & Daily Living Form
Stella et al (2009)	50		NPI – distress scale			
Takeda et al (2005)	14		Zung Self-Rating Depression Scale	Questions regarding: i) impact on social life ii) No. of hours with care-recipient iii) No. of hours providing care	Expenses from: i) Transport ii) Medical devices iii) Care devices iv) Social services	Presence of fatigue
Tanji et al (2008)	96			Mutuality Scale		
Thommessen et al (2002)	58	RSS				

Wallhagen & Brod (1997)	45	ZBI	MOS			
Washio et al (2002)	70		CES-D			

Beck Depression Inventory (BDI); Caregiver Burden Inventory (CBI); Caregiver Burden Scale (CBS); Centre for Epidemiological Studies Depression Scale (CES-D); Cost of Care Index (CCI); Family Caregiving Inventory (FCI); General Health Questionnaire (GHQ); Geriatric Depression Scale (GDS); Hamilton Depression Scale (HAM-D); Hospital Anxiety and Depression Scale (HADS); Interpersonal Support Evaluation List (ISEL); Machin Strain Scale (MSS); Medical Outcomes Study Mental Health Index (MOS); Neuropsychiatric Inventory (NPI); Relationship Assessment Scale (RAS); Relatives' Stress Scale (RSS); Scale of Quality of Life of Caregivers (SQLC); Short-Form Health Survey – 36 item (SF-36); Zarit Burden Inventory (ZBI)

The examination of the comprehensiveness of the studies' CB measurement will consider how they have addressed Zarit's (1980; 1986) conceptualisation of burden: social functioning, physical health, emotional well-being, and financial well-being.

2.1 Generic Burden Measures

Those questionnaires termed 'generic burden measures' refer to tools specifically developed for measuring CB and are multidimensional in construct. Their perceived strength is that, having been developed with caregiver samples, they should address issues salient to CB. However, as Chou et al (2003) note, the majority have been developed with dementia caregivers and have questionable validity with other caregiver samples. None have been examined for their discriminant validity or test-retest reliability in PD. Across the 17 reviewed studies that utilised such measures, nine different questionnaires were used. Each scale conceptualises burden slightly differently, making comparisons of results between studies difficult. The two scales used most commonly were the Zarit Burden Inventory (ZBI; Zarit et al, 1980) and the Scale of Quality of Life of Caregivers (SQLC; Glozman et al, 1998). Whilst there is some overlapping conceptualisation of burden between these scales, the ZBI includes items on the financial and health-related costs of care which is neglected by the SQLC. In contrast the SQLC examines how caregiving interferes with occupational demands; an area neglected by the ZBI. Varied conceptualisation of burden is found across all burden measures in the reviewed studies. Furthermore, whilst there are overlapping dimensions in these measures, some scales do not permit summary scores for individual dimensions or authors have not taken advantage of this and instead have presented the composite score. As well as creating difficulties with between-study comparisons, the failure to report subscale scores means that the reader is unable to determine which

aspects of burden are most affected by various PD symptoms. Only four studies examined these individual subscales (Carter et al, 1998; 2008; Lyons et al, 2009; Kim et al, 2007).

2.2 Measures of specific components of burden

A means through which to overcome the difficulties described above is to use questionnaires measuring a single construct. Eighteen studies used such measures. The most common dimension under assessment was caregiver mental well-being. This was assessed through psychometric measures of depression, anxiety, self-esteem, stress/distress, and general mental health, all of which were recognised measures with satisfactory psychometric properties. Far fewer studies measured other components of burden. In terms of social well-being, two studies used psychometric measures examining quality of the caregiver/recipient relationship (Goldworthy et al, 2008; Tanji et al, 2008). Speer et al (1993) measured ability to undertake social pursuits and satisfaction from this. Another did not use a psychometric measure and instead asked directly about the impact of caregiving on the caregiver's social life (Takeda et al, 2005). Five studies examined impact on caregiver physical health. Three examined health-related quality of life (Martinez-Martin et al, 2007; 2008; Speer et al, 1993), whilst two looked at specific symptoms (Happe & Berger, 2002; Takeda et al, 2005). Only one study addressed the financial consequences of caregiving (Takeda et al, 2005), but made no attempt to examine lost earnings, even though this is the greatest financial burden in PD (Whetten-Goldstein et al, 1997).

Single construct measures therefore allow greater clarity in understanding which aspects of burden are affected by patient symptoms. They also increase the feasibility of

comparing results between studies. However, with the exception of caregiver emotional well-being, only a few studies have examined other specific burden dimensions. Furthermore, since these measures have not been developed with caregiver samples, they may not actually address the issues most pertinent to caregivers.

3.0 RELIANCE ON CROSS-SECTIONAL METHODOLOGY

Of the 26 studies included in the review, 24 adopted a cross-sectional design whereby the relationship between patient symptoms and CB was measured at a single point in time. In the context of this review, the limitation of this approach is that such studies do not permit an examination of how patients' symptoms are likely to predict CB over time. Only two studies used a longitudinal design to approach the research question, whereby the impact of changes in patient symptoms on CB was examined (Lyons et al, 2009; Reading et al, 2001). However, the study by Reading et al (2001) was limited by a reliance on descriptive statistical analysis regarding the relationship between patient symptoms and CB.

4.0 THE IMPACT OF MOTOR SYMPTOMS

4.1 Disease Stage

Parkinson's disease motor symptoms are often categorised by disease stage through use of the Hoehn & Yahr (H&Y) assessment tool. It differentiates stages of PD by the presence/absence of bilateral motor impairment *and* the presence/absence of postural instability. Sufferers are classified into one of five stages, with higher stages indicating greater symptom severity.

Fifteen studies examined whether H&Y stage was associated with CB (see Table 1). Three used between-groups methodology whereby level of CB was compared across H&Y stages (Carter et al, 1998; Kim et al, 2007; Martinez-Martin et al, 2008), with the remainder of studies examining the correlation between H&Y stage and level of CB. Higher H&Y stages were associated with higher scores on generic burden measures, including the Caregiver Burden Inventory (Caap-Ahlgren & Dehlin, 2002; D'Amelio et al, 2009; Schrag et al, 2006), Family Caregiving Inventory (Carter et al, 1998; Lyons et al, 2009), SQLC (Martinez-Martin et al, 2003; 2005; Schrag et al, 2006), ZBI (Martinez-Martin et al, 2007; 2008), and the Machin Strain Scale (Miller et al, 1996). Kim et al (2007) found that higher H&Y stages were associated with increased scores on a scale assessing the objective/tangible costs of care, but did not impact on subjective burden (i.e. the emotional impact of caring). Related to this, most studies found no relationship between H&Y stage and caregiver mood (Fernandez et al, 2001; Miller et al, 1996; Stella et al, 2009) or at best a weak association (Martinez-Martin et al, 2008; Schrag et al, 2006). The only study to examine its impact on caregiver health-related quality of life found a weak correlation (Martinez-Martin et al, 2008). It did not correlate with the quality of the caregiver/receiver relationship (Tanji et al, 2008) or financial burden (Takeda et al, 2005), although the latter study had a very small sample size (n=14).

The above studies suggest that higher disease stage is associated with higher scores on generic burden measures, with some evidence that it affects caregiver health related quality of life. However, a critique of the H&Y is that it does not provide a 'pure' measure of motor symptom severity as disease stage is partly determined by patient functionality, i.e. ability to complete daily living tasks (Goetz et al, 2004). Therefore the

above results may in fact be associated with patient functionality rather than motor symptom severity per se. Five of the above studies examined whether H&Y independently predicted CB by entering it into a regression analysis alongside other variables found to correlate with CB. The two studies that controlled for the effect of patient functionality found H&Y no longer independently predicted CB (Martinez-Martin et al, 2005; Miller et al, 1996). Those studies that did not control for this variable did find an independent effect of H&Y stage (Caap-Ahlgren & Dehlin, 2002; D'Amelio et al, 2009; Lyons et al, 2009). Therefore, patient functionality appears to be a better predictor of CB and could possibly mediate the relationship between H&Y and CB, although this was not examined directly.

4.2 Extent of Motor Symptoms

An alternative approach to measuring motor symptom severity has involved using scales which sum the severity scores of each of the PD motor symptoms. The Unified Parkinson's Disease Rating Scale – motor subscale (UPDRS-motor) is the best known of these clinician-rated measures and was used in five studies. Scores on this measure correlated with all burden measures, which included caregiver distress (D'Amelio et al, 2009), depression (Fernandez et al, 2001), sleep disturbance (Happe & Berger, 2002), the ZBI (Marsh et al, 2004) and quality of life (Martinez-Martin et al, 2003). No studies examined its relationship with physical health, social or financial well-being of carers. A number of these studies examined the independence of the relationship when other variables were entered into a regression analysis. It continued to predict caregiver sleep disturbance (Happe & Berger, 2002). However the relationship with caregiver distress was no longer significant, and instead patient mental health was the main predictor (D'Amelio et al, 2009). Of note, caregiver distress was measured by the

Neuropsychiatric Inventory (NPI) distress scale which specifically examines carer distress caused by patient mental health symptoms. Therefore it is not surprising that psychiatric symptoms were a better predictor than UPDRS-motor. Carer depression was no longer predicted by UPDRS-motor (Fernandez et al, 2001). Patient functionality was found to be a better predictor of carer quality of life than UPDRS-motor (Marsh et al, 2004).

Five studies used alternative motor severity scales. Two studies (Meara et al, 1999; Miller et al, 1996) used the Webster scale. Neither found a significant correlation with caregiver mood, nor were depressed caregivers more likely to be caring for patients with higher Webster scores. Miller et al (1996) found that motor severity correlated with a measure of objective burden (Machin Strain Scale), although once other variables were entered into a regression analysis this relationship no longer remained significant; patient functionality instead emerged as the strongest predictor of carer strain. The lack of a relationship between motor symptoms (as measured by the Webster scale) and caregiver depression stands in contrast to the results reported by Fernandez et al (2001) using the UPDRS-motor. Of note, the Webster scale has been criticised for being conceptually unclear since it combines both motor symptoms and functional impairment (Ramaker et al, 2002). There is also little published evidence for its validity and reliability; with some studies finding poor inter-rater reliability (Geminiani et al, 1991). In contrast, the UPDRS-motor is found to have stronger clinimetric properties (Ramaker et al, 2002). This may offer some explanation for this inconsistency.

Martinez-Martin et al (2005) found that motor symptom severity, as measured by the Intermediate Scale for Assessment of Parkinson's Disease (ISAPD), correlated with reduced caregiver quality of life. Unfortunately the authors did not report whether this

remained significant following a regression analysis alongside other covariates, although they noted it was not a major determinant of burden. Again patient functional ability was the most significant predictor. Martinez-Martin et al (2008) used the Scales for Outcomes in Parkinson's Disease (SCOPA) to assess motor symptom severity. This correlated with caregiver mood, quality of life, and the ZBI. However, following factor analysis it was not identified as a significant determinant of burden.

Only one study found a relationship between motor symptom severity and caregiver burden (specifically depression) that remained significant after other covariates were included in a regression analysis (Wallhagen & Brod, 1997). However this study differed from those above in that instead of using an objective symptom measure, participants were asked to rate *perceived control* over motor symptoms. Therefore this study is examining a different concept to the above studies. Since lack of perceived control is a dimension often linked to psychological distress (Seligman, 1974) it is perhaps less surprising that this study found an association with burden. It does however raise an interesting consideration that it is not so much the extent of motor symptom severity but its perceived controllability which may influence burden.

4.3 Medication induced motor impairments

Levodopa can result in significant motor impairments such as dyskinetic movement which can unpredictably fluctuate to periods of akinesia. None of the scales outlined above measure this motor disturbance. Martinez-Martin et al (2005) measured this with the ISAPD complication subscale. This correlated with reduced caregiver quality of life. Unfortunately the authors did not report whether this relationship remained significant after it was entered into a regression analysis alongside other covariates, although they

noted that it was not a major determinant of burden. A similar difficulty is found in interpreting Martinez-Martin et al's (2008) study. This study found that motor complications, as measured by the SCOPA, were associated with greater caregiver depression, anxiety and ZBI scores. However, it was grouped with disease duration and disability during factor analysis and as such its individual contribution remains unclear.

4.4 Specific symptoms

A difficulty with assessing the impact of motor symptoms through a cumulative score on a clinimetric measure is that it does not allow for the examination of whether specific symptoms are particularly challenging for caregivers. A number of studies have therefore examined the role of individual motor symptoms in contributing to burden. Tanji et al (2008) examined how scoring on each of the UPDRS items affected the quality of the caregiver/receiver relationship. Increases in the following symptoms correlated with poorer relationships: gait impairment, postural instability, and motor fluctuations. Only gait disturbance emerged as a significant predictor following inclusion in a regression analysis alongside other covariates, although postural instability was not examined due to its large intercorrelation with gait. Somewhat similar results were found by Schrag et al (2006) who used a group comparison approach to examine burden in caregivers whose care-recipients either did or did not have the motor impairment in question. The motor impairments consisted of falls, involuntary movements, and motor fluctuations. Only carers whose recipients experienced falls had higher Caregiver Burden Inventory scores and lower quality of life; no group differences were found on measures of mood. This study also asked patients to indicate the percentage of the day that they were in an akinetic state. This was found to correlate with all three measures of burden, although the relationship was

not explored through regression analysis. Finally, Takeda et al (2005) examined the relationship between burden and tremor, rigidity, akinesia, bradykinesia, posture, and gait. With the exception of tremor, these all correlated with at least one aspect of caregiver burden. However, the reliability of these results is questionable given the small sample size.

5.0 THE IMPACT OF PSYCHIATRIC DISTURBANCE

5.1 Patient Depression

Patient depression was the most commonly examined aspect of patient mental health, addressed in 16 studies (see Table 1). Using a between-groups methodological design, Stella et al (2009) found higher rates of caregiver distress (as measured by the NPI) in those caring for a patient with a DSM-IV diagnosis of depression than in caregivers of non-depressed patients. However, as noted in Section 4.2, the NPI is biased toward finding higher caregiver distress in patients with mental health problems and is therefore a poor measure in this context. The remaining 15 studies used correlation to investigate the relationship between patient depression and CB. Patient depression was measured by a range of psychometric measures, with all measures found to have satisfactory psychometric properties for the measurement of depression in PD (Schrag et al, 2007). Patient depression consistently correlated with caregiver mood (Carter et al, 2008; Fernandez et al, 2001; Happe & Berger, 2002; Martinez-Martin et al, 2008; Meara et al, 1999; Miller et al, 1996; Schrag et al, 2006; Speer et al, 1993). Only one study did not find that greater patient depression was associated with higher levels of caregiver mood disturbance (Takeda et al, 2005), although this study has a number of weaknesses of which its small sample size is the most significant. Three studies

examined whether depression continued to be associated with carer mood following entry of other covariates in a regression analysis (Carter et al, 2008; Fernandez et al, 2001; Miller et al, 1996). Only one found the relationship remained (Miller et al, 1996), although this study included a large number of predictor variables in what was a relatively small sample. Yet Carter et al (2008), who found no predictive relationship, used a much larger sample (n=219) and so more confidence can be placed in their results. However the mean depression score for this PD sample was very low and so one might question whether a significant independent relationship would have been found if more patients had depression scores in the clinically significant range.

Patient depression was also found to correlate with a number of generic burden measures, including the Caregiver Burden Inventory (Caap-Ahlgren & Dehlin, 2002; D'Amelio et al, 2009 Schrag et al, 2006), Family Caregiving Inventory (Carter et al, 2008), ZBI (Marsh et al, 2004; Martinez-Martin et al, 2007; 2008), Machin Strain Scale (Miller et al, 1996), SQLC (Martinez-Martin et al, 2005; Schrag et al, 2006) and the Relatives' Stress Scale (Thommessen et al, 2002). Only one generic burden measure (Cost of Care Index) was not found to correlate with patient depression (Speer et al, 1993). After other covariates were included in a regression analysis, patient depression no longer independently predicted scores on the Caregiver Burden Inventory (Caap-Ahlgren & Dehlin, 2002; D'Amelio et al, 2009), ZBI (Marsh et al, 2004), and SQLC (Martinez-Martin et al, 2005). Most found patient functionality to be a better predictor. However the Family Caregiving Inventory (Carter et al, 2008), Machin Strain Scale (Miller et al, 1996) and Relatives' Stress Scale (Thommessen et al, 2002) continued to be predicted by patient depression, even after controlling for patient functionality. Given that each of these scales conceptualises burden slightly differently, it is possible

that there is some salient dimension inherent in all measures where findings remained significant.

In relation to health-related quality of life, whilst one study found that it was correlated with patient depression (Martinez-Martin et al, 2008), another did not (Martinez-Martin et al, 2007). The results of the former study came from a much larger sample (289 versus 80 caregiver/receiver dyads), hence more value can be attached to these findings. Patient depression was not related to caregiver physical health complaints (Speer et al, 1993) or fatigue (Takeda et al, 2005). In terms of social burden, patient depression was associated with caregiver's decreased perceptions of social support (Speer et al, 1993), but not their level of social activity (Speer et al, 1993; Takeda et al, 2005). It was not found to be associated with financial burden (Takeda et al, 2005).

5.2 Patient Anxiety

Three studies investigated the correlation between patient anxiety and CB. Martinez-Martin et al (2008) found higher scores on the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS) correlated with worse caregiver emotional well-being and quality of life, and higher scores on the ZBI. Using the Hamilton Anxiety scale, Miller et al (1996) found that anxiety correlated with worse caregiver emotional well-being and increased objective burden (as measured by the Machin Strain Scale). However after other covariates were included alongside patient anxiety in a regression analysis this relationship was no longer significant, with patient depression found to be a better predictor. Martinez-Martin et al (2005) found that higher scores on the HADS correlated with poorer quality of life in caregivers. Again this relationship no longer

remained significant when other covariates were included alongside patient anxiety in a regression analysis, with patient functionality found as a better predictor.

The evidence therefore suggests that anxiety, whilst associated with caregiver burden, is not a significant independent predictor. Instead patient depression and degree of functional impairment are better predictors, although none of the studies examined whether these variables mediated the relationship between patient anxiety and burden. Of note, whilst the above anxiety measures are routinely used in mental health settings, a recent review highlighted weaknesses in their application to PD samples (Leentjens et al, 2008). Specifically, the HADS is poor at discriminating between anxiety and depression, and the Hamilton scale has not been validated with this population. This is a significant concern given that PD symptoms can overlap with symptoms of anxiety (e.g. restlessness, sweating, muscle tension). Finally, regression studies had insufficient participants for the number of predictor variables included in their analyses (Tabachnick & Fidell, 2006).

5.3 Psychotic symptoms

Four studies investigated the impact of psychotic symptoms on caregiver burden. Schrag et al (2006) found that those individuals caring for a patient with hallucinations had higher scores on the Caregiver Burden Inventory and lower quality of life than carers of patients without such disturbance. However, caring for someone with hallucinations did not impact on caregiver mood (Schrag et al, 2006; Fernandez et al, 2001). Reading et al (2001) found that improvements in patient psychotic symptoms were accompanied by reduced caregiver distress, as measured by the NPI distress scale. However the authors did not actually examine the degree of correlation between these

variables. Furthermore this study had a very small sample size (n=12) and, as discussed in previous sections, the use of the NPI scale is biased towards recording reduced burden when psychiatric symptoms reduce.

A weakness of the above studies is that none attempt to control for covariates. For example, hallucinations are common in PD patients with dementia (Stella et al, 2009) and it is possible that cognitive decline rather than hallucinations per se are the salient predictor of this relationship. Only one study attempted to control for covariates through regression analyses (Marsh et al, 2004). They found that the presence of psychotic symptoms independently predicted caregiver burden (as measured by the ZBI) when controlling for the effects of patient cognitive status, mood, motor symptoms, and functionality. The analysis is however weakened by the poor predictor variable to participant ratio.

These studies therefore suggest that the presence of psychosis has little impact on caregiver mood, although it is at least associated with burden more generally as well as poorer quality of life. Unfortunately, none of the above studies differentiated between benign and florid hallucinations. The former are more common in PD whilst the latter are more likely to be associated with disruptive behaviour. One might therefore expect them to have a differential effect on burden. Furthermore, none of the studies examined the frequency of hallucinations and whether this mediated any relationship with burden.

6.0 THE IMPACT OF COGNITIVE IMPAIRMENT

6.1 Global Cognitive Functioning

The most common approach to assessing the impact of care-recipient cognitive functioning involved using global cognitive functioning measures commonly used to screen for dementia. Seven studies used the Mini-Mental State Examination (MMSE) which examines cognitive functioning along five dimensions: concentration and working memory, language and praxis, orientation, memory, and attention span. It correlated with a number of generic burden measures including the Caregiver Burden Inventory (D'Amelio et al, 2009), the ZBI (Marsh et al, 2004) and the Relatives' Stress Scale (Thommessen et al, 2002). Only the latter finding remained significant once other covariates were added to a regression analysis, the relationship with the ZBI being better predicted by patient functionality, and the Caregiver Burden Inventory predicted by H&Y stage. As noted in Section 4.1, H&Y correlates with patient functionality and the above study did not control for this variable suggesting that this may be a more significant predictor. In terms of carer mental well-being, Fernandez et al (2001) found no significant difference in caregiver depression scores as a function of whether they were caring for a patient who scored either above or below the overall sample's average MMSE score. However, the average MMSE score was high suggesting that many of those patients included in the 'impaired' group had only mild cognitive deficits. Takeda et al (2005) also found no correlation with carer mood, although this study had a very small sample size (n=14). Using a longitudinal design, Reading et al (2001) found that treatment of PD patients with an antipsychotic led to both improved cognition (as measured by the MMSE) and reduced caregiver distress. However, the authors did not directly examine the relationship between cognition and carer distress using inferential

statistical analysis. Furthermore, the sample size was small (n=12). In terms of caregiver social well-being, reduced MMSE scores were associated with a worse caregiver/receiver relationship (Tanji et al, 2008) and lifestyle restrictions (Takeda et al, 2005). The latter study also found that cognitive impairment correlated with financial burden.

Four studies used global cognitive assessments other than the MMSE. Goldworthy & Knowles (2008) found that the relationship between performance on the Mental Status Examination and burden (Caregiver Burden Inventory) was mediated by patient functionality and behavioural problems. Martinez-Martin et al (2005) also found a correlation between patient cognition (Pfeiffer's Short Portable Mental Status Questionnaire) and caregiver quality of life although, following entry of other covariates into a regression analysis, only patient functionality predicted burden. The only study to use a cognitive measure designed for PD samples (Scales for Outcome in Parkinson's disease – Cognition subscale) found that poorer cognition correlated with increased burden scores on the ZBI. This study benefits from having a large sample size (n=286), although unfortunately the authors did not conduct a regression analysis. All of the studies discussed above have examined patient cognition using brief cognitive measures and thus could be seen as insensitive to the subtle cognitive sequelae typically seen in PD. Meara et al (1999) instead examined patient cognition using the Cambridge Cognitive Examination (CAMCOG) which is over twice the length of the MMSE and measures similar cognitive modalities. This study found that cognition scores did not correlate with caregiver depression. However this study excluded participants who had CAMCOG scores suggestive of dementia and therefore at best can only claim that mild-moderate cognitive impairment is not associated with caregiver depression.

In reviewing these studies as a whole, their major weakness relates to the use of cognitive measures which are inappropriate for examining the cognitive modalities and degree of impairment typically seen in PD. Measures tended to be brief and thus possibly insensitive to the subtle cognitive sequelae of PD. Mamikonyan et al (2009) found the MMSE to be poor at detecting cognitive impairment in PD, which they attributed to the MMSE's narrow focus on memory and language in addition to its high probability of ceiling effects. Similar criticisms around validity have been made regarding other measures, including the CAMCOG (Kulisevsky & Pagonabarraga, 2009). In support of this, those studies which reported the sample's mean and standard deviation of scoring on these measures all showed limited cognitive impairment and small variations in scoring between participants. The only study to use a measure that was designed to assess the cognitive sequelae of PD was that of Martinez-Martin et al (2008).

6.2 The Impact of Dementia

Two studies used group comparison approaches to examine the link between severe cognitive impairment and CB. Washio et al (2002) found that depressed caregivers were no more likely to be caring for dementing PD sufferers than non-depressed caregivers. Stella et al (2009) grouped PD care-recipients by whether or not they had a diagnosis of dementia. In contrast to the preceding study, they found that caregivers of dementing patients showed higher levels of distress, as measured by the NPI distress scale. However, as stated previously, the NPI is limited to measuring distress caused by neuropsychiatric symptoms. Since PD dementia is associated with psychotic symptoms (Sanchez-Ramos et al, 1996) it is unsurprising that this study found higher ratings of caregiver distress. This group analysis approach is also problematic in so far as it does

not control for other variables that may also impact on burden. For example, in the above study care-recipients with dementia also had longer disease duration, worse motor symptoms, and higher rates of depression.

6.3 Specific Cognitive Functions

A criticism of most of the above studies is that they have examined the most severe form of cognitive impairment in PD (i.e. dementia) or have used instruments which may be insensitive to the specific forms of cognitive deterioration seen in PD. Two studies have instead focused on more specific forms of cognition. Carter et al (2008) assessed delayed recall in a verbal memory task in a large sample of 219 PD participants. Using regression analyses they found that this was an independent predictor of caregiver strain and depression. In contrast to these results, Miller et al (1996) found that patient's general intellectual functioning, delayed verbal recall memory, and spatial awareness were not correlated with burden, as conceptualised by caregiver depression and a measure of objective burden (Machin Strain Scale). The reasons behind these inconsistent findings are unclear since both found cognition to be impaired, both had similar predictor and dependent variables, and the composition of the sample was similar (spouse caregivers, similar age). Neither study measured whether caregivers were supported in their role or how much time they spent with the care-receiver and it is possible that this might mediate the impact of caring for a cognitively impaired patient. Given that Carter et al's (2008) study had a substantially larger sample size, this result has more credibility.

Discussion

Overview of findings

The reviewed studies indicate that patient symptoms are associated with burden to varying degrees. More advanced disease stage was associated with increased scores on generic burden measures, with care-recipient impairments on daily living tasks possibly mediating this relationship, although this was not directly examined. Disease stage did not substantially impact on caregiver mood. Few studies examined its impact on other aspects of burden. Composite measures of motor symptom severity (e.g. UPDRS) tended to correlate with generic burden measures, quality of life and caregiver mood, although patient functionality was a better independent predictor. Medication-induced motor impairments correlated with burden, although it is unclear whether they predict burden. Gait disturbance and postural instability associated with falls were found to be the most burdensome motor symptoms.

Increased patient depression was typically associated with poorer caregiver mood and higher scores on generic burden measures. The evidence is less consistent in relation to caregiver physical and social well-being. It did not impact on financial burden. It is unclear whether patient depression predicts CB, or what variables might mediate this relationship. Higher patient anxiety was associated with reduced caregiver mood, quality of life, and increased scores on generic burden measures. Patient anxiety did not predict burden. The presence of psychotic symptoms was associated with increased scores on generic burden measures and reduced caregiver quality of life. It had no impact on caregiver mood. There was some evidence that it predicted burden.

Cognitive impairment tended to be measured using assessments of global cognitive functioning with questionable validity for PD samples. However, cognitive impairment correlated with generic burden measures, caregiver physical wellbeing, quality of life, the quality of the caregiver-receiver relationship, and financial burden. It tended not to impact on caregiver mood. Its relationship with burden may be mediated by patients' ability to complete daily living tasks, with one study directly examining this link. Only two studies examined whether impairments in specific cognitive modalities resulted in burden; results were contradictory and require further examination.

Methodological weaknesses

Studies used generic burden measures not validated with PD samples. A number of such measures were used across studies, with their questionable convergent validity resulting in difficulties comparing study findings. Since they are multidimensional in construct, studies' reporting of only the composite score meant that it was not possible to examine the impact of PD symptoms on specific aspects of burden. Whilst unidimensional measures were employed by some studies, this focused on caregiver mood and largely neglected other aspects of burden.

Recruitment biases meant caregivers tended to be spouses; possibly affecting the validity of results for other caregiver/receiver relationships. Few studies ensured that 'caregiver' participants were the primary caregivers or attempted to examine how much care was provided. Therefore they may not be ideal participants for examining how symptoms impact on burden.

The majority of studies limited their statistical analyses to correlation or between-group statistical analysis without matching groups or controlling for covariates. Since the severity of PD symptoms often inter-correlate this causes difficulties in determining whether the symptom under investigation is independently impacting on burden. Whilst some studies used regression to control for covariates, many had an insufficient sample size for the number of covariates included in the analyses.

Finally, motor and cognitive symptoms were typically measured through composite scales such as the UPDRS and MMSE; the limitation being that it potentially obscures the impact of individual symptoms which may disproportionately predict burden.

Clinical implications

In the introduction to this review it was noted that the findings might suggest how caregivers could be supported by services. This review found evidence to suggest that it is not so much symptoms which impact on CB, but rather the patient's ability to complete daily living tasks (which in some cases may mediate any impact of certain symptoms). The finding of the salient role of patient functional disability in impacting on CB is in line with research in this area (Edwards & Scheetz, 2002). The reviewed studies did not examine why patient disability was so burdensome for caregivers, although one might hypothesise that it is due to increased caregiver workload. Services may be able to aid caregivers through supporting them with such tasks, providing respite, or working with care-recipients to enable them to function more independently. Clinical Psychologists may also be able to help caregivers adjust to their role and help them develop coping strategies to manage the increased demands placed on them. Interestingly a number of studies have revealed efficacious results from cognitive-

behavioural interventions with PD caregivers around this area (A'Campo et al, 2010; Secker & Brown, 2005).

A further consideration was how PD treatment options might impact on CB. It was noted that STN-DBS has a differential impact across the PD symptom profile. Interestingly, whilst gait disturbance and postural instability were found to be the most burdensome motor symptoms for caregivers, they tend to be less well controlled by STN-DBS (Halpern et al, 2007). However, the finding that patient disability is a key predictor of burden offers more promise since STN-DBS can improve patients' ability to complete daily living tasks (Limousin et al, 1998).

Directions for future research

Future research would benefit from more consistency in the measurement of CB. Examination of the psychometric properties of these measures when applied to PD samples would be beneficial, as would an examination of the convergent validity of these scales with one another. Where studies choose to use generic burden measures, results would be enhanced through the reporting of scores on each of the questionnaire's dimensions, and their relationship with PD symptoms examined. More research is needed into the relationship between PD symptoms and caregiver physical, social, and financial well-being. Rather than measuring motor and cognitive symptoms through composite scales, examining the role of individual symptoms would be useful. A move away from cross-sectional studies would allow for examination of how symptoms predict future levels of burden. Related to this, a useful area of examination would be to study how symptom change following STN-DBS impacts on CB.

Limitations of this review

The large number of studies included in this review meant that it was not possible to provide a detailed description and critique of *each* of the studies. Instead the critique primarily focused on weaknesses inherent across studies, such as limitations in the measures used. These seemed most salient since they provided some explanation for inconsistent results and are important considerations when approaching further research in this area.

Whilst an examination of the predictive role of symptoms in causing CB is a valuable area of enquiry, a number of studies have found that their role is less significant than that played by such factors as patient and caregiver sociodemographics, personality factors and coping strategies (Hooker et al, 1998; 2000; Lyons et al, 2004). Therefore whilst the results of this review add to our understanding of the area, they need to be considered in the context of this wider research.

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Research Report

**Understanding Expectations of, and Satisfaction with,
Deep Brain Stimulation of the Subthalamic Nucleus:
patient and carer perspectives in Parkinson's disease**

Abstract

Deep Brain Stimulation (DBS) is a neurosurgical procedure that can improve certain Parkinsonian motor symptoms. Yet its impact across the wider symptom profile is more variable. Few studies have examined how service users evaluate this intervention. This study examines the expectations of DBS held by Parkinson's disease patients and their respective caregivers prior to surgery, the extent to which post-surgical evaluations of DBS involves discussion around similar themes to those discussed pre-surgery, and whether patients' and caregivers' perceptions of surgery differ. Eight patients and 6 respective caregivers completed pre- and post-surgical interviews, with transcripts analysed using Template Analysis. Expectations of surgery centred on desired change in motor symptoms and quality of life. Subtle differences emerged between patients and caregivers in relation to quality of life expectations. All participants accepted that problems were likely to remain post-surgery, although their significance would be diminished. The occurrence of perioperative complications was expected to result in dissatisfaction. Post-surgery, evaluations of DBS continued to centre on changes in motor symptoms and quality of life. However, themes around fluctuations in improvement, the occurrence of new problems, and medical processes were also discussed. Again, only relatively subtle differences emerged in the accounts of patients and caregivers. Findings are discussed in relation to previous research around DBS, with clinical implications, study limitations and directions for future research proposed.

Introduction

Parkinson's disease (PD) is a chronic progressive neurological disorder resulting in depletion of dopamine neurons in the substantia nigra. It is characterised by cardinal motor impairments, specifically tremor at rest, rigidity and bradykinesia, with additional axial symptoms including festinating gait and postural instability. PD affects 0.5% of people aged 65-74, and 1-2% of people 75 years and over, with about 10,000 people diagnosed each year, making it the second most prevalent neurodegenerative disorder behind Alzheimer's disease (National Collaborating Centre for Chronic Conditions, 2006).

Whilst primarily identified by its motor symptoms, PD is associated with significant psychiatric, behavioural and cognitive disturbance. With regard to psychiatric symptoms, 30-40% of sufferers are clinically depressed, with a similar percentage presenting with anxiety (Aarsland et al, 2009). More severe neuropsychiatric disturbances include psychotic symptoms such as visual hallucinations, which present in up to 25% of outpatients (Sanchez-Ramos et al, 1996). Behavioural impairments include apathy (Pedersen et al, 2009), sexual disturbance (Hand et al, 2010) and fatigue (Friedman et al, 2007), which present independent to mood disturbance. Cognitive sequelae are consistent with frontal-subcortical pathology and include impaired visuospatial skills, memory retrieval, executive functions and verbal fluency (Marder & Jacobs, 2008; Taylor & Saint-Cyr, 1995). A significant percentage of sufferers develop Parkinson's Disease Dementia, with clinical features resembling a progressive dysexecutive syndrome. Not surprisingly the quality of life of PD sufferers has been found to be reduced (Kuopio et al, 2000; Schrag et al, 2000).

Since the disorder was first documented in James Parkinson's 'Essay on the Shaking Palsy' (Parkinson, 1817), 190 years of subsequent research has yet to produce a clear understanding of its pathogenesis and aetiology (Factor & Weiner, 2008). However, since the late 1960s there have been developments in the use of pharmacological treatments for the motor symptoms of PD, with drugs such as Levodopa aiding the production of dopamine in nigrostriatal neurons. Yet this treatment has a number of limitations. Its effectiveness over time diminishes and users experience unpredictable fluctuations between states of akinesia (i.e. lack of movement) and dyskinesia (i.e. uncontrollable movement), with the length of 'on' periods (i.e. when medication is working) reduced. Medication has also been linked to neuropsychiatric disturbance, including psychotic symptomatology (Factor et al, 1995) and impulse control disorders (Dodd et al, 2005).

In the past two decades there has been a resurgence of interest in the use of neurosurgical procedures to reduce the severity of cardinal symptoms of PD in patients who no longer respond significantly to medication. Ablative surgical techniques have largely been replaced by a potentially reversible lesioning approach known as deep brain stimulation (DBS). This neurosurgical intervention involves the stereotactic implantation of electrodes which deliver continuous high frequency electrical stimulation to a targeted area of the brain without the need to destroy brain tissue. A number of neuronal areas have been targeted in PD, although in recent years the subthalamic nucleus has become "the target of choice in most patients" (Lang, 2008, p. xiv). The mechanisms through which DBS works are not clearly understood, with stimulation appearing to produce both excitatory and inhibitory effects in surrounding neurons. Volkmann (2007) notes that deep brain stimulation of the subthalamic nucleus (STN-DBS) has a number of advantages over previous neurosurgery techniques: 1) it

does not involve destructive neuronal lesioning; 2) bilateral procedures are comparatively safe; 3) post-operative adjustment of stimulation parameters can improve efficacy, reduce adverse effects, and adapt DBS to disease progression; and 4) it can be reversed, thereby permitting the use of possible future interventions which require intact basal ganglia circuitry.

Since lesioning of the subthalamic nucleus was first identified as an effective approach for reducing motor symptoms in Parkinsonian-induced primates (Aziz et al, 1991; DeLong, 1990), and the subsequent application of STN-DBS to human samples (Pollak et al, 1993), a wealth of research has amassed demonstrating the therapeutic value of STN-DBS. In reviewing the literature, Lozano et al (2004) conclude that its greatest impact on motor symptoms relates to improvement in dyskinesia and ‘on-off’ fluctuations (i.e. the comparative severity of motor symptoms when patients are ‘on’ medication versus ‘off’ medication). Benefits are most noticeable when ‘off’ medication states are compared pre- and post-surgery, with around a 40-60% improvement in motor scores on the Unified Parkinson’s Disease Rating Scale. In addition to improvements in dyskinesia and medication use, a review by Halpern et al (2007) noted significant improvements in tremor, rigidity and bradykinesia. Improvements are still present 5 years post-surgery (Benabid et al, 2001). Therefore, strong evidence exists supporting the beneficial use of STN-DBS in improving at least some PD motor symptoms, often with reductions in medication usage (Rodriguez-Oroz et al, 2005). In addition, reviews into its impact on quality of life also support its efficacy. Diamond & Jankovic (2005) reviewed eight studies with all noting improvements in overall quality of life. Subscales measuring mobility, activities of daily living, stigma, emotional well-being and bodily discomfort tended to show the largest improvements. Studies published subsequent to

this review draw similar conclusions and additionally note that benefits remain at two year follow-up (Lyons et al, 2005; Siderowf et al, 2006).

These positive findings have meant that over 35,000 people worldwide have had DBS for treatment of tremor or Parkinson's disease (Volkman, 2007) with estimates suggesting that 1 in 10 PD sufferers would be suitable for this treatment (National Institute for Clinical Excellence, 2003). Yet there is a danger of assuming that reduction in motor symptoms equates to patient satisfaction with treatment. There are a number of reasons why this presumption may be erroneous. Whilst STN-DBS typically results in improvements in dopamine-responsive symptoms, a number of other symptoms remain, progress or appear following surgery. STN-DBS has little effect on axial symptoms such as postural instability, speech and dysphagia (Halpern et al, 2007). It also fails to improve certain aspects of quality of life, notably social support, cognition and communication (Diamond & Jankovic, 2005). Some studies have found that, for a minority of patients, post-surgical emotional well-being deteriorates and rates of suicide increase (Berney et al, 2002; Voon et al, 2008). Cognitively, whilst most patients remain intact following surgery, declines in verbal fluency, speed of information processing, executive functioning, and working memory have been reported (Ardouin et al, 1999; Saint-Cyr et al, 2000; Woods et al, 2002; York et al, 2008). Around 41% of patients experience some cognitive deterioration post-surgery (Temel et al, 2006). Behavioural disturbances include increased apathy and irritability (Castelli et al, 2006; Houeto et al, 2002). The surgical procedure itself can result in complications, including intracranial bleeding, stroke, infection, eyelid opening apraxia, dysarthria, dysphagia and hardware-related problems (Limousin & Martinez-Torres, 2008). Another reason to suspect that improvements in motor symptoms may not equate to care-recipient satisfaction emanates from a study by Schüpbach et al (2006), who found that a

significant number of patients highlighted difficulties with social adjustment post-surgery despite improvement in motor symptoms. In addition they reported that 58% of PD caregivers were disappointed with the results of STN-DBS.

It is surprising that the investigation of patient satisfaction with STN-DBS has been given limited attention in the research literature up until now. Weaver et al (1997) highlight that “patient satisfaction is likely to be the distinguishing outcome of many treatments for chronic diseases for which living with treatment is a more realistic objective than cure” (p. 579). Indeed, patient satisfaction is a significant goal of medical treatment (Cleary & McNeil, 1988), with satisfied patients more likely to adhere to medical advice (O’Brien et al, 1992; Sherbourne et al, 1992), show better health outcomes (Brody & Miller, 1986) and less likely to pursue legal action against the hospital for malpractice (Hickson et al, 1994). It is also an increasingly desired outcome in a health service that has over the past two decades seen a shift towards consumerism (Pager, 2004).

Due to the lack of research into patient satisfaction following STN-DBS, it is unclear what factors impact on this variable. Many models of patient satisfaction propose that a salient predictor of this variable is the expectations held by patients (Ross et al, 1987; Weaver et al, 1997). Indeed Okun et al (2005) propose that research around STN-DBS should focus on understanding patients post-operative evaluations of surgery relative to their pre-surgical expectations. Yet investigation of this relationship has been lacking. Instead, trials of STN-DBS effectiveness have adopted a ‘top-down’ approach whereby the value of this surgery has been measured against criteria deemed important by clinicians and researchers. What is needed is a more ‘bottom-up’ approach whereby those factors deemed important by the patient are made prominent.

Furthermore, such research needs to provide a voice to those informal caregivers who play a significant role in supporting PD sufferers on a day-to-day basis. Research highlights the degree of burden experienced by this group. Estimates suggest that around 20% of PD caregivers have clinical levels of depression (Fernandez et al, 2001), with the demands of caregiving having a substantial impact on their social functioning, physical health, and relationships with other family members (Schrag et al, 2006). This group is therefore likely to hold expectations in relation to possible benefits from STN-DBS. Dissatisfaction may impact on their ability to continue providing assistance.

In the past decade there has been a rapid expansion in the use of qualitative methodologies in health care research (Pope & Mays, 2006). Quantitative studies have often been criticised for examining issues deemed important by investigators, but which may have little meaning for those individuals under investigation (Guba & Lincoln, 1998). Qualitative methodologies in contrast provide a means through which care-recipients can voice their perspectives and, through identifying aspects important to them, allow for subsequent quantitative examinations of the impact of any medical interventions on such factors. This author proposes that qualitative approaches provide an exciting opportunity to examine care-recipients' perceptions of STN-DBS, in particular the expectations they hold and the factors deemed important when evaluating its impact.

The aim of this research is to examine the expectations patients with PD and their caregivers have in relation to STN-DBS prior to the patient undergoing surgery. In addition, the study aims to examine how these patients and carers subsequently evaluate surgery and the extent to which the criteria used to judge its success overlap with the

topics discussed pre-surgery. Finally, this study will examine whether the factors considered salient by patients overlap with those discussed by caregivers.

Method

Rationale for Design

Given the exploratory nature of this research, a qualitative methodology was adopted. Semi-structured face-to-face interviews with patients and caregivers were undertaken, with each participant interviewed separately thus encouraging the discussion of themes important to them as individuals. The study was longitudinal, with pre-surgical interviews conducted in the days prior to surgery and follow-up interviews occurring 3-6 months post-surgery. The time frame for follow-up was determined through consultations with service-users and a PD Nurse Specialist who felt it would provide sufficient time to appraise any surgical change. Follow-up interviews occurred as close to the 6 month mark as possible to facilitate this, although time constraints meant some were interviewed earlier.

The desired sample size was 8 patients and their respective caregivers. This sample size falls within recommendations for the chosen data analysis approach, Template Analysis (King, 2004), and represents a realistic estimate of the number of patients likely to undergo STN-DBS during the course of this study.

Participants

Patients were recruited from NHS movement disorder clinics based at the John Radcliffe Hospital (Oxford) and the Royal Hallamshire Hospital (Sheffield). All had

undergone a routine pre-surgical assessment, ensuring they: (i) had idiopathic PD, (ii) presented with dopamine-responsive symptoms likely to improve following STN-DBS, (iii) were able to provide informed consent based on an accurate understanding of the likely benefits / risks of surgery, (iv) did not present with dementia, and (v) were free from psychiatric disturbance that might be exacerbated by surgery. All participants passed this health screen and were due to receive bilateral STN-DBS.

A purposeful sampling strategy was adopted whereby patients were approached in the order in which they were due to undergo surgery. The first 8 to agree to participate comprised the study sample. This provided a 'snap shot' of patients undergoing STN-DBS which was free of recruitment bias, hence increasing the likelihood that their viewpoints would be representative of other surgical candidates. Potential participants were excluded if they had dementia, were unwilling / unable to commit to the follow-up interview, had difficulty conversing in English or had speech-language impairments (e.g. dysarthria) likely to affect the transcription of recorded interviews. The first 8 patients that were approached all agreed to participate. They were asked to enquire as to their carer's willingness to participate. One patient did not have an informal caregiver present and another's caregiver did not wish to participate. The study sample therefore included 8 patients and 6 carers, with their details displayed in Table 1.

Interviews

Interview schedules (Appendix 4) for pre- and post-surgical discussions were designed to be open, non-leading and unambiguous, in line with recommendations by Breakwell (2002). They were piloted with service-users to ensure that questions were appropriate to the research question and would lead to detailed discussions.

Pre-surgery interviews were concerned with understanding participants' expectations of STN-DBS. In order to elicit information relevant to this research question, interviews focused on:

- Life with Parkinson's disease and the reasons for seeking surgery.
- Expectations of change from surgery.
- Hopes around change from surgery.
- How the effectiveness of surgery will be judged.
- Aspects which are unlikely to change, or could deteriorate, following surgery.

Post-surgical interviews were concerned with understanding the participant's satisfaction with STN-DBS and the factors central to this evaluation. In order to elicit this information, the following topics were discussed:

- Reviewing pre-surgical expectations
- Changes noticed since surgery
- The most important changes since surgery
- Factors that hadn't changed since surgery
- Perceptions of the future and how this has been influenced by surgery

Measures

Elliot et al (1999) state that qualitative research should 'situate the sample' through providing information that allows the reader to judge the 'range of persons' participating in the research. Given that this study is concerned with an intervention designed to alleviate patients' symptoms, clinical details of the sample are presented in Figure 1 alongside sociodemographic characteristics. This information was obtained (with the patient's consent) from their routine pre-surgical medical evaluation, which involved administering the following measures:

- The Unified Parkinson's Disease Rating Scale – Motor Section (UPDRS; Fahn & Elton, 1987). This clinician-rated scale measures motor symptom severity, with scores ranging from 0 – 52. Higher scores indicate greater symptom severity.
- The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). This measures patient anxiety and depression on separate subscales, with scores greater than 10 suggesting clinical significance.
- The Wechsler Abbreviated Scale of Intelligence (WASI; The Psychological Corporation, 1999), which provides a measure of general cognitive functioning. The Full-2 IQ score is presented which has a mean score of 100 with a standard deviation of 15. Higher scores indicate higher cognitive functioning.

As a requirement for participation in this study, caregivers completed the Zarit Burden Inventory (ZBI; Zarit et al, 1980) which measures caregiver burden (Appendix 5). Scores range from 0-88, with higher scores indicating greater burden. The ZBI shows high internal consistency ($\alpha = 0.93$) with PD caregivers (Martínez-Martín et al, 2007). Test-retest reliability has been found to be 0.71 (Zarit & Zarit, 1990). Scores on this measure were used to provide an indication of the impact of PD on caregivers.

Patients and caregivers were asked to complete a visual analogue scale (Appendix 6) indicating their degree of satisfaction with STN-DBS using a scale of 0-100, with higher scores indicating greater satisfaction.

Table 1 – Details of Participants

ZBI score	Relation to Carer	Location of Interview	Time till Follow-up Interview (months)	WASI Full-2 IQ	HADS Anxiety score	HADS Depression score	UPDRS score (off medication)	Disease Duration (years)*	Age (years)*	Patient Pseudonym
14	Spouse	Clinic	6	96	9	2	32	10-15	40-50	Kathy
54	Spouse	Clinic	6	118	2	7	21	16-20	60-70	Matthew
30	Spouse	Clinic	5	117	2	2	47	10-15	60-70	Paul

David	70-80	10-15	28	1	4	113	5	Home	Sibling	50
Alex	40-50	10-15	17	2	8	127	5	Home	Spouse	11
Pamela	60-70	10-15	20	4	8	109	3	Home	N.A.	N.A.
Ewan	80-90	16-20	28	5	9	126	3	Clinic	N.A.	N.A.
Ronald	60-70	10-15	44	9	9	117	3	Clinic	Partner	16

* Patient age and disease duration are not specified exactly, so as to protect anonymity

Researcher Characteristics

Most qualitative traditions state that the ideological stance of the researcher is likely to influence the conduct and analysis of research. In this study the researcher was a third year Trainee Clinical Psychologist who was a 27-year-old White-British male who previously had been involved in a large multicentre trial examining the effectiveness of STN-DBS and its impact on neuropsychological functioning. As such he had significant experience of conducting clinical interviews with surgical patients and their carers both prior to and following STN-DBS. This included discussions around expectations and evaluations of surgical outcome. These experiences led the researcher to believe that STN-DBS can be a very effective treatment for motor symptoms in the majority of patients. Yet it was felt that outcomes from surgery can vary substantially with a minority experiencing deterioration in aspects of their symptom profile.

Procedure

The procedure for recruiting participants was slightly different between the two recruitment sites. At the John Radcliffe Hospital, a member of the movement disorder healthcare team provided potential participants with an information sheet (Appendices 7 and 8) relating to this study during their stay on the hospital ward in the days leading up to surgery. Patients and carers subsequently informed the healthcare professional of their decision to participate, who in turn informed the researcher. Interviews were conducted in a private room within the hospital.

For the Sheffield cohort, potential participants who were shortly due to undergo surgery were contacted by telephone by a member of the healthcare team. Patients who expressed a willingness to be contacted by the researcher were sent an information sheet by post. The researcher subsequently contacted the patient to enquire about willingness

to participate and arrange an interview time. Interviews took place in the participant's home and occurred roughly 2 weeks before surgery.

On meeting with participants, all received spoken instructions as to the nature of the study, requirements of their participation, issues around confidentiality and consent, and their rights to withdraw. Participants were given the opportunity to ask questions prior to completing a consent form (Appendices 9 and 10).

Patients and carers were interviewed separately. Each interview lasted approximately 30 minutes. Afterwards, participants were given the opportunity to discuss any emotive issues that arose from the interview. Carers were asked to complete the ZBI. This measure was given following the interview so as not to prime participants' interview responses around domains assessed by the ZBI. The researcher took field notes around the interview experience.

Patients' clinical and sociodemographic details (displayed in Table 1) were collected following the interview so as to minimise any assumptions about the participant that the researcher might take into the interview.

Prior to follow-up, participants were contacted by telephone to confirm their willingness to undertake a further interview. Before contacting participants, the researcher enquired with the healthcare team whether surgery had been associated with any significant complications (e.g. death, stroke). This inquiry was designed to minimise any potential upset to the patient or family through the phone call. No further information regarding the patient's surgical outcome was requested.

Participants from the Sheffield site were again interviewed in their homes and Oxford participants interviewed during their stay on the hospital ward during routine post-surgical medical assessments. Where possible, interviews were scheduled for 6 months post-surgery. Similar procedures to the pre-surgery interview were followed, with participants given information regarding the study and asked to sign a consent form.

Following the interview both patients and caregivers were asked to rate their level of surgical satisfaction using the visual analogue scale.

Data Analysis

Interviews with participants were recorded and transcribed verbatim. Template Analysis (TA), as described by King (2004), was employed to analyse interview data. TA is a form of thematic analysis which involves developing a coding template to summarise themes considered relevant by the researcher, and then organise them into meaningful higher-order themes. Its ability to compare and contrast perspectives between groups was in line with this study's aims, in which themes are compared pre- and post-surgery as well as between caregivers and patients. TA is not fixed to a particular epistemological position and is therefore suitable for the *subtle realist* stance of this research. This epistemological position postulates that qualitative research should aim to explore an underlying reality, but unlike a *pure realist* position it accepts that the ability to examine that reality may be obscured by subjective biases in the research process (Mays & Pope, 2000).

TA proposes that analysis may begin with *a priori* codes, which may be modified or rejected as new themes emerge from the data. This fits well with the stance of this study since research suggests that changes in motor symptoms and quality of life may well

feature in participants' accounts. At the same time, given our lack of understanding regarding the importance participants attach to such change, any analytical approach needs the flexibility to adapt to alternative perspectives that emerge from the data, with TA allowing for this.

King (2003) describes a number of stages involved in the analysis of data using TA:

1. **Define *a priori* themes:** Based on the research literature outlined in the introduction of this paper, it was expected that participants would discuss change in relation to :
 - i. Motor symptoms associated with PD
 - ii. Quality of life
2. **Transcribe interviews:** The researcher transcribed the majority of interviews so as to become familiar with the content and context of the interview.
3. **Conduct initial coding of the data:** Coding of interview transcripts was undertaken using an open coding procedure, whereby the researcher identifies, names, categorises and describes aspects of the interview transcript considered relevant to the research question by means of a succinct label. The first stage involved reading through the transcript and highlighting text that was perceived to relate to expectations/satisfaction with surgery. Following this, each highlighted aspect of the text was labelled through summarising its content and providing an interpretation of how it related to the research question. During coding, consideration was given to whether selected statements could be coded by *a priori* themes. When this did not accurately describe/interpret a statement

then an alternative code was proposed. Coding continued until all highlighted aspects of the text had been labelled. Once the entire transcript was coded, these codes were listed and the researcher began to explore how they could be grouped based on commonalities in their meaning. This phase led onto the development of the initial template.

4. Develop an initial template: The initial template was developed from the first coded transcript. Emergent themes were grouped into a smaller number of higher-order themes which described broader themes in the data. The initial template should incorporate all relevant themes identified in the transcript. Four templates were produced: (i) Patient Expectation Template, (ii) Carer Expectation Template, (iii) Patient Satisfaction Template, and (iv) Carer Satisfaction Template. This meant it was possible to compare patient vs carer surgical perceptions as well as pre- vs post-treatment surgical perceptions. ‘Expectation’ templates were produced following completion of all pre-surgical interviews. It was felt that producing the template prior to this could bias the interviewer to pursuing themes deemed salient by this analysis, thus potentially minimising the range of themes discussed by participants. The same approach was used to develop the ‘satisfaction’ templates.

5. Apply the template to the full data set: The comprehensiveness of the initial template was assessed through applying it to successive transcripts. The template was expected to be revised during this process. This involved insertion, deletion or modification of themes based on considerations emerging from the full data set. Where modifications took place, the accuracy of the template in describing preceding transcripts was reassessed.

6. **Present the final template:** The final template should provide a comprehensive overview of the themes relevant to the research question that have emerged from the transcripts.

Reliability and Validity

The epistemological stance of this research rejects the use of terms such as ‘reliability’ and ‘validity’ as defined by those of the *pure realist* tradition, whereby interpretation of data is seen as free of coder bias. Instead, TA proposes that researchers should demonstrate the ‘credibility’ and ‘trustworthiness’ of their analysis through a process of reflexivity and transparency (King, 2004). The following methods were used:

1. The interview schedule was piloted with 5 PD service-users who had undergone STN-DBS. Their feedback on the appropriateness of the research questions for addressing the study’s aims allowed the researcher to recognise and modify any personal biases in these questions.
2. A reflective journal was kept by the researcher throughout the course of the study. In line with recommendations by Ortlipp (2008) it aimed to increase the researcher’s awareness of how intrinsic biases impacted on the research process, data analysis, and derived conclusions.
3. The development of the initial template took place alongside discussions with a Clinical Psychologist who independently coded two patient and caregiver interviews. She was a 27-year-old White-Asian-British Clinical Psychologist.

Her detachment from the field of movement disorders encouraged an ‘outsider perspective’ on the themes discussed.

4. The comprehensiveness of the final template was examined by asking a Consultant Clinical Neuropsychologist to apply the template to a randomly selected patient and caregiver transcript. He was a 57-year-old White-British male with 20 years experience of working within the movement disorder field. Discussion took place around the comprehensive of the template, and final refinements were made.
5. An audit trail was kept, in line with recommendations by Wolf (2003). This made explicit the steps taken by the researcher from data collection through to the presentation of results. Transparency of the research process is facilitated through providing the reader with a detailed description of the research methodology. A worked example of TA applied to the data set is provided in Appendix 11. The presentation of results is ‘grounded in examples’ using extracts from participant interviews.

Ethical Considerations

It was recognised that discussing surgery and the experience of having PD might be emotive for participants. Interview schedules were therefore piloted with volunteers from the Parkinson’s Disease Society. All felt it was appropriately sensitive, but suggested providing participants with the opportunity to discuss any difficult issues following the interview. This suggestion was incorporated in the research procedure.

Participant information sheets and consent forms were also evaluated by this panel to ensure they were easily understandable and included an appropriate level of detail so that participants could make an informed choice as to whether to participate. Suggestions were incorporated into the final version of these forms.

Participants were referred to by pseudonyms with any identifiable details altered or omitted, thereby ensuring anonymity. Where transcription of interviews was undertaken by an employed transcriber, this individual signed a confidentiality agreement (Appendix 12).

Prior to the commencement of this research, it underwent ethical review from the South Yorkshire NHS Research Ethics Committee. This panel approved the study (Appendix 3).

Results

1. EXPECTATIONS OF SURGERY

Whilst separate templates were produced for patients and caregivers, there was significant overlap in the themes discussed. As such Table 2 shows a combined template, with themes discussed solely by either patients or carers highlighted in italics. This section will therefore discuss each of these themes, with extracts from participant interviews shown in italics.

Table 2 – Template of Participants’ Expectations

1. EXPECTATIONS OF SURGERY

1.1 CHANGE FOLLOWING SURGERY

1.11 Improved motor symptoms and medication

1.12 Improved quality of life

- (1) Daily living tasks
- (2) Hobbies
- (3) *Employment opportunities – (P)*
- (4) Socialising
- (5) Self-image
- (6) Freedom / Independence
- (7) *Emotional well-being – (C)*
- (8) *Patient safety – (C)*

1.13 Uncertainty around change

1.14 *Hearing about others – (P)*

1.2 PROBLEMS LIKELY TO REMAIN

1.21 “Not a cure”

1.22 “Hadn’t thought about it like that”

1.23 Reduced significance of remaining symptoms

1.3 HOW SURGERY WILL BE JUDGED

1.31 Size of motor symptom improvement

1.32 Markers of improvement

1.33 Complications

(P) – Themes discussed solely by patients; (C) – Themes discussed solely by caregivers

1.1 CHANGE FOLLOWING SURGERY

1.11 IMPROVED MOTOR SYMPTOMS AND MEDICATION

All participants (patients and carers) expected improvements in motor symptoms and/or medication. A range of symptoms were discussed. Improvements in involuntary movement (dyskinesia) were mentioned by all participants:

*“The dyskinesia is the major, major thing at the moment ...
As much as I know about Deep Brain Stimulation, I
understand that that is what it’s designed to do.” (David’s
carer)*

Improvements in cardinal motor symptoms were raised by many, most commonly in relation to stiffness and bradykinesia. Less severe and more predictable fluctuations in symptoms were discussed, with Pamela describing this as a desire for *“a more even day.”* Some felt gait would improve due to reduced stiffness, with David noting how *“when my muscles bind up tight I can’t walk.”* Only a few participants felt surgery was likely to improve their balance. Patients and caregivers did not differ in relation to expectations around symptoms.

1.12 IMPROVED QUALITY OF LIFE

All participants expected an *“improvement in quality of life” (Alex)* through reduced motor symptoms. A range of areas fell under this heading:

1.121 Daily living tasks

Participants expected patients to show improved ability in completing day-to-day tasks. Patients described how various symptoms affected their competence in these areas. Kathy noted that dyskinesia caused her to “*throw things across the room*”, whilst stiffness meant “*tasks take longer to do.*” She hoped surgery would improve such areas:

“It’d be nice to be able to stir up a pot or cut up things.”

Caregivers also expected improvements. For some this was important due to its symbolic value. David’s carer noted it would show “*he can do normal things that you and I can do.*” Others discussed the increased burden placed on them by the patient’s disability, with Paul’s carer stating “*I’m the one that’s doing more.*”

1.122 Hobbies

Patients discussed expectations around ability and desire to engage in hobbies. Some noted that increased disability had reduced their enjoyment of such pursuits:

“It’s kind of a struggle rather than an enjoyment sometimes.” (Alex)

For others, motor symptoms had meant that pursuing such hobbies had become impractical:

“One has to think how you’re going to organise the whole thing – where is the bathroom, how am I going to get there and do I need my wheelchair.” (Ewan)

Caregivers also expected improvements, with Paul’s carer hoping *“he will be able to go and play golf again, he will be able to go fishing again, he will be able to play green bowls.”*

1.123 Employment opportunities

Patients alone discussed expectations around surgery improving their ability to engage in employment. Most were unemployed and felt that surgery could help them gain employment, with Kathy reporting *“I’d be able to get a job again”*. The only patient that was currently employed noted:

“That’s another thing about me having the operation is to prolong my work time.” (Alex)

1.124 Socialising

All participants expected surgery would improve their ability to spend time with others. Patients described a current lack of desire to socialise due to *“embarrassment” (Ronald)* around dyskinesia. Being *“on the go all the time with people looking” (Kathy)* made patients feel *“awkward” (Alex)*. Socialising with strangers was particularly unpleasant:

“You walk in anywhere new and all eyes are on you because you’re twisting away.” (Ronald)

Some also spoke of how motor symptoms affected their social skills:

“I have to concentrate on silly things instead of concentrating on what’s going on around me.” (Alex)

Through doing so Alex noted that he does not *“contribute as much”* to conversation which *“isn’t really the point of going out.”*

Caregivers also hoped that through the surgery the patient *“would want to be a bit more social” (David’s carer)*. They recognised the patient as *“being embarrassed” (David’s carer)* by their symptoms, noting patients would *“sometimes decline invitations because he never knows how bad his symptoms are going to be” (David’s carer)*.

Carers also felt that their own social lives had suffered and hoped for improvements. Paul’s carer noted her enjoyment of socialising had diminished due to feelings of *“guilt”* when socialising whilst her husband was forced to be at home. She hoped surgery would *“get his social life back”* because then she would be *“entitled to do that (socialise) as well.”*

1.125 Self-image

Patients spoke of reduced self-confidence due to motor symptoms and hoped this would change. Increased perceptions of disability caused some to note *“your confidence goes”*

(Paul), with surgery expected to allow them *“to feel useful again”* (Paul). Others spoke of a desire to be *“normal”* (Ronald) or *“more human again”* (Ronald), with this negative image formed by the reaction of others:

“You see a Mum and her children kind of look the other way, cross the road, in case there’s something weird about me.” (Ronald)

Caregivers also expected surgery would *“give him his confidence back”* (Paul’s carer) and allow the patient *“to feel normal”* (Ronald’s carer). One caregiver felt that her husband’s lack of confidence caused him to be *“neurotic ... always looking around to see what other’s reactions to things are”* (Matthew’s carer). She felt this caused her husband to be defensive and hoped increased confidence would allow him to *“accept that he’s wrong sometimes.”*

1.126 Freedom / Independence

Patients spoke of life lacking *“freedom”* (Pamela) in which there was *“no spontaneity”* (Pamela), often as a result of unpredictable ‘on-off’ fluctuations:

“We don’t do things because we don’t know how I’m going to be in 20 minutes.” (Paul)

Pamela noted that motor symptoms amounted to a *“loss of independence”* in which she was *“increasingly reliant on others.”* She hoped surgery would offer the *“freedom to do what I want, when I want.”*

Caregivers also expected more independence/freedom. For most, they expected increased patient independence/freedom to result in more enjoyable time spent with the patient where there was *“more scope to go somewhere and do something”* (Ronald’s Carer). For others, increasing the patient’s independence was expected to lead to their own independence. They spoke of feeling *“trapped by Parkinson’s”* (Paul’s carer) and hoped:

“If he gains his independence, he’ll be less dependent on me.” (Matthew’s carer)

1.127 Emotional well-being

Caregivers alone explicitly discussed the expected impact of surgery on the patient’s mood. They noted that symptoms *“must get him down”* (David’s carer), with one carer noting her main aim of surgery was *“for him to be happy”* (Paul’s carer).

Caregivers also expected improvements in their own mood. David’s carer noted that seeing her brother overcome by his symptoms *“breaks my heart”* and Ronald’s carer commented that the social stigma her partner experiences around his symptoms causes her to feel *“hurt that people can treat someone like that.”* Others spoke of reduced *“guilt”* (Paul’s carer) at pursuing their own social lives if the patient was more independent, whilst Matthew’s carer hoped she would feel less *“resentful”* if her husband was less dependent on her following surgery.

1.128 Patient safety

Caregivers alone spoke of hoping surgery would improve the patient's safety. They felt they "*had to keep an eye on him (the patient) all the time*" (Paul's carer) causing them to feel "*afraid*" (David's carer).

1.13 UNCERTAINTY AROUND CHANGE

A number of participants felt uncertain as to what might change following surgery. Some highlighted that "*every surgery done on every Parkinson's sufferer is likely to have a different effect*" (Paul's carer). Many accepted this lack of certainty through placing their faith in the treating clinician's judgement:

"If the powers that be didn't think that he was an ideal candidate then they wouldn't have put him forward"
(Paul's carer).

Similarly, Ronald noted "*I haven't really been told that much about it ... I just know that the people who are doing it are very capable and I trust in them completely.*" Others accepted the lack of uncertainty since they felt there were no other treatment options available. Alex's carer noted "*with Parkinson's pretty much anything you are doing is experimental*", but highlighted "*what is there on the horizon for people with Parkinson's? Well, not a great deal*".

1.14 HEARING ABOUT OTHERS

Patients alone discussed how their expectations were based on hearing about others undergoing STN-DBS. In all cases, stories involved positive change. Some patients spoke of media stories:

“I read about this guy who was a professional golfer in the States who’d had deep brain stimulation and went back and became a professional golfer again, so I thought ‘well that can’t be too bad’.” (Paul)

Others spoke of hearing ‘stories on the hospital ward’ about “*incredible*” (Ronald) changes in others, leading them to conclude:

“Well if it works for them, it must work for me.”
(Ronald)

1.2 THINGS LIKELY TO REMAIN THE SAME

1.21 “NOT A CURE”

All participants noted that surgery was “*not a cure*” (Paul) and that problems would remain:

“It won’t change the fact that I’ve got it (Parkinson’s), and I understand it doesn’t affect the development of the disease.” (Alex)

1.22 “HADN’T THOUGHT ABOUT IT LIKE THAT”

A number of patients and carers alike noted that they had given little consideration to what problems might remain following surgery. Alex commented *“I’ve not thought about if it doesn’t work”*, whilst Ronald’s carer emphasised:

“I’m not looking at that, I’m looking at things that are going to get better.”

A number of patients and carers spoke of an optimistic perspective:

“I hadn’t thought about that. I’m thinking of the half-full versus half-empty, and I work on the half-full.”
(Matthew)

Similarly, Paul’s carer noted that *“there’s too many positives to it to actually worry about negatives.”*

1.23 REDUCED SIGNIFICANCE OF REMAINING PROBLEMS

Participants believed some problems would remain, but felt that their significance would be diminished. Alex noted that whilst postural instability was likely to remain,

“if the rest of my symptoms are better then I’ll be able to concentrate more on doing that (retaining balance).” Caregivers took a similar approach, with David’s carer noting that whilst falling is likely to remain, the risk posed by this is minimal:

“He knows when he is going to fall and he falls very well actually.”

Some patients even joked about the significance of the remaining symptoms. Pamela commented *“well I’m sure I shan’t be able to run a mile”*, and when discussing any new restrictions that might result from surgery Paul joked *“well I’ve been told I can’t bungee jump – quite a relief really!”*

1.3 HOW SURGERY WILL BE JUDGED

1.31 SIZE OF MOTOR SYMPTOM IMPROVEMENT

Most participants spoke of judging surgery by the extent to which motor symptoms improved. All noted that dissatisfaction would occur *“if you had no improvements in your symptoms”* (Alex’s carer). The degree of satisfaction would correspond to the magnitude of the improvement, with some improvement expected and large improvements seen as a possibility:

“If it stops it (dyskinesia) completely I’ll be extremely happy. But if it just goes a bit, then I’ll still be okay about it. Just as long as it goes a bit.” (Kathy)

1.32 MARKERS OF IMPROVEMENT

Participants varied in the extent to which they felt it would be possible to judge surgery's effectiveness through objective markers, with some noting *"I'll just know"* (Alex). However, many participants expected they would measure their satisfaction against the patient's functional ability:

"If one looked at one's diary and saw what you've done over the last three months (since surgery), and what you couldn't have done before." (Ewan)

1.33 COMPLICATIONS

Complications arising from the surgery were viewed as a factor likely to lead to dissatisfaction. Participants spoke of surgical side effects, such as stroke, as being *"a really bad outcome from our point of view"* (Alex's carer). Other surgical side-effects discussed by participants included *"paralysis"* (Matthew's carer), *"a bleed on the brain"* (Pamela), and *"being alive but a vegetable"* (Paul).

One caregiver noted that surgery could also lead to complications in the patient's motor symptoms profile; a possibility that would lead to dissatisfaction:

"There is a risk that he might develop other symptoms, or something might become worse than it was before."
(Alex's Carer)

2. SATISFACTION WITH SURGERY

Following post-surgical interviews, patients and caregivers rated their satisfaction with surgery. Results are displayed in Table 3. It shows a wide range of scores, with the majority of participants indicating overall satisfaction with treatment.

Table 3 - Satisfaction with Surgery

Patient Pseudonym	Patient Satisfaction with Surgery	Carer Satisfaction with Surgery
Kathy	59	75
Matthew	50	45
Paul	96	95
David	65	76
Alex	81	90
Pamela	85	N.A.
Ewan	18	N.A.
Ronald	100	100

Whilst separate templates were produced for patients and caregivers, there was again significant overlap in the themes discussed. A combined template is displayed in Table 4, with themes discussed solely by patients or carers highlighted in italics.

Table 4 - Template of Post-surgical Evaluations

2. SATISFACTION WITH SURGERY

2.1 EVALUATIONS OF MOTOR SYMPTOM CHANGE

2.11 Change in motor symptoms and/or medication

2.12 Balancing up change across motor symptoms

2.13 Progressive change / changing satisfaction

2.2 EVALUATIONS OF CHANGE IN 'QUALITY OF LIFE'

2.21 *General functional ability – (P)*

2.22 Daily living tasks

2.23 Socialising

2.24 Self-image

2.25 Freedom / Independence

2.26 Emotional well-being

2.27 *Patient safety – (C)*

2.3 UNEXPECTED IMPACT OF THE STIMULATOR

2.31 Discomfort from the stimulator

2.32 Side effects / new symptoms

2.4 MEDICAL INTERVENTIONS

2.41 *The surgical procedure – (P)*

2.42 The process of stimulator adjustment

2.43 The role of the medical team

(P) – Themes discussed solely by patients; (C) – Themes discussed solely by caregivers

2.1 EVALUATIONS OF MOTOR SYMPTOM CHANGE

2.11 CHANGE IN MOTOR SYMPTOMS AND/OR MEDICATION

All participants evaluated surgery by its impact on motor symptoms and/or medication. Reductions in medication or motor symptom severity were evaluated positively. Desirable improvements were reported in ‘off’ medication states, gait, balance, and ‘on-off’ fluctuations. The most common improvement was reduced dyskinesia:

“Well the main thing was my involuntary movements have completely gone, which is really good.” (Alex)

Where symptoms deteriorated there was dissatisfaction. Two patients and their respective caregivers spoke about worse ‘off’ states. Kathy noted *“now I am all stiffness”* whilst David stated *“I am much slower”*. This had knock-on effects on their gait, with David commenting *“I am stiff and can hardly walk.”* Ewan also discussed frustration with a deterioration in the quality of his movement when ‘on’ medication. Where there was no change across motor symptoms this also led to dissatisfaction.

2.12 BALANCING UP CHANGE ACROSS MOTOR SYMPTOMS

Patients varied in the extent to which they experienced improvement across motor symptoms. Some noted *“everything has got better” (Alex)*, yet most reported that improvements in certain symptoms were accompanied by deterioration in others. Participants described evaluations of surgery as involving ‘balancing up’ the impact of their new motor symptom profile. David spoke of improved dyskinesia but worse

stiffness, leading him to conclude *“I’ve exchanged one thing for another.”* However, he evaluated surgery overall as a success stating *“to get rid of dyskinesia was the main thing. That was terrible.”* Kathy also found that post-surgery she had reduced dyskinesia and worse stiffness:

“I must admit I don’t shake as much as I did before I went in. But now I am all stiffness.”

In contrast to David, she concluded that stiffness was a greater problem, commenting *“well if I can’t move, I can’t do anything. I need to walk!”*

2.13 PROGRESSIVE CHANGE / CHANGING SATISFACTION

All participants spoke of fluctuating levels of symptom change over time which had a resultant impact on their satisfaction. All noted positive change immediately post-surgery. However, most found that improvements deteriorated during the post-operative recovery period. David’s carer described how *“once he had the operation to sink the wires into his chest he seemed to go downhill a bit.”* She described this experience as *“heartbreaking”*.

Most participants noted how symptoms improved again as the medical team adjusted the stimulator. Yet Pamela highlighted *“I haven’t quite got back to where I was then”*, the impact being *“a bit annoying because I had tasted how much better it was.”*

The pace of change impacted on participants' satisfaction, as discussed by Paul and his carer. Paul commented "*it has taken me longer to achieve that (desired motor symptom reduction). I rather thought it would probably be more instant.*" He noted:

"I think now I've had the chance to live with it for 5 months I've got a much better appreciation of what it has achieved for me ... I've got a much happier relationship with it than I did probably a couple of months ago."

One patient and his carer described a process of "*one step forward, two steps back*" (Matthew) in relation to temporary symptom improvement following stimulator adjustment which subsequently remitted after a few days:

"What has changed?! Nothing has changed! It's temporarily improved and when it has improved it has been good, but it hasn't lasted." (Matthew)

2.2 EVALUATIONS OF CHANGE IN 'QUALITY OF LIFE'

Participants described their evaluations of surgery being linked to how motor symptom change impacted on 'quality of life'. The manner in which this was conceptualised by participants is outlined below.

2.21 GENERAL FUNCTIONAL ABILITY

Patients alone evaluated surgery in terms of their functional ability in undertaking tasks. Rather than specifying a context in which this occurred, patients talked more generally of this improvement/deterioration in ability. Where patients were pleased with surgery they spoke of being able to do things “*quicker and better now*” (Alex). Dissatisfaction arose when patients felt “*clumsier*” (Ewan) or they “*couldn't do anything*” (Kathy).

2.22 DAILY LIVING TASKS

Participants evaluated surgery by its impact on the patient's ability to complete daily living tasks. Patients spoke of increased ability to do things and improvements in the quality of how tasks were completed. Pamela noted “*I do much more housework than I used to*” and Ronald commented such tasks “*were much easier because I don't shake so much.*” Paul felt such changes had “*totally transformed my life.*”

Caregivers also spoke of evaluations around such tasks, but more so around its symbolic value:

“Sometimes it's these really small things that you think 'five months ago he couldn't do that and now he can'.” (Alex's carer)

2.23 SOCIALISING

Participants evaluated surgery by its impact on the patient's level of social functioning. Patients described feeling less uncomfortable in social situations. Pamela noted reduced dyskinesia meant *"I do feel I can go out more and be in company"* and described this change as *"great"*, highlighting *"I haven't been out like that in ages"*. Increased social activity was also facilitated by reduced disability. Paul's renewed ability to drive meant *"I can travel locally to see friends."* Dissatisfaction arose when patients felt that they were unable to fully participate in social events. Ewan felt his poorer 'on' periods meant he enjoyed socialising less since he had to *"desperately try to keep up"* with what was going on around him.

Caregivers also evaluated surgery under this theme. Some noted desirable increases in social activity. Ronald's carer highlighted that previously *"he shied away from things because people looked at him. But now that's fine."* Others highlighted the importance of the patient enjoying such activities. Alex's carer noted that *"he has really enjoyed that (socialising again) and consequently I've enjoyed that."*

2.24 SELF-IMAGE

Participants evaluated surgery by whether it had resulted in patients holding a more positive self-image. Patients reported desirable changes in their confidence. Alex commented *"I feel more confident about it (Parkinson's) and myself again, just like I used to be."* Others spoke of how surgery had allowed them to reclaim their identity:

“(Prior to surgery) My position as breadwinner had changed and I felt as though I was losing my position as husband and father as well and I just felt as though I was being rubbed out of the equation ... Now I feel that has changed. I haven’t got back my position totally, but I’m now a fully paid up member of the household again.” (Paul)

Some patients described negative changes in self-image as impacting on their evaluations of surgery. On discussing the deterioration in his ‘off’ state, David noted *“it makes you feel like an old man, in his 80s”* and reflected *“I’m well past my shelf life.”*

Caregiver’s also evaluated surgery under this theme. Alex’s carer noted *“he’s much more confident, more relaxed, his old personality has kind of come back and that’s just amazing to see.”* However, Matthew’s carer was disappointed that since STN-DBS her husband continued to have *“a lack of confidence”* which meant he *“just sits at home all day.”*

2.25 INDEPENDENCE / FREEDOM

Patients evaluated surgery based on whether it had increased their independence / freedom. Matthew noted that his improved ability to dress himself was *“good as I am less dependent upon people doing up my buttons.”* Paul noted that surgery *“has given me back my freedom.”*

Caregivers also evaluated surgery under this theme. Ronald's carer felt that the greatest benefit of his reduced dyskinesia was that *"it gives him more freedom."* Paul's carer noted that surgery *"just makes life so much more free"* noting *"he has begun to get his independence back."* Carers also spoke of the impact on their own independence / freedom. Paul's carer noted that her husband's increased independence had *"relieved some of the pressures from me"* noting that now *"I have taken more time for me."* Where surgery had not resulted in increased patient/carer independence, this was appraised negatively. Matthew's caregiver noted frustration that since surgery she still has *"to give up what I want to do so that he can go somewhere or do something."*

2.26 EMOTIONAL WELL-BEING

Both patients and caregivers evaluated the impact of surgery on the patient's mood. Patients who evaluated change under this theme talked of surgery reducing their emotional well-being. David noted that he gets *"very depressed at times"*, stating that since surgery *"I'm not interested in a lot of things now."* Kathy spoke of having *"emotional problems"* and *"crying all the time"*

In contrast, when caregivers spoke of evaluating surgery around the patient's mood, they spoke of improvements. Ronald's carer noted that *"he is not as moody as he used to be"*. Paul's carer felt that without surgery *"he would have very easily spiralled into quite a deep depression"* and concluded *"personally I'm glad I didn't have to go there."*

Caregivers alone evaluated surgery's impact on their own mood. Paul's carer noted *"there's less mental stress"* whilst Alex's carer felt *"it has created some hope in*

something that is pretty hopeless.” Yet Matthew’s carer was disappointed that surgery had not reduced her feelings of “*guilt*”.

2.27 PATIENT SAFETY

Caregivers alone spoke about evaluating surgery based on its impact on patients’ safety. Ronald’s caregiver noted “*I used to worry an awful lot. I don’t so much now.*” Similarly Paul’s carer noted:

“I don’t have to be constantly worrying ‘what is he up to, what is he doing?’ I don’t have to ring three or four times a day just to say ‘are you alright’.”

2.3 UNEXPECTED IMPACT OF THE STIMULATOR

2.31 DISCOMFORT FROM THE STIMULATOR

Patients alone spoke of unexpected discomfort from the apparatus used to power the deep brain stimulator. Two patients spoke of ‘body image’ discomfort in relation to the prominence of the battery pack implanted in the chest, with Pamela commenting:

“I am a bit self-conscious of the stimulator. I was expecting it would be much further under the skin.”

Alex also assumed *“it would be like a little pacemaker thing”*, highlighting *“it just would have been nice to know.”* Patients also described physical discomfort from the wires that run under the skin to power the stimulator:

“I can feel the tube under my skin and I don’t like to sleep on my left side because of the fact that I think I might press on it, so I have forced myself to sleep on my back.” (Ewan)

Ewan stated this made him feel *“vulnerable”* and noted *“I suppose it wouldn’t bother me, but amazingly it does.”*

2.32 SIDE EFFECTS / NEW SYMPTOMS

Patients and caregivers spoke of evaluating surgery on side effects from stimulation. The extent to which these unexpected changes impacted on satisfaction differed in relation to what had been affected. Where motor symptoms deteriorated this was perceived as an unexpected negative effect of the stimulator, with David noting *“I didn’t think it would send me back to this stiffness.”* However, a number of non-motor symptom side effects were also reported. Weight gain was reported by participants and was generally appraised positively, with Pamela noting *“it makes me look better than I was. I was looking a bit haggard before.”* A number of patients and carers noted an unexpected and undesirable impact on the clarity of the patient’s speech, which Paul noted was *“completely new since they turned up the setting (on the stimulator).”* He felt *“a slight cautionary note might have been helpful.”* Patients and carers reported negative effects on the patient’s mood. Paul, Alex and Kathy described being *“weepy”*,

which Alex explained as *“crying for a reason, but I wasn’t really sure why or what the reason was.”* One patient (David) felt the stimulator had made him *“mentally slower”*.

2.4 MEDICAL INTERVENTIONS

2.41 THE SURGICAL PROCEDURE

STN-DBS is a neurosurgical procedure conducted under local anaesthetic. Patients discussed evaluations around the surgical procedure itself. For those patients that provided positive evaluations of the procedure, this often centred on the length of time in surgery:

“The surgery wasn’t nearly as bad as I thought, because I was really scared. Everything went so smooth. The team was wonderful and everybody was relaxed. It was so quick.” (Kathy)

However, a number of patients found surgery unpleasant, with Pamela describing it as *“traumatic”*. She noted *“it wasn’t pain as such, but it was very very uncomfortable.”* Ronald described discomfort during the subsequent subcutaneous implantation of the wires leading from the electrode:

“When they shoved the wires down – that bloody hurt!”

2.42 THE PROCESS OF STIMULATOR ADJUSTMENT

In the months after surgery, a number of ‘stimulator adjustments’ take place during which the strength of the pulse emitted by the stimulator is altered in an attempt to maximise symptom reduction. Both patients and carers discussed dissatisfaction relating to this process. Ewan described it critically as “*more of an art than a science*”, noting bewilderment at why the adjustment process was conducted in an ‘off’ medication rather than ‘on’ medication state:

“I don’t think the adjustments have been done as cleverly as they might have been ... I have suggested several times, why don’t they try me at my best rather than at my worst. I guess they understand the procedure and I don’t. I just want them to get on with it.”

Caregivers also described frustration around this process. David’s carer noted confusion regarding the hospital’s “*reluctance to what they call ‘tweak it’, they don’t want to do that for whatever reason.*” One caregiver noted the inconvenience of the repeated hospital appointments:

“It’s something that I don’t feel is thought about to be quite honest. And I do accept that having a hospital appointment can be difficult and I wouldn’t expect it on that day or that day, but it always seems to be at the worst time.”

2.43 THE ROLE OF THE MEDICAL TEAM

Patients, and in particular caregivers, highlighted the role of the medical team in impacting on their satisfaction. Patients made general statements such as *“the team was wonderful”* (Kathy) or *“they were absolutely fantastic”* (Paul). Caregivers were more specific in their evaluations and spoke of the importance of staff being supportive, with Ronald’s carer noting *“there is always someone there”*. Staff were seen to play a key role in the provision of information. Where this occurred this increased carer satisfaction, with Alex’s carer commenting *“the team is a huge support in the whole process because they are preparing you mentally for what is going to happen.”* In contrast, Paul’s carer felt the team could have provided more information:

“Nobody had actually given us an idea of the recovery period, the actual getting over the surgery, and what to expect immediately after the surgery ... We would have benefitted from somebody just saying ‘don’t expect this, don’t expect that’.”

Satisfaction increased when caregivers felt included in the decision making process, with Alex’s carer noting *“You do feel that you are in partnership with them. It’s like you are working on the same project if you like.”* In contrast, Matthew’s carer felt frustration that she was left ‘out of the loop’:

“I don’t feel I am particularly involved. I feel that (patient) will tell them what he wants them to know, but my opinion isn’t sought.”

Discussion

This section summarises the themes discussed by participants and how these overlap with theoretical considerations of the efficacy of STN-DBS as well as the wider literature around expectations / satisfaction with medical care. This author will outline the clinical implications of these findings, comment on the strengths and weaknesses of this study, and suggest directions for future research.

Expectations of STN-DBS

All participants expected surgery to improve motor symptoms and/or medication. This included reduced dyskinesia, less severe ‘off’ medication symptoms, less severe and more predictable ‘on-off’ fluctuations, and improved gait. Patients and caregivers expected change in similar symptoms. Siddiqui et al (2008) emphasise the importance that patients have ‘realistic’ expectations of STN-DBS. In this regard, the symptoms described were ‘realistic’ targets since research finds them most amenable to improvement (Halpern et al, 2007; Lozano et al, 2004).

All expected that improved motor symptoms would improve ‘quality of life’. A range of themes fell under this heading, specifically daily living tasks, hobbies, employment, socialising, self-image, independence, mood, and patient safety. Most were ‘realistic’ expectations when considering research evidence around quality of life change

following STN-DBS (Diamond & Jankovic, 2005). Within these areas, differences in patient and carer expectations became apparent. Firstly, whilst patients spoke of hopes around employment, this was not salient for caregivers. In contrast, caregivers hoped surgery would improve mood (both their mood and the patient's) and patient safety. The importance attached to mood may relate to consistent findings of caregiver depression in PD (Dura et al, 1990; O'Reilly et al, 1996) and the reciprocal relationship between caregiver and patient mood (Miller et al, 1996). Secondly, when patients and caregivers discussed change under similar themes, their motives were sometimes different. This was most apparent in relation to discussions around independence/freedom, in which some caregivers hoped increased patient independence would increase their own independence. Caregiving in PD impairs carers' social functioning (Schrag et al, 2006), and their desire for increased independence may reflect this.

A number of participants had uncertain expectations of STN-DBS, yet were willing to proceed with surgery partly due to confidence in the treating clinician. This perhaps resonates with Williams' (1994) observation that "the greater the perceived esoteric or technical nature of treatment the more likely it is that many service users will not believe in the legitimacy of holding their own expectations" (p.513). Some patients also formed their expectations on hearing other patients' outcomes. Thompson & Suñol (1995) refer to these as 'normative expectations', suggesting what 'ought to happen' based on others' accounts. Interestingly patients spoke of others who had experienced very positive outcomes. Yet Folkes (1990) postulates that satisfaction is greater when people perceive their outcome as more favourable than that of others. By this rationale, expectations based on others' positive outcomes may be unhelpful.

All participants believed problems would remain after surgery, but they would be more manageable. Many commented that they had not really considered what issues would remain. Participants expected their subsequent evaluations of STN-DBS would be influenced by the extent of motor symptom improvement. Many felt STN-DBS could have a substantial impact on symptoms, yet believed even a small improvement would be evaluated positively. Many described setting objective markers to evaluate improvement, whilst others described a more subjective experience of “*I’ll just know*”. Complications of surgery, in particular perioperative complications, were factors expected to result in dissatisfaction.

Satisfaction with STN-DBS

Participants evaluated STN-DBS based on reductions in motor symptoms and medication, largely consistent with those symptoms discussed pre-surgery. Patients and caregivers did not differ in the symptoms discussed. Dissatisfaction occurred when symptoms did not improve or deteriorated. The possibility of symptoms becoming worse had not been anticipated. A number of participants found improvements in some symptoms were accompanied by deterioration in others, with evaluations of STN-DBS based on the wider implications of this new symptom profile. All spoke of fluctuations in symptom change, with corresponding fluctuations in their satisfaction. For some, whilst STN-DBS had improved symptoms from pre-surgical levels, if this represented an attenuated effect on their immediate post-surgical improvement then there was some dissatisfaction. Dissatisfaction also arose if participants felt the pace of improvement had been slow. These factors had not been identified as issues expected to impact on satisfaction.

All evaluated STN-DBS's impact on 'quality of life', largely overlapping with pre-surgical expectations. However, participants no longer discussed hobbies or employment opportunities. It is unclear why these themes were no longer discussed, although many talked of improvements in 'general functional ability' which may have incorporated hobbies. Patients and caregivers again showed some subtle differences in discussion around 'quality of life'. The only notable change from pre-surgical discussion was that patients now discussed the impact of STN-DBS on their emotional well-being. Interestingly this only occurred when patients felt surgery had impacted negatively on their mood. Deterioration in mood following STN-DBS has been found in a minority of patients (Berney et al, 2002).

Participants evaluated surgery based on unexpected implications of the stimulator. Patients noted the stimulator apparatus resulted in physical discomfort and body image concerns. Other studies have found these issues are raised by patients following STN-DBS (Schüpbach et al, 2006). Both patients and caregivers also noted side effects of stimulation. This included deterioration in motor symptoms, but also non-motor problems such as "*weepiness*" without accompanying negative affect (i.e. pseudobulbar crying), dysarthria, mental slowness and mood disturbance. These side effects have been reported elsewhere (Berney et al, 2002; Limousin & Martinez-Torres, 2008; Okun et al, 2004; Temel et al, 2006). Whilst prior to surgery participants identified surgical complications as likely to result in dissatisfaction, this typically corresponded to perioperative trauma rather than effects related to neuronal stimulation.

Participants also based satisfaction around how medical interventions were delivered, congruent with Parasuraman et al's (1991) proposal that satisfaction is based not only on outcome, but also process issues around service delivery. Patients spoke of

satisfaction based on the timeliness and comfort of the surgical procedure. Both patients and caregivers described dissatisfaction around the process of stimulator adjustment; often from feelings of confusion around how such adjustments were undertaken. The inconvenience of attending numerous hospital appointments for stimulator adjustments was also noted. Finally, participants spoke of the important role of the medical team when evaluating surgery. Increased satisfaction occurred when staff were supportive and available to carers, provided information and prepared the caregiver for the post-operative recovery period, and where they were inclusive of caregivers in a collaborative approach to patient care. None of the above issues were raised by participants in their pre-surgical discussion of how they expected surgery would be evaluated.

Clinical Implications:

Ensuring *informed* consent:

Siddiqui et al (2008) stress that in STN-DBS “the importance of instilling realistic patient expectations before surgery cannot be overemphasised” (p.85). Indeed, clinicians have a duty of care to ensure patients provide *informed* consent prior to treatment (Department of Health, 2001). This study suggests patients and caregivers require more guidance around considering the possibility that motor symptoms may deteriorate or new symptoms appear post-surgery. Participants’ discussions of complications focused on perioperative complications rather than side effects from neuronal stimulation; yet the latter are far more common (Hariz, 2002). Interestingly all patients undergoing surgery at the movement disorder clinics in this study are provided with an information leaflet outlining these risks. Therefore services may wish to

evaluate how the provision of this information is undertaken so that patients are more alert to such risks and their potential impact on satisfaction.

Improving satisfaction with evolving post-surgical change

The post-operative recovery period is recognised as a demanding time for patients (Okun et al, 2007). Participants identified fluctuating motor symptom improvements and the stimulator adjustment process as significant factors impacting on satisfaction. Interestingly participants' accounts suggest that satisfaction could be improved through the actions of medical staff. Dissatisfaction was more likely when participants felt 'confused' regarding how stimulator adjustments were conducted. Ensuring care-recipients are kept informed regarding the rationale behind such interventions, and allowing them to contribute to this process, may increase satisfaction. Indeed, this study found that when the medical team encouraged collaboration this was positively received. It may also be helpful for services to consider the demands repeated hospital visits places on caregivers, and where necessary be flexible regarding appointments or help facilitate the patient's attendance without the involvement of caregivers.

Considering the formation of expectations

This study found that many patients form their expectations of surgery through hearing stories of other surgical candidates that have received STN-DBS. In all cases, these stories described very positive outcomes, which are unlikely to be fully representative of all surgical patients. High 'normative expectations' are more likely to result in dissatisfaction (Boulding et al, 1993) and staff need to be aware of such influences and ensure that patients understand that such outcomes, whilst possible, are not typical. This may be facilitated through providing patients with the opportunity to speak to previous STN-DBS patients whom staff feel have had a more typical outcome.

Furthermore, a number of participants who felt uncertain about likely surgical outcomes described placing their faith in the treating clinician. Yet, the danger is that should the outcome not match the patient's unspoken expectations then frustration may be directed towards staff, which could in turn impact on compliance with post-operative medical management. As Ross et al (1987) highlight, "In the long term, 'faith in the physician' may be a poor substitute for informed consumption of services" (p. 24). Surgical candidates should therefore be encouraged to make explicit their hopes around STN-DBS and accept ownership of such expectations.

Strengths and Limitations of this Research

The main strength of this research is that it represents the first study to provide a voice to those patients and caregivers undergoing STN-DBS. Encouraging service-user evaluations of NHS services is increasingly seen as essential for service development (Department of Health, 2004). Furthermore, since a number of aspects of this study's methodology were developed alongside service-user input, it increases the likelihood that the findings represent areas of importance for this patient group. Finally, the use of a qualitative design was not only appropriate for the research question, but also adds to the expanding literature using qualitative methodologies in examining patients' experiences of neurosurgical services (Knifed et al, 2008; Palese et al, 2008).

However, it is important to recognise that results may be influenced by the context of the study and characteristics of the researcher and sample. Given the researcher's clinical experience of evaluating STN-DBS from a medical perspective, this may have biased the interpretation of data towards a more symptom-based analysis. Whilst

employing a second coder aimed to reduce such biases, this would not impact on data collection. Furthermore, participants may have associated the researcher with the healthcare team, priming them to frame their responses around medical issues. Given that staff facilitated participants' recruitment into the study, this is a possibility.

It is also important to consider the composition of the sample. The majority of patients were male and caregivers tended to be female. Most participants were elderly. Whilst these sociodemographics are broadly representative of the wider PD population (Van den Eeden et al, 2003), the extent to which this study's findings are applicable to care-recipients of differing sociodemographics is uncertain. Furthermore, the context in which participants were recruited may have impacted on the generalisability of results. Both hospital sites conduct comprehensive examinations of patients' suitability for surgery, including examining the appropriateness of their expectations. This may explain why participants voiced 'realistic' expectations in relation to change in motor symptoms and quality of life. Whether similar results would have been obtained from participants at hospitals adopting a less rigorous pre-surgical evaluation remains unknown.

A further limitation in the study was the inconsistent follow-up period for participants. Delays in participant recruitment meant that a number of post-surgery interviews had to be conducted prior to the desired 6 month mark, limiting the amount of time these participants had to evaluate change. However, it is noteworthy that the majority of PD service-users who provided input into the study's design felt that a 3 month follow-up would be appropriate.

A final limitation is that respondent validation was not undertaken. Whilst TA rejects the use of validity assessments, it accepts that respondent “feedback” can aid the researcher’s consideration of alternative data interpretations. Practical constraints, primarily participants’ infrequent and time pressured hospital visits, meant this approach was not feasible. The employment of two independent coders was felt an appropriate alternative.

Directions for Future Research

A number of areas require further research. Firstly, it is important to investigate whether these results are found in other PD patient and caregiver samples due to undergo STN-DBS. Qualitative methodologies accept the generalisability of results may be questionable since they are seen to be influenced by such things as contextual factors and researcher biases in data analysis. Should similar findings be uncovered by other researchers in other contexts then this increases the credibility of claims that these findings are more widely applicable.

Secondly, this qualitative study provides an essential grounding for further quantitative research into satisfaction with STN-DBS. In particular, examination of the relative predictive power of themes outlined in this study in determining satisfaction would be beneficial.

Thirdly, research is needed into how services can improve rates of care-recipient satisfaction with STN-DBS. One approach could be to develop and evaluate a pre-surgical educational intervention designed to ensure surgical candidates have realistic expectations of surgical outcome, particularly in relation to the possibility of new

symptoms. Another could be to examine whether satisfaction with STN-DBS can be improved through adapting post-operative medical procedures (e.g. stimulator adjustment) so that care-recipients have a greater sense of understanding and control in relation to how these are undertaken.

Conclusions

Deep brain stimulation is an effective intervention for motor symptom reduction in PD and remains one of the few treatments available to patients whose symptoms can no longer be managed by medication. Yet prior to this study, there had been limited examination of how care-recipients appraise this treatment. The current findings suggest that care-recipients expect satisfaction with STN-DBS to arise following improvements in motor symptoms and quality of life, when perioperative side effects are absent. In reality post-surgical outcomes are more complex. Many care-recipients find themselves evaluating a post-surgical outcome which includes improvements in some areas, but with contrasting deterioration in other aspects of their symptom profile. Furthermore, desired change is not instant and care-recipients often face a prolonged and uncertain post-operative recovery period involving fluctuations in symptom improvement. Services which provide STN-DBS need to ensure that surgical candidates are aware of the complexity of possible outcomes and work collaboratively with care-recipients during the post-surgical adjustment period to facilitate increased satisfaction.

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APPENDICES

Appendix 1

Notes for contributors to Movement Disorders

Author Guidelines

Scope

Movement Disorders publishes Full-length Articles, Reviews, Viewpoints, Brief Reports, and Letters. Case reports in which interesting diagnostic difficulties arose in which a definitive pathological or genetic diagnosis was ultimately made can be submitted for the Clinico-Pathological Grand Round section of the journal. The case history and the pathological findings should be submitted to the editors. If the editor determines that the report is appropriate for the Grand Round format two referees can be solicited to discuss the case and become co-authors of the report. All articles in *Movement Disorders*, including letters, can be accompanied by a video when appropriate.

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found at www.blackwellpublishing.com/bauthor/english_language.asp. **Japanese authors can also find a list of local English improvement services at <http://www.wiley.co.jp/journals/editcontribute.html>**. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

- **Full-Length Articles:** Full-length articles present new data in any field related to movement disorders. Suggested length: Abstract up to 250 words, text up to 2700 words, and up to 5 tables and/or figures, legends. The word count must appear on the title page.
- **Reviews and Viewpoints:** Clinical and basic science Reviews or Viewpoints that provide a position statement or summary are generally published upon request or after agreement with the editors of *Movement Disorders*. Authors interested in writing Reviews or Viewpoints may contact the respective Editor-in-Chief, and unsolicited Reviews and Viewpoints will also be considered for publication. Suggested length will be individually discussed.
- **Brief Reports:** Brief reports are short reports, original studies, or evaluations. Suggested length: Abstract up to 150 words, text up to 1500 words, and up to 2 tables, and/or figures, legends. The word count must appear on the title page. This section may also include video-based reports of interesting cases or educational observations with a very brief clinical description. In addition, patient photographs or samples of imaging studies demonstrating a unique observation or educational point accompanied by a very brief commentary legend can be submitted.
- **Letters:** Letters to the Editor allow publication related to previously published material in the Journal or interesting new observations. This section is also the appropriate venue for brief reports or case histories with or without videos. A letter related to published materials may be submitted up to 12 weeks after the paper to which it refers was published in print. Text length can be up to 500 words with up to 5 references for letters related to published articles, up to 250

words and up to 5 references for letters related to published letters, and up to 700 words with up to 7 references for new cases. Letters may have up to 1 table and/or figure with legends. No abstract is needed but a title page is required.

- **Clinical Trial Reports:** Clinical Trial Reports must be written in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher D et al., JAMA 2001;285:1987–1991; see also Moher D et al., Lancet 2001;357:1191–1194). Authors should ensure that information on all of the critical design features listed in the CONSORT checklist is reported in the manuscript. (Reviewers are provided with the checklist to assess the manuscript for the relevant content). The CONSORT flow diagram (figure) should be included with the manuscript, clearly outlining the flow of patients through the trial. In addition, a statement is required in the cover letter specifically confirming that there has been no ghost writing by anyone not named on the author list (see Editorial in *Movement Disorders* 2005;20:1536). The precise financial relationship between a clinical trial sponsor and the authors must be delineated in the manuscript.

Form of Manuscripts.

The text of the manuscript should be in the following sequence: (1) Title page, (2) Abstract, (3) Introduction, (4) Methods, (5) Results, (6) Discussion, (7) Acknowledgment, (8) Authors' Roles, (9) Financial Disclosures of all authors (for the preceding 12 months), (10) References, (11) Video Legend, (12) Figures, and (13) Tables. Pages should be numbered in succession, the title page being one.

Title: Titles should be short, specific, and clear. They should not exceed 100 characters. Do not use abbreviations in the title.

Title Page: The opening page of each manuscript should include only: (1) article title; (2) authors' names and affiliations (indicate the specific affiliation of each author by superscript, Arabic numerals); (3) name, address, and telephone and fax numbers of the person to whom proofs should be addressed; (4) word count; (5) any necessary footnotes to these items; (6) a running title not exceeding 45 letters and spaces; (7) Key words; (8) Financial Disclosure/Conflict of Interest concerning the research related to the manuscript: All information on support and financial issues from all authors relative to the research covered in the submitted manuscript must be disclosed regardless of date. Other financial information unrelated to the current research covering the past year will be documented at the end of the manuscript (see below). Note that submissions without this Financial Disclosure on the Title Page will be returned to the author. For clinical trials, a statement on ghost-writing is required (*Movement Disorders* 2005;20:1536).

Abstract: The page following the title page of Full-Length Articles should include a brief abstract of up to 250 words describing the background, methods, results, and conclusions of the study. We encourage authors to submit papers with structured abstracts, especially for clinical trial papers. The page following the title page of a Brief Report should include a brief abstract of up to 100 words.

Key words: Up to six key words or terms should be provided following the abstract.

Introduction: Give a brief description of the background of the scientific contribution.

Methods: Informed consent: For experimental investigation of human or animal subjects, please state in this section that an appropriate institutional review board

approved the project. For those investigators who do not have formal ethics review committees, the principles outlined in the “Declaration of Helsinki” should be followed. For investigations in human subjects, state in this section the manner in which informed consent was obtained from the subjects. A letter of consent must accompany all photographs, patient descriptions, and pedigrees in which a possibility of identification exists. The authors are responsible for proper anonymisation of their patients.

Results: No specific regulations.

Discussion: No specific regulations.

Acknowledgment: No specific regulations.

Author Roles: List all authors along with their specific roles in the project and preparation of the manuscript. These may include but are not restricted to: 1) Research project: A. Conception, B. Organization, C. Execution; 2) Statistical Analysis: A. Design, B. Execution, C. Review and Critique; 3) Manuscript: A. Writing of the first draft, B. Review and Critique.

Full Financial Disclosures of all Authors for the Past Year: Information concerning all sources of financial support and funding for the preceding twelve months, regardless of relationship to current manuscript must be submitted with the following categories suggested. List sources or “none”.

Stock Ownership in medically-related fields	Intellectual Property Rights
Consultancies	Expert Testimony
Advisory Boards	Employment
Partnerships	Contracts
Honoraria	Royalties
Grants	Other

References: See “Details of Style” for the proper formatting of citations and References.

Video Legend: No specific regulations.

Tables and Figure Legends: Double-space legends of fewer than 40 words for tables and figures. For photomicrographs, include the type of specimen, original magnification, and stain type. Include internal scale-markers on photomicrographs. Where applicable, indicate the method used to digitally enhance images.

Tables: Tables should be typed neatly, each on a separate page, with a title above and any notes below. Explain all abbreviations. Do not repeat the same information in tables and figures or tables and text.

Figures and Illustrations: Adapt any figures to an appropriate size of art and letters to make them readable in the printed version. Illustrations in full color are accepted at additional charge from the publisher. Any illustration or figure from another publication must be acknowledged in the figure legend, and the copyright holder’s written permission to reprint in print and online edition of *Movement Disorders* must be submitted to the editors.

Copyright and Disclosure Forms The corresponding author should upload one PDF file that includes copyright and disclosure forms for all authors to the Movement Disorders submission site with the revised version of the paper. These forms also can be emailed to mdjedoffice@movementdisorders.org.

Digital Artwork Preparation

For best reproduction, electronic artwork files must be in TIFF or EPS format, at a resolution of 600 dpi or higher, sized to print. *Movement Disorders* offers Rapid Inspector™ to help ensure that your electronic graphics files are suitable for print purposes. This free, stand-alone software application will help you to inspect and verify illustrations right on your computer. Go to <http://rapidinspector.cadmus.com/wi/index.jsp> and create a new account.

Details of Style

No patient identifiers (e.g., patient initials) are to be included in the manuscript or video (e.g., case reports, tables, figures, etc.).

Units of measure: Conventional units of measure according to the *Systeme International* (SI) are preferred. The metric system is preferred for length, area, mass, and volume. Express temperature in degrees Celsius.

Drug Names: Use generic names only in referring to drugs, followed in parentheses after first mention by any commonly used generic variant.

Abbreviations: Follow the list of abbreviations given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (see section on References). For additional abbreviations, consult the CBE Style Manual (available from the Council of Biology Editors, 9650 Rockville Pike, Bethesda, Maryland 20814, USA) or other standard sources.

Spelling: American spelling is used throughout the Journal.

References

Movement Disorders complies with the reference style given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals". (See *Annals of Internal Medicine* 1982;96:766-771, or *British Medical Journal* 1982;284:1766-1770.)

References are to be cited in the text by number, and in the list of References they are to be numbered in the order in which they are cited. The reference section should be double-spaced at the end of the text, following the sample formats given below. Provide all authors' names when fewer than seven; when seven or more, list the first three and add et al. Provide article titles and inclusive pages. Accuracy of reference data is the responsibility of the author. For abbreviations of journal names, refer to List of Journals Indexed in Index Medicus (available from the Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402, USA, DHEW Publication No. (NIH) 83-267; ISSN 0093-3821).

Sample References

Journal article:

1. Horgan JH, O'Callaghan WG, Teo KK. Therapy of angina pectoris with low-dose perhexiline. *J Cardiovasc Pharmacol* 1981;3:566-572.

- Book:
 2. Vanhoutte PM, Leusen I, editors. Vasodilatation. New York: Raven Press; 1981. 96 p.
- Chapter in a book:
 3. Patrono C, Ciabattoni G, Pugliese F, et al. Effect of dietary variation in linoleic acid content on platelet aggregation and the major urinary metabolites of the E prostaglandins and (PGE-M) in infants. In: Hegyeli RJ, editor. Prostaglandins and cardiovascular disease. New York: Raven Press; 1981. p 111–122. (Atherosclerosis reviews; vol. 8).

Appendix 2

Letter of approval from the Chair of the Research Subcommittee,

Clinical Psychology Unit, University of Sheffield



The
University
Of
Sheffield.

Department Of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy) Programme
Clinical supervision training and NHS research training
& consultancy.

**Clinical Psychology Unit
Department of Psychology
University of Sheffield
Western Bank
Sheffield S10 2TP UK**

Telephone: 0114 2226550
Fax: 0114 2226610
Email:

24 February 2010

Alan Gray
Third year trainee
Clinical Psychology Unit
University of Sheffield

Dear Alan

I am writing to indicate our approval of the journal(s) you have nominated for publishing work contained in your research thesis.

Literature Review: Movement Disorders

Research Report: Movement Disorders

Please ensure that you bind this letter and copies of the relevant Instructions to Authors into an appendix in your thesis

Yours sincerely

Dr Andrew Thompson
Director of Research Training

Appendix 3

Literature search tables

Included below are the results of literature searches conducted using the key words as stated in the Search Strategy section of the Literature Review.

The following comes from a combined search of PsycINFO, OVID Medline, the and British Nursing Index:

earch Form

<http://ovidsp.tx.ovid.com.eresources.shef.ac.uk/sp-2.3.1b/ovidw>

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Search History (6 searches) (Click to close)

	# ▲	Searches	Results	Search Type	Actions
<input type="checkbox"/>	1	Parkinson's disease.mp. [mp=ti, ab, hw, ot, nm, an, ui, tc, id]	▶ 46249	Advanced	<input type="button" value="Display"/> More »
<input type="checkbox"/>	2	(caregiver burden or caregiver distress or caregiver strain or caregiving or caregiver stress).mp. [mp=ti, ab, hw, ot, nm, an, ui, tc, id]	▶ 15331	Advanced	<input type="button" value="Display"/> More »
<input type="checkbox"/>	3	1 and 2	▶ 133	Advanced	<input type="button" value="Display"/> More »
<input type="checkbox"/>	4	limit 3 to journal article [Limit not valid in British Nursing Index; records were retained]	▶ 111	Advanced	<input type="button" value="Display"/> More »
<input type="checkbox"/>	5	limit 4 to english language [Limit not valid in British Nursing Index; records were retained]	▶ 106	Advanced	<input type="button" value="Display"/> More »
<input type="checkbox"/>	6	limit 5 to peer reviewed journal [Limit not valid in British Nursing Index,Ovid MEDLINE(R); records were retained]	▶ 105	Advanced	<input type="button" value="Display"/> More »

| Combine selections with:

The table below shows the search results from the Cumulative Index to Nursing and Allied Health Literature (CINAHL):

EBSCOhost: Search History

http://web.ebscohost.com.eresources.shef.ac.uk/ehost/history?vid=1...

EBSCOhost: Search History

Searching: **CINAHL** | [Choose Databases »](#)

Suggest Subject Terms

UNIVERSITY OF SHEFFIELD

in Select a Field (optional)

AND in Select a Field (optional)

AND in Select a Field (optional) [Add Row](#)

[Basic Search](#) | [Advanced Search](#) | [Visual Search](#) | [Search History/Alerts](#) | [Preferences »](#)

Search History/Alerts

[Print Search History](#) | [Retrieve Searches](#) | [Retrieve Alerts](#) | [Save Searches / Alerts](#)

Select / deselect all

Search ID#	Search Terms	Search Options	Actions
<input type="checkbox"/> S1	Parkinson's disease and (Caregiver burden OR caregiver distress OR caregiver strain OR caregiving OR caregiver stress)	Limiters - Peer Reviewed; Language: English Search modes - Boolean/Phrase	View Results (37) Revise Search View Details

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The last table shows the search results from Web of Science:

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All Databases

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ALL DATABASES

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Results Topic=(Parkinson's disease) AND Topic=(caregiver burden OR caregiver distress OR caregiver strain OR caregiving OR caregiver stress)
Refined by: Languages=(ENGLISH)
Timespan=All Years.

Results: **119**

Appendix 4

Interview schedule

Interview schedule

PRE-SURGERY INTERVIEW FOR PATIENTS AND CARERS

Instructions to be read to participant:

"Thank you for attending today. I am interested in findings out more about what you hope surgery will achieve and any changes you envisage. Over the next half hour I want to discuss a number of areas with you. The discussion of each topic will start with me asking you a question in order to stimulate our discussions. There will be five topics of discussion which I expect will lead to a discussion of around half an hour. You are not obliged to answer any of the questions, although any answers you do give will be kept confidential. In answering these questions, please do not assume that I have a detailed understanding of the issues you discuss. Instead, I want you to give me as much detail as possible. Do not feel rushed into giving your answers. Instead, take time to think about each of the questions. However, there are no 'right' or 'wrong' answers, as ultimately I am interested in your experience. Do you have any questions before we begin?"

Questions:

1) What has caused you/your partner to seek STN-DBS?

- Prompts:
- Describe life with Parkinson's disease
 - Tell me about some of the difficulties you have with Parkinson's disease
 - How has Parkinson's disease impacted on your life?
 - What is your understanding of what surgery can offer?

2) How would you expect things to be different after surgery?

- Prompts:
- Do you feel surgery will change things for you?
 - What types of things do you think surgery will change?
 - Are there things that you don't think surgery will change?
 - How will life be after surgery?

3) What are your biggest hopes from surgery?

- Prompts:
- What is the main thing you want surgery to achieve?
 - How would you like things to be different after surgery?
 - What might be the most important things surgery will achieve?
 - What aspects of your life do you most hope surgery will alter?

4) How would you know if you were satisfied with the outcome of surgery?

- Prompts:
- How will you judge whether surgery has been effective?
 - What criteria will you use to judge whether surgery has achieved its aims?
 - What might make you feel that surgery hasn't been effective?
 - What changes would you look for in order to be happy with surgery?

5) What problems do you imagine will remain after surgery?

- Prompts:
- What things are unlikely to change after surgery?
 - Do you envisage any new problems resulting from surgery?
 - What things will surgery not fix?
 - What do you expect will remain the same after surgery?

END OF INTERVIEW

POST-SURGERY INTERVIEW FOR PATIENTS AND CARERS

Instructions to be read to participants:

"Thank you for attending today. I am interested in findings out more about your evaluation of surgery and any changes you have noticed. Over the next half hour I want to discuss a number of areas with you. The discussion of each topic will start with me asking you a question in order to stimulate our discussions. There will be five topics of discussion which I expect will lead to a discussion of around half an hour. You are not obliged to answer any of the questions, although any answers you do give will be kept confidential. In answering these questions, please do not assume that I have a detailed understanding of the issues you discuss. Instead, I want you to give me as much detail as possible. Do not feel rushed into giving your answers. Instead, take time to think about each of the questions. However, there are no 'right' or 'wrong' answers, as ultimately I am interested in your experience. Do you have any questions before we begin?"

Questions:

1) In what ways has surgery lived up to your expectations?

- Prompts:
- What were your expectations of surgery?
 - Has surgery been worthwhile?
 - Which expectations have been fulfilled?
 - Have any expectations not been fulfilled?

2) What has changed since surgery?

- Prompts:
- Has surgery changed things for you?
 - How have things been different since surgery?
 - Describe the changes in your life since surgery?
 - What things can you do now which you couldn't before?

3) What have been the most important changes and why?

- Prompts:
- What has been the biggest change since surgery?
 - What changes are you most happy with?
 - What changes have had the biggest impact on your life?
 - What significance have these changes had?

4) What issues remain difficult since surgery?

- Prompts:
- What things have remained difficult despite surgery?
 - Have any things become more difficult?
 - What things has surgery not had an impact on?
 - Has surgery failed to improve areas you feel to be important?

5) How do you see the outcome of surgery impacting on your future?

- Prompts:
- How do you see your future now?
 - What role has surgery played in your hopes and dreams for the future?
 - How might the future have been if you/the patient hadn't had surgery?
 - What opportunities do you have now which you might not have had without surgery?

END OF INTERVIEW

Appendix 5

Zarit Burden Inventory

(QUESTIONNAIRE REMOVED TO COMPLY WITH COPYRIGHT REGULATIONS)

(QUESTIONNAIRE REMOVED TO COMPLY WITH COPYRIGHT REGULATIONS)

(QUESTIONNAIRE REMOVED TO COMPLY WITH COPYRIGHT REGULATIONS)

Appendix 6

Visual Analogue Scale

VISUAL ANALOGUE SCALE

Please use the scale below to indicate your overall level of satisfaction with the outcome of the surgical procedure. Indicating a score of 0 indicates you are 'highly dissatisfied with surgical outcome', where as marking a score of 100 indicates you are 'highly satisfied with surgical outcome.'

Mark a straight vertical line through the part of the scale that most accurately shows your degree of satisfaction:



Appendix 7

Participant information sheet for patients



The
University
Of
Sheffield.

Department Of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy)
Programme
Clinical supervision training and NHS
research training & consultancy.

**Clinical Psychology Unit
Department of Psychology
University of Sheffield
Western Bank
Sheffield S10 2TN UK**

PATIENT INFORMATION SHEET (Version 3, 6th October 2009)

Understanding Expectations of, and Satisfaction with, Deep Brain Stimulation of the Subthalamic Nucleus: Patient and carer perspectives in Parkinson's disease

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read through the following information carefully and discuss it with friends, relatives, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Deep brain stimulation is effective in reducing the symptoms of Parkinson's disease. However, we still know little about what patients and their carers expect of surgery and what effect their expectations have on whether they think the operation is a success. We hope that this study will provide more information into this area.

Who is conducting this study?

This study is being conducted by Alan Gray (Trainee Clinical Psychologist) as part of a thesis for his Doctorate in Clinical Psychology at the University of Sheffield. Dr Claire Isaac (Clinical Lecturer) will be supervising the research. Dr Hazel Reynders (Consultant Clinical Neuropsychologist) and Dr Richard Scott (Consultant Clinical Neuropsychologist) are collaborating on this study.

Why have I been invited?

You and your relative/carer have been invited because you are due to undergo deep brain stimulation surgery.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet with you. We will then ask you to sign a consent form to show that you have agreed to take part. You are

free to withdraw from the study at any time, without giving a reason. Your decision will not affect the standard of care you receive.

What will be involved if I/we agree to take part in the study?

We would like to interview you and your relative/carer in the weeks running up to your surgery. Both of you will be asked about your expectations of surgery. Your relative/carer will also be asked to complete a short questionnaire measuring the amount of caregiving provided. Around 6 months after surgery, you and your relative/carer will be asked to complete another interview, this time looking at how satisfied you are with the outcome of the surgery. It is expected that each interview will last around 30 minutes. Where possible interviews will be arranged for a time when you are expected to be in the hospital, thereby limiting your inconvenience. Each interview will be recorded on audio-cassette which will be stored securely, thereby retaining your right to confidentiality.

Will you need to access my clinical notes?

With your permission, your clinical notes will be consulted. All information gained will be kept in the strictest confidence.

Can I withdraw from the study at any time?

Yes. You are free to refuse to join the study and may withdraw at any time or choose not to answer certain questions. Your decision to withdraw will not affect your medical care in any way.

Will my travel expenses be reimbursed?

If your sole reason for travelling to the hospital is to take part in the interview then the costs of public transport to and from sessions will be paid for. Car drivers will be reimbursed at the rate of 26p per mile.

What are the possible disadvantages of taking part?

The main disadvantage is that you will have to give your time to attend the interview. It is possible that talking about your experience of Parkinson's disease and surgery may cause some emotional distress.

What are the possible benefits of taking part?

This is a new area of investigation and one which we hope will improve future treatment. Your views may help improve the levels of care received by future patients having this form of surgery.

What happens when the research study stops?

All information you have provided will be kept securely in order to protect your right to confidentiality. When all the information has been collected the results will be written up as part of a clinical psychology doctoral thesis. The results will also be published in research journals.

Will the information obtained in the study be confidential?

Yes. Confidentiality is taken very seriously. Anything you say will be treated in confidence and the study will follow all ethical and legal practices surrounding the protection of your anonymity. A transcriber will be asked to convert the taped interview into written form. This transcriber will also be legally obliged to protect your right to confidentiality and will not discuss your interview with anyone other than the main researcher. Once the study is complete all audio tapes will be destroyed. Your name will not be mentioned in any reports and any identifiable information will be altered.

Will anyone else be told about my participation in the study?

It will be necessary to speak to hospital staff to arrange a suitable time for your interview. However, they will not be told of what you discuss in the interviews.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Yorkshire Research Ethics Committee.

What if there is a problem?

If you have a concern about any aspect of this study, please contact the study manager, Dr Claire Isaac, by post (Clinical Psychology Unit, Department of Psychology, The University of Sheffield, Western Bank, Sheffield, S10 2TP), or telephone 0114 271 3370. If you remain unhappy and wish to complain formally, please contact Dr David Fletcher, the Registrar and Secretary of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN), telephone (0114 222 1100) or e-mail (D.E.Fletcher@sheffield.ac.uk). You can also contact the Patient Advice and Liaison Service (PALS) at the hospital by post (PALS Manager Sheffield Teaching Hospitals NHS Foundation Trust, Patient Partnership Department, B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF), telephone (0114 271 2450) or e-mail (pals@sth.nhs.uk). The PALS service will listen to your concerns and advise you on how to make a complaint if that is what you wish to do.

Further information and contact details:

Please contact Dr Claire Isaac, Clinical Psychology Unit, Department of Clinical Psychology, The University of Sheffield, Western Bank, Sheffield, S10 2TP. Tel. 0114 222 6570. Your message will be passed onto Alan Gray (Trainee Clinical Psychologist) who will talk to you about any questions you may have.

Appendix 8

Participant information sheet for carers



The
University
Of
Sheffield.

Department Of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy)
Programme
Clinical supervision training and NHS
research training & consultancy.

**Clinical Psychology Unit
Department of Psychology
University of Sheffield
Western Bank
Sheffield S10 2TN UK**

CARER INFORMATION SHEET (Version 3, 6th October 2009)

Understanding Expectations of, and Satisfaction with, Deep Brain Stimulation of the Subthalamic Nucleus: Patient and carer perspectives in Parkinson's disease

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read through the following information carefully and discuss it with friends, relatives, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Deep brain stimulation is effective in reducing the symptoms of Parkinson's disease. However, we still know little about what patients and their carers expect of surgery and what effect their expectations have on whether they think the operation is a success. We hope that this study will provide more information into this area.

Who is conducting this study?

This study is being conducted by Alan Gray (Trainee Clinical Psychologist) as part of a thesis for his Doctorate in Clinical Psychology at the University of Sheffield. Dr Claire Isaac (Clinical Lecturer) will be supervising the research. Dr Hazel Reynders (Consultant Clinical Neuropsychologist) and Dr Richard Scott (Consultant Clinical Neuropsychologist) are collaborating on this study.

Why have I been invited?

You have been invited because you are caring for someone who is due to undergo deep brain stimulation surgery.

Do I have to take part?

No. It is up to you to decide. We will describe the study and go through this information sheet with you. We will then ask you to sign a consent form to show that you have agreed to take part. You are

free to withdraw from the study at any time, without giving a reason. Your decision will not affect the standard of care the patient receives.

What will be involved if I agree to take part in the study?

We would like to interview you in the weeks running up to the surgery. You will be asked about your expectations of surgery and will also be asked to complete a short questionnaire measuring the amount of caregiving you provide. Around 6 months after surgery, you will be asked to complete another interview, this time looking at how satisfied you are with the outcome of the surgery. It is expected that each interview will last around 30 minutes. Where possible, interviews will be arranged for a time when the patient is expected to be in the hospital, thereby limiting your inconvenience. Each interview will be recorded on audio-cassette which will be stored securely, thereby retaining your right to confidentiality.

Can I withdraw from the study at any time?

Yes. You are free to refuse to join the study and may withdraw at any time or choose not to answer certain questions. Your decision to withdraw will not affect the patient's medical care in any way.

Will my travel expenses be reimbursed?

If your sole reason for travelling to the hospital is to take part in the interview then the costs of public transport to and from sessions will be paid for. Car drivers will be reimbursed at the rate of 26p per mile.

What are the possible disadvantages of taking part?

The main disadvantage is that you will have to give your time to attend the interview. It is possible that talking about your experience of Parkinson's disease and surgery may cause some emotional distress.

What are the possible benefits of taking part?

This is a new area of investigation and one which we hope will improve future treatment. Your views may help improve the levels of care received by future patients having this form of surgery.

What happens when the research study stops?

All information you have provided will be kept securely in order to protect your right to confidentiality. When all the information has been collected the results will be written up as part of a clinical psychology doctoral thesis. The results will also be published in research journals.

Will the information obtained in the study be confidential?

Yes. Confidentiality is taken very seriously. Anything you say will be treated in confidence and the study will follow all ethical and legal practices surrounding the protection of your anonymity. A transcriber will be asked to convert the taped interview into written form. This transcriber will also be legally obliged to protect your right to confidentiality and will not discuss your interview with anyone other than the main researcher. Once the study is complete all audio tapes will be destroyed. Your name will not be mentioned in any reports and any identifiable information will be altered.

Will anyone else be told about my participation in the study?

It will be necessary to speak to hospital staff to arrange a suitable time for your interview. However, they will not be told of what you discuss in the interviews.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Yorkshire Research Ethics Committee.

What if there is a problem?

If you have a concern about any aspect of this study, please contact the study manager, Dr Claire Isaac, by post (Clinical Psychology Unit, Department of Psychology, The University of Sheffield, Western Bank, Sheffield, S10 2TP), or telephone 0114 271 3370. If you remain unhappy and wish to complain formally, please contact Dr David Fletcher, the Registrar and Secretary of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN), telephone (0114 222 1100) or e-mail (D.E.Fletcher@sheffield.ac.uk). You can also contact the Patient Advice and Liaison Service (PALS) at the hospital by post (PALS Manager Sheffield Teaching Hospitals NHS Foundation Trust, Patient Partnership Department, B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF), telephone (0114 271 2450) or e-mail (pals@sth.nhs.uk). The PALS service will listen to your concerns and advise you on how to make a complaint if that is what you wish to do.

Further information and contact details:

Please contact Dr Claire Isaac, Clinical Psychology Unit, Department of Clinical Psychology, The University of Sheffield, Western Bank, Sheffield, S10 2TP. Tel. 0114 222 6570. Your message will be passed onto Alan Gray (Trainee Clinical Psychologist) who will talk to you about any questions you may have.

Appendix 9

Consent form for patients

Appendix 10

Consent form for carers

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM FOR CARERS
(Version 3, 6th October 2009)

Title of Project:

Understanding Expectations of, and Satisfaction with, Deep Brain Stimulation of the Subthalamic Nucleus: Patient and carer perspectives in Parkinson's disease

Name of Researcher:

Alan M Gray

Please initial box

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights or the patient's medical care being affected.

3. I understand that interviews will be audio-recorded and agree to this process. I understand that my identity will be kept confidential and any information that may identify me will be changed in any written reports.

4. I understand that interview material will be transcribed by a person other than researcher (Alan Gray). This person will be made to sign a contractual agreement to protect your identity.

5. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

6. I agree to take part in the above study.

Name of Carer

Date

Signature

Name of Person taking consent

Date

Signature

Appendix 11

Worked example of Template Analysis

Worked Example of Template Analysis

This section provides an example of how transcript examination was undertaken with Template Analysis. The focus will be patients' pre-surgical interviews. This first step involved identifying sections of text concerned with surgical expectations. Codes were placed in the right hand column summarising and interpreting the meaning of such text.

The example below is a short extract from Paul's interview.

Transcript

Open Coding

I And then I guess that kind of brings us up to surgery. What are your thoughts now when you think about surgery – deep brain stimulation?

P Well really having been almost volunteered by someone who was pretty knowledgeable about it, I never really thought too deeply about it. Again, I've never looked at the downsides, I've always tried to be very positive. I looked at certain case histories and by then I'd started taking up golf and was playing green bowls as well and, um, realised that was becoming more difficult. And then I read about this guy who was a professional golfer in the States who'd had Deep Brain and went back and became again a professional golfer, so I thought 'well that can't be too bad if you can achieve that kind of success then there might be something really worthwhile here'. I never really had the expectations of becoming a professional golfer (LAUGHTER) as a result of deep brain stimulation. I just wanted relief from the discomfort of the tremor, because I was then on my maximum medication. But the chance to reduce that would be good.

*Reliant on opinion of physician
Confidence in treating clinician
Limited consideration of outcome
Acceptance of downsides
Limited consideration of downsides
Optimism
Expectations based on hearing about others*

Expectations based on hearing about others

Improvements in hobbies

Possibility of good outcome

Improvement in tremor

Reduced medication

The next stage involved examining whether codes could be grouped into higher-order themes. The *a priori* assumptions of the study were that themes around change in motor symptoms and quality of life would be discussed. Where these themes did not accurately describe codes, alternative themes were proposed:

<u>First Order Theme</u>	<u>Second Order Theme</u>	<u>Codes</u>
CHANGE FOLLOWING SURGERY	MOTOR SYMPTOMS AND/OR MEDICATION	Improvement in tremor Reduced medication
	QUALITY OF LIFE	Improved hobbies
	UNCERTAINTY AROUND CHANGE	Reliant on opinion of clinician Confidence in opinion of treating clinician
PROBLEMS THAT COULD REMAIN / NEW PROBLEMS	HEARING ABOUT OTHERS	Expectations based on others' case histories Expectations base on media stories Possibility of a good outcome from stories
	NOT A CURE	Acceptance of downsides
	LIMITED CONSIDERATION OF DOWNSIDES	Limited consideration of downsides Optimism

Whilst in practice the initial template was more detailed due to being developed on a larger transcript, for the sake of this worked example the themes outlined above shall be considered the initial template.

The next stage involved applying the template to the next participant interview to examine whether it accurately summarised the themes that emerged. Overleaf is an extract from Alex's interview. The initial template will be applied in the right-hand column. Where the template does not accurately describe emergent themes, a question mark is put in place.

<u>Transcript</u>	<u>First order themes</u>	<u>Secondary themes</u>	<u>Codes</u>
I So what is your understanding of what surgery can offer?			
P The main thing for me is dropping my meds down, they say it will cut them by at least a half which will be the main benefit for me I think. That should get rid of my involuntary movements. I've been falling lately, over the last few months and that's another reason why I went for the surgery but I understand it's not going to be effective for that, but that's alright, I can cope with that if the rest is better.	PROBLEMS LIKELY TO REMAIN	CHANGE FOLLOWING SURGERY	<i>Reduced medication</i>
			<i>Reduced dyskinesia</i>
I So can you tell me why those things are important for you?			<i>Falling will remain</i>
P I mean I'm quite into sport so, I used to play badminton and go cycling a lot and go walking, skiing. I will be able to do all those things better than I can now. I mean I still do most of them, but just like walking, I can't do, well I can do I suppose but it would knacker me out to do a ten mile walk so we tend to do two or three miles now. Yeah, just play more sport and socialise more I think. I think I'm fine with socialising with my friends but if I am meeting new people I find that quite difficult because I think they will be wondering what is wrong with me.	CHANGE FOLLOWING SURGERY (QUALITY OF LIFE)	NOT A CURE	<i>Falling will be manageable</i>
			MOTOR SYMPTOMS
			<i>Be better at sports</i>
		Hobbies	<i>More energy for sports</i>
			<i>Socialise more</i>
		?	<i>Less discomfort around strangers</i>

Applying the template to Alex's script revealed some overlap in the themes discussed in Paul's interview. However, there were also some areas of the transcript that the initial template was not able to summarise. The initial template from Paul's interview is presented below. Modifications made to the template based on Alex's interview are shown in italics.

<u>First Order Theme</u>	<u>Second Order Theme</u>	<u>Codes</u>
CHANGE FOLLOWING SURGERY	MOTOR SYMPTOMS AND/OR MEDICATION	Improvement in tremor Reduced medication <i>Reduced medication</i> <i>Improved dyskinesia</i>
	QUALITY OF LIFE	Hobbies Improved hobbies <i>Being better at hobbies</i> <i>More energy for sports</i>
		Socialising <i>Socialise more</i> <i>Less discomfort around strangers</i>
	UNCERTAINTY AROUND CHANGE	Reliant on opinion of clinician Confidence in opinion of treating clinician
	HEARING ABOUT OTHERS	Expectations based on others' case histories Expectations base on media stories Possibility of a good outcome from stories
PROBLEMS THAT COULD REMAIN / NEW PROBLEMS	NOT A CURE	Acceptance of downsides <i>Falling will remain</i>
	LIMITED CONSIDERATION OF DOWNSIDES	Limited consideration of downsides Optimism
	<i>REMAINING PROBLEMS NOT SO BAD</i>	<i>Falling will be more manageable</i>

As can be seen, the analysis of Paul's transcript:

- Added to some already formed themes (e.g. dyskinesia was added to the 'motor symptom' theme)
- Resulted in the modification of themes (e.g. the 'quality of life' theme was split into changes in 'hobbies' and 'socialising')
- Necessitated the formation of new themes (e.g. 'Remaining problems not as bad' theme).

This modified template was then re-applied to Paul's transcript to ensure that it continued to accurately summarise his transcript. Following this, the modified template was then applied to the next participant's transcript. This process of modifying the template based on considerations emerging from successive interviews continued until a final template was produced which accurately summarised all codes deemed relevant to the research question across all transcripts.

Appendix 12

Transcriber confidentiality form

Doctorate in Clinical Psychology, University of Sheffield

Confidentiality Form

Type of project: Clinical Skills Assessment / Research thesis

Project title _____

Researcher's name _____

The tape you are transcribing has been collected as part of a research project. Tapes may contain information of a very personal nature, which should be kept confidential and not disclosed to others. Maintaining this confidentiality is of utmost importance to the University.

We would like you to agree:

- Not to disclose any information you may hear on the tape to others,
- To keep the tape in a secure locked place when not in use,
- When using the tape to ensure it cannot be heard by other people,
- To adhere to the *Guidelines for Transcribers in relation to the use of computers*, and
- To show your transcription only to the relevant individual who is involved in the research project.

If you find that anyone speaking on a tape is known to you, we would like you to stop transcription work on that tape immediately and inform the person who has commissioned the work.

Declaration

I have read the above information, as well as the *Guidelines for Transcribers*, (appendix 1) and I understand that:

1. I will discuss the content of the tape only with the individual involved in the *research project*
2. I will keep the tape in a secure place where it cannot be heard by others
3. I will treat the transcription of the tape as confidential information
4. I will adhere to the requirements detailed in the *Guidelines for transcribers in relation to transcribing tapes onto a computer*

5. If the person being interviewed on the tapes is known to me I will undertake no further transcription work on the tape

I agree to act according to the above constraints

Your name _____

Signature _____

Date _____

Occasionally, the conversations on tapes can be distressing to hear. If you should find it upsetting, please stop the transcription and raise this with the researcher as soon as possible.

Appendix 13

Letters confirming ethical approval from
South Yorkshire Research Ethics Committee



National Research Ethics Service
South Yorkshire Research Ethics Committee

1st Floor Vickers Corridor
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Telephone: 0114 226 9153
Facsimile: 0114 256 2469
Email: joan.brown@sth.nhs.uk

2 October 2009

Mr Alan Gray
701 Ecclesall Road
Sheffield
S11 8TG

Dear Mr Gray

Study Title: Understanding Expectations of, and Satisfaction with,
Deep Brain Stimulation of the Subthalamic Nucleus:
Patient and carer perspectives in Parkinson's disease

REC reference number: 09/H1310/68

Protocol number: 2

The Research Ethics Committee reviewed the above application at the meeting held on the 24 September 2009. Thank you for attending to discuss the study.

Discussion

It was observed this was a very good and clearly completed application.

It was noted that you intended to interview candidates twice – once before and once after surgery and that they would also be consented twice. You were asked to explain the reasoning behind this and informed members that you had had some previous experience of working in this area and felt there was always the risk that any kind of condition may be exacerbated by surgery. You felt it would be appropriate to check whether the participant still had the capacity to consent after the surgery. Also, you accepted that it might be difficult for participants to talk about their experiences and felt it fitting to give them the option of consenting again. You added that if any participants should lose capacity to consent they would be excluded from the study. The committee accepted this explanation.

It was noted that you intended to keep the data for over three years and it was queried whether this would include the actual tapes on which the recordings were made. You confirmed that the transcriptions would be kept for that length of time but not the tapes themselves and added it was university policy to keep the data for five years after completion of the study. The committee accepted this explanation.

It was queried which sites were involved in the study and you confirmed that it was a collaborative study between Oxford and Sheffield involving eight patients and eight carers. As you had just learned you were to be based in Oxford you felt the majority of patients would be recruited there but you had applied for research governance at both sites and would therefore be in a position to recruit from either site. The committee accepted this clarification.

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

There were some minor issues that needed addressing in the participant information sheets and consent form that are detailed below.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

1. Submit amended Participant Information Sheets (Version 3 with a new date) for both patients and carers as follows:
 - After the heading "Will anyone else be told about my participation in the study?" insert an additional heading i.e. "Who has reviewed this study?" under this heading insert "All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Yorkshire Research Ethics Committee"
2. Submit amended consent form (Version 3 with a new date) for patients as follows:
 - Amend Point 5 to read "I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by the researcher and by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records".
3. Submit amended consent form (Version 3 with a new date) for carers as follows:
 - Insert an additional Point as No.5 to read "I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records".

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The REC nominated the Co-ordinator, Mrs Joan Brown to be the point of contact should further clarification be sought by the applicant upon receipt of the decision letter.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Supervisor's CV - Claire Isaac		
REC application		21 August 2009
Protocol	2	17 March 2009
Investigator CV		14 August 2009
Participant Information Sheet	2	17 March 2009
Participant Information Sheet: Carers	2	17 March 2009
Letter from Sponsor		07 August 2009
Questionnaire: Non-validated - Visual Analogue Scale	2	17 March 2009
Interview Schedule	2	17 March 2009
Letter from Sponsor		07 September 2009
Participant Consent Form	2	17 March 2009
Participant Consent Form: Carers	2	17 March 2009
Referees or other scientific critique report		26 June 2009
Questionnaire: Validated - Burden Interview		
Guidelines for Transcribers	2	17 March 2009
Confidentiality Form for Transcribers	2	17 March 2009
Scaling & Scoring of the Zarit Burden Interview		
Letter re Funding		20 July 2009

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

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The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email

09/H1310/68

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Miss Jo Abbott
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" SL-AR2

Copy to: Lauren Smaller, Research Office, Sheffield University, New Spring House, 231 Glossop Road, Sheffield, S10 2GW

STH R&D Department

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National Research Ethics Service
South Yorkshire Research Ethics Committee

1st Floor Vickers Corridor
Northern General Hospital
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Sheffield
S5 7AU

Telephone: 0114 226 9153
Facsimile: 0114 256 2469
Email: joan.brown@sth.nhs.uk

07 October 2009

Mr Alan Gray
15 Demesne Furze
Oxford
OX3 7XF

Dear Mr Gray

Full title of study: Understanding Expectations of, and Satisfaction with,
Deep Brain Stimulation of the Subthalamic Nucleus:
Patient and carer perspectives in Parkinson's disease
REC reference number: 09/H1310/68
Protocol number: 2

Thank you for your email of 6 October 2009. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 2 October 2009. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

Document	Version	Date
Covering Email		06 October 2009
Participant Information Sheet: Patients	3	06 October 2009
Participant Information Sheet: Carers	3	06 October 2009
Participant Consent Form: Patients	3	06 October 2009
Participant Consent Form: Carers	3	06 October 2009

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

09/H1310/68 Please quote this number on all correspondence

Yours sincerely

Joan Brown

Mrs Joan Brown
Committee Co-ordinator

Copy to: Lauren Smaller, Research Office, Sheffield University, New Spring House,
231 Glossop Road, Sheffield, S10 2GW

STH R&D Department

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