Correlates of constipation in people with Parkinson's

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ABSTRACT

Purpose: to investigate clinical, demographic and dietary factors associated with constipation in a sample of community dwelling people with Parkinson's disease, recruited through a specialist outpatient clinic. Partners / carers provided a convenience control group.

Scope: Participants completed a baseline questionnaire (background information, diet and exercise, activities of daily living: mobility and manual dexterity, health-related quality of life (SF-12), stool frequency and characteristics, extent of concern due to constipation, laxative taking), and a four week stool diary. The Rome criterion was used to determine constipation status. Multiple regression methods were used to explore the correlates of constipation. Baseline data were provided by 121 people with Parkinson's, (54 controls), of whom 73% (25%) met the Rome criterion. Prospective diary data from 106 people with Parkinson's (43 controls) showed lower proportions: 35% (7%) meeting the Rome criterion. Constipation is predicted by having Parkinson's disease ($p = .003$; odds ratio 4.80, 95% CI 1.64 to 14.04) and mobility score ($p = .04$; odds ratio 1.15, 95% CI 1.01 to 1.31), but not by dietary factors. Amongst people with Parkinson's constipation is predicted by number of medications ($p = .027$). Laxative taking masks constipation, and is significantly associated with wearing protection against bowel incontinence ($p = .009$; odds ratio 4.80, 95% CI: 1.48 to 15.52).

Conclusions: constipation is disease-related, not a lifestyle factor. More research is needed on optimal management and laxative use.

INTRODUCTION

Constipation is common in older people [1]. It adversely affects quality of life [2], and incurs significant healthcare costs for laxatives and the treatment of complications. Constipation is a symptom of neurological disease [3,4] and studies show that 50% [5] to over 70% [6] of people with Parkinson's suffer from constipation; and the excess burden relative to age matched controls may be as high as 60% [7-10]. Laxatives are estimated to be taken by approaching 40% of people with Parkinson's [6,10]. Constipation is one of several autonomic system failures associated with Parkinson's [7-9,11-14]. Manometric investigations show two causes: anorectal 'outlet' dysfunction, causing straining, and slow colonic transit, suggesting local / peripheral nervous system effects and CNS mechanisms underlie constipation [4,5,14-17].

Diagnosing constipation is difficult because it means different things to different people [3,14]. Infrequent bowel movement in the absence of other symptoms (straining, hard / lumpy stools, feeling of obstruction or incomplete evacuation) may lie within the normal spectrum [18]. Constipation is assessed by objective means (for example, self report of frequency), subjectively (expressions of 'bothersomeness' or concern caused by it) or behaviour (laxative taking or other self help measures).

It is not known why only some people with Parkinson's experience constipation. Improved understanding of the risk factors will help ensure that health professionals implement evidence – based management strategies [12]. The aim of this study was to investigate clinical, demographic and dietary factors associated with constipation in a sample of community dwelling people with Parkinson's disease.

METHODS

Recruitment and data collection

Ethical approval was obtained from the local NHS ethics committee. All people with Parkinson's attending a specialist outpatient clinic (except new patients and those with a recorded diagnosis of dementia) were sent an information sheet about the study and a letter inviting them to take part. Where appropriate, a separate information sheet and invitation was enclosed for partners / carers, who were included in the study to provide a convenient control group, and one that shared food preparation arrangements. Those interested in participating contacted the research team, and attended an interview at their next clinic visit. Repeat invitations were mailed to non responders, but only after a 12 month delay, on ethical grounds. At the clinic interview (conducted in private), a researcher received consent (separately for patients and partner / carers). Partners were asked to self complete baseline questionnaires, whilst the researcher collected data from patients. The researcher then gave participants a four week stool diary, and explained how to complete it. Participants were phoned after two weeks to assess progress. Completed diaries were returned in prepaid envelopes.

The target recruitment was 100 people with Parkinson's, and record reviews suggested that about 80% of community dwelling patients would have a partner / carer who could be invited to join the control group. Sample size calculations suggested that if 100 people with Parkinson's were recruited, using a 5% significance level, a comparison of patients with partner / carers (controls) will yield 80% power against a medium sized standardised difference of 0.6.

Measurement of constipation

The baseline questionnaire was used to collect retrospective self report information on participants' experiences of constipation including: the extent to which constipation was a cause for concern; frequency of bowel movements; use of prescribed and purchased over-the-counter laxatives; self help measures (increased fluid, fibre, fruit and vegetable intake, other dietary change, extra exercise); soiling and use of protection due to bowel incontinence (see Table 3). The first version of the Rome criterion (Rome I) was used to objectively assess whether a participant suffered from constipation. This internationally recognised standard asks subjects whether, for at least a quarter of the time during the last three months, they have: had to strain

when opening their bowels; had lumpy / hard stools; had a sensation of incomplete evacuation; had less than three bowel movements per week. Constipation is present if the subject answers 'yes' to two or more of the four symptoms [19].

To avoid inaccuracies from poor recall, diaries are recommended for collection of data on bowel function [20]. A bowel diary was purposefully developed for the study. Records were arranged one week to a page, and participants were asked to note daily the date and time of each bowel movement, (zero if no bowel opening), and use of laxatives / home remedies. Further information was recorded for each bowel movement: minutes spent, whether they felt empty afterwards (yes/ no), straining (0= none, 1= mild, 2= moderate, 3= severe), stool consistency (referring to pictures on the Bristol Stool Form Chart [21], range 1, separate hard lumps, like nuts (difficult to pass) to 7, watery, no solid pieces, entirely liquid). A sample of 12 diaries was independently reviewed by six nurses and continence advisors who concluded that the data generated were reliable and complete, enabling appropriate clinical interpretations to be drawn. Diary data were analysed to assess whether the bowel activity recorded met the Rome criterion (see footnote to Table 5). Participant's constipation status reported retrospectively at baseline was compared with that recorded prospectively in the diary.

Other variables

Baseline questionnaires were used to collect data from patients and partner / carers on factors potentially associated with constipation: socio – demographic, economic characteristics; life style behaviours, including exercise, liquid, fruit / vegetable and fibre intake; activity of daily living (ADL) disability measure [22]; physical and mental functioning component summary scores (PCS and MCS) of SF – 12 [23], an internationally validated measure of health- related quality of life (Table 2). Clinical information for people with Parkinson's was extracted from medical notes by a Parkinson's specialist nurse: Hoehn and Yahr disease stage [24], number of co-morbidities and prescribed medications; taking COMT inhibitors (yes/ no - because diarrhoea is a side effect); taking agonists or anticholinergics (yes/ no - because constipation is a side effect).

Statistical analysis

Data were entered into SPSS version 14. Basic analyses were undertaken using t-tests, Pearson's correlation, ANOVA and contingency table tests as appropriate. Correlates of constipation (socio- economic and demographic, lifestyle behaviours, ADL, Parkinson's status) were explored using multiple regression and multiple logistic regression, with the Rome criterion (≥ 2 symptoms) from the background questionnaire as the dependent variable. Patient only analyses additionally included clinical features: disease stage, number of co-morbidities and medications, whether or not taking COMT inhibitors, agonists, anticholinergics, and the presence / absence of dementia and hypotension. Statistical significance was attained at $p < .05$.

RESULTS

Characteristics of samples

A total of 238 people with Parkinson's and 188 partner /carers (controls) were invited to participate over a 2 year period (2005 – 7). Consent and baseline information was obtained from 121 (50.8%) people with Parkinson's and 54 (28.7%) partners / carers. Of these, 106 (87.6%) people with Parkinson's and 43 (79.6%) carers returned stool diaries. Recruitment continued beyond the planned target of 100 people with Parkinson's to increase the size of the control group.

About one half of people with Parkinson's recruited were Hoehn and Yahr stage 2 and reported no other health conditions (Table 1). A higher proportion of people with Parkinson's than partner / carers were male; there were no significant differences between groups in other socio – demographic, economic variables (Table 2). People with Parkinson's reported relatively high levels of independence (mean of 2, i.e. able to do activity alone with a little effort, on each item of the ADL disability scale), but in comparison to controls, their mobility, manual dexterity and PCS scores were significantly worse. Partners / carers reported eating significantly more fruit and

vegetables, but there were no differences between groups in other self reported behaviours (Table 2).

TABLES 1 AND 2 GO HERE

Baseline reporting of constipation

On each measure, people with Parkinson's were significantly more likely to report constipation than controls (Table 3). Measures of constipation were closely correlated (Table 4). Patients (controls) stating that constipation caused them a lot of concern were 8.26 (11.5) times more likely to be taking any laxative, and 14 (7.2) times more likely to be constipated according to the Rome criterion than people who stated they were not greatly concerned by constipation.

TABLES 3 AND 4 GOES HERE

Bowel incontinence

Nine percent of respondents with Parkinson's, 3.7% of partner / carer controls, reported wearing protection against faecal incontinence (Table 3). This behaviour was significantly associated with taking any laxative ($p=.009$). Of the 13 people wearing protection, 8 (61.5%) take laxatives, compared to 40 of 165 (24.7%) of those not wearing protection. People taking a laxative are almost five times more likely to wear protection than those who do not take a laxative (odds ratio 4.80, 95% CI: 1.48 to 15.52). This relationship persists even after allowing for Parkinson's status ($p=.019$; odds ratio 4.25, 95% CI: 1.27 to 14.29).

Stool diary analysis

People with Parkinson's were significantly more constipated than controls (Table 5). Lower proportions of people with Parkinson's and of partner / carers were defined as constipated (Rome criterion) in the diary analysis than in retrospective reporting at baseline (35% vs 73%, 7% vs 24.5% respectively). There was no difference in constipation status at baseline between the people who completed the stool diary and

those who did not, nor between the characteristics of people whose constipation status changed between baseline and diary and the characteristics of those whose status did not (data not shown).

TABLE 5 GOES HERE

Diaries show laxatives (and home remedies such as fibre) were taken by 45, 42.4% (11, 10.4%) of people with Parkinson's and 2, 4.6% (0) of partner / carers at least once during the 28 day observation period. The mean number of days laxatives (home remedies) were taken was 10 (6). Eight patients who took home remedies also used laxatives. Twenty three (21.7%) patients and 2 (4.7%) partner / carers reported taking laxatives at least once per week. The equivalent rates at baseline were 35% (11%). Patients taking daily laxatives (n=7) had the highest mean frequency of stools (1.04, range 0.9 – 2.3). Over half of patients (n=61, 57.5%) reported no laxative use in their diaries and a mean of 1.0 stools per day (0.3 – 3.9). The lowest stool frequency was recorded by occasional (once or twice a week) laxative users (0.73, 0.5 – 1.0).

Correlates of constipation

In multiple regression analysis, the only factors predictive of constipation were having Parkinson's disease ($p = .003$) and ADL mobility ($p = .04$). People with Parkinson's are nearly five times more likely to meet the Rome criterion than partner / carer controls (odds ratio 4.80, 95% CI 1.64 to 14.04). An increase of one unit in ADL mobility score raises the odds of meeting the Rome criterion by 1.15 (95% CI 1.01 to 1.31). When the two ADL variables are not in the model, only a diagnosis of Parkinson's disease is a significant predictor of constipation (odds ratio 9.38, 95% CIs 3.91 to 22.52).

Stating that constipation has been a cause for concern over adult life is significantly associated with meeting the Rome criterion at baseline ($p = .031$), including when Parkinson's diagnosis is incorporated in the model ($p = .048$). Hence, patients and partners / carers reporting constipation at baseline are equally likely to have reported concern over constipation throughout their adult life.

Amongst patients, a significant association exists between constipation and number of medications ($p=.027$), the major effect coming from taking ≥ 4 medications (odds ratio relative taking 0 or 1 medication 8.62, 95% CI 1.60 to 46.45). There is no evidence of any association between constipation and number of comorbidities, having hypotension, or taking COMT inhibitors, agonists or anticholinergic medications.

DISCUSSION

The study confirms higher levels of self reported constipation amongst people with Parkinson's than partner / carer controls. The excess burden (according to Rome I criterion) amongst patients, compared to partner / carer controls (48% at baseline (73% vs 25%), and 28% (35% vs 7%) stool diary) is comparable to other studies [7-10]. Retrospectively, respondents self report higher levels of constipation according to the objective Rome criterion than by subjective (cause of concern) and behavioural (use of laxatives or other self help measures) indicators. The lower level of constipation reported through prospective diary data contrasts with other research which suggests that diaries over estimate constipation by under reporting stool frequency [5]. In this study, the discrepancy may arise because the retrospective reporting at baseline used the validated Rome criterion, with a 3 month reference period, but the diary data was collected over four weeks (to avoid jeopardising data quality by increasing participant burden). Applying the Rome criterion to one month of data might be expected *a priori* to result in a lower observed frequency of constipation because less time has elapsed for constipation episodes to occur.

Data from the baseline questionnaire suggest that only ADL mobility and having a diagnosis of Parkinson's disease are significantly associated with constipation. The link between female gender and psychological morbidity and constipation identified by other researchers [3,15,25] was not found. In the patient sample, the number of medications taken is an independent predictor of constipation. Anticholinergic medications are known to have a constipating side effect (26,29,45), but may not have been significant in our study because relatively small numbers of patients were taking

them. Unlike other studies, the evidence reported here failed to find an association between constipation in Parkinson's and the disease process severity, diet or activity [4,7,12,26] and low fibre, fluid intake or lack of exercise [5,14,16,17]. This may be because the data collection was not sufficiently detailed, or 'doses' were inadequate [2,27].

High proportions of people with Parkinson's report straining, a sign of anorectal dysfunction (53), but there is less evidence of low frequency, a sign of slow transit, possibly because it is masked by laxative taking. Only 13 (12.3%) people with Parkinson's completing the diary show less than four bowel movements per week across the 28 days. Higher stool frequency is associated with taking more laxatives, and there is some evidence that this is linked to bowel incontinence. No evidence was found that having Parkinson's is associated with reporting constipation over adult life despite other studies suggesting that constipation is a preclinical indicator [16,28,29].

The data used in the analysis are robust. Baseline questionnaires were administered by researchers in a clinic setting, and recognised objective measures of constipation (Rome I, and Bristol Stool Form Chart) were used. The stool diary was independently validated by a panel of experienced nurses. The four week reporting period allows sufficient time for usual patterns to be observed. Participants who completed diaries undertook the task seriously and recorded data meticulously such that missing observations were minimal.

The limitations of this study are that partner / carer recruitment fell short of expectations (47 vs 78). Many partners/ carers were not willing to take part, and this affected the statistical comparisons between groups. Other trials of constipation have also reported problems recruiting participants due to the sensitive nature of the subject [18]. The representativeness of people recruited to the study is not known. Gender imbalance in the sample (more women in the carer group than patient group) may affect the interpretation of the findings if constipation is not equally experienced by men and women. The patient sample covered all disease stages, although 50% were Hoehn and Yahr stage 2, and as a group, they reported relatively little disability in ADL. The most up-to-date version of the Rome criterion [30] was not used in the

study because, in piloting, participants found the lengthened reference period (12 rather than three months) problematical.

This study suggests that constipation is disease related, rather than a life style issue. Constipation – related problems cause daily concern for significant numbers of people, and there is a need for further research into optimal management regimens, including robust trials to provide an evidence-base for practitioners.

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AUTHOR ROLES

Gage: conception and organisation of research and wrote first draft of manuscript; Kaye: conception, organisation and execution of research; Kimber: statistical analysis; Storey: conception, organisation and execution of research; Egan: execution of research; Qiao: execution of research; Trend: conception and execution of research. All authors reviewed and critiqued the manuscript.

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TABLE 1: Clinical characteristics of participants with Parkinson's disease*

Characteristic	n	Values	Frequency	%
Hoehn and Yahr disease stage	106	Stage 1	5	4.7
		Stage 2	53	50.0
		Stage 3	44	41.5
		Stage 4	4	3.8
Number of comorbidities Mean 0.93 Standard Deviation 1.14	108	None	53	49.1
		1	25	23.2
		2	20	18.5
		3	6	5.6
		4 or more	4	3.7
Number of medications Mean 2.76 Standard Deviation 1.72	108	None	5	4.6
		1	16	14.8
		2	34	31.5
		3	27	24.5
		4	15	13.9
		5 or more	11	10.3
Takes COMT inhibitor	108	Yes	8	7.4
Takes dopamine agonist	108	Yes	71	65.7
Takes anticholinergic	108	Yes	5	4.6

* Clinical data were available from the medical notes of 108 of the 121 people with Parkinson's who consented to participate in the study (89.3%)

TABLE 2: Socio – demographic, economic, diet, activity and health related quality of life: comparison of people with Parkinson’s and partners / carers (controls)

Item	Responses	People with Parkinson’s (PwP) n=121*		Partners /Carers (Controls) n=54*		Significant difference PwP vs Controls
		n	%	n	%	
Gender	Male	73	60.3	18	33.3	p= .001
Mean age (n=52 carers)	In years	69.8	SD = 8.5	68.1	SD = 9.9	p=.342
Highest level of education	Below age 15/16	51	42.8	19	35.2	<= 18 vs >18 p=.992
	Age 17/18	13	10.9	10	18.5	
	College	36	30.3	19	35.2	
	University	19	16.0	5	9.3	
Employment status	Full time	8	6.6	3	5.6	Employed vs not employed p =.942
	Part time	5	4.1	3	5.6	
	Retired	106	87.6	46	85.2	
	Other	2	1.7	2	3.8	
Household net annual income (n=100 PwP, n= 43 carers)	< £10,000	18	18.0	7	16.3	p= .599
	£10,000 – 19,999	41	41.0	17	39.5	
	£20,000 – 20,999	20	20.0	10	23.2	
	>= £30,000	21	21.0	9	20.9	
ADL disability scale# (n= 120, 113 PwP, n = 51, 46 carers) High is worse	8 item Mobility (range 8-40)	Mean 15.6	SD=5.9	Mean 9.5	SD=3.1	p<.001
	14 item Manual dexterity (14-70)	Mean 27.7	SD=9.9	Mean 14.8	SD=1.7	p<.001
HRQoL:SF-12 (n= 52 carers) Worst 0 - 100 Best	PCS mean	35.9	SD=11.3	45.7	SD=9.8	p<.001
	MCS mean	43.3	10.0	44.5	9.5	p=.442
How often do you exercise per day, not including normal duties?	Every day	58	47.9	18	33.3	> = once per week vs < once per week p =.839
	2 -3 times per week	22	18.2	19	35.2	
	About once a week	17	14.1	7	13.0	
	1-2 times / month	2	1.7	0	0	
	Rarely, never	20	16.5	9	16.7	
	Don’t know	2	1.7	2	4.6	
Type of exercise (n=97 PwP, n= 43 carers). Other: bowling, gym, weights, tennis, gardening, cycling, golf, aerobics, exercise bike.	Walking	52	53.6	31	72.1	Walking v rest p=.060
	Swimming	3	3.1	1	2.3	
	Stretch / yoga	6	6.2	0	0	
	Physiotherapy	14	14.4	1	2.3	
	Other	22	22.7	10	23.3	
Cups of liquid per day	0 -4 (score 1)	24	19.8	5	9.3	0-8 vs >=9 p =.179
	5 – 8 (score 2)	74	61.2	35	64.8	
	>= 9 (score 3)	23	19.0	14	25.9	
Portions of fruit and vegetables per day (n= 53 carers)	0 (score 1)	2	1.7	0	0	0-2 vs >2 p=.163
	1 – 2 (score 1)	25	20.7	7	13.2	
	3 – 4 (score 2)	51	42.2	21	39.6	
	>=5 (score 3)	43	35.5	25	47.2	
Choose high fibre bread (n=120 PwP)	Always/usually (score 3)	72	60.0	37	68.5	Always/usually vs rest p =.283
	Sometimes (score 2)	37	30.1	14	26.0	
	Never (scores 1)	11	9.2	3	5.5	
‘Bowel friendly diet’ score: (n=120 PwP, n=53 carers).	Score from sum of 3 diet variables above (Range: 3-9)	Mean 6.48	SD=1.38	Mean 7.11	SD=1.20	p=.003

Key: * Missing observations for some variables; SD: Standard Deviation;

ADL: Activities of Daily Living Disability (45), 25 items measured on a 5 point scale across 2 dimensions (Mobility and Dexterity): 1= able to do it alone without difficulty to 5 = unable to do it at all. Items relating to use of public transport and getting in and out of the bath were not applicable to many respondents and removed from the analysis.

HRQoL: Health Related Quality of Life from SF-12 (46); PCS / MCS: Physical / Mental Component Summary

TABLE 3: Reporting of constipation: comparison of people with Parkinson's and partner / carer (controls) from baseline questionnaires

Item	Responses	People with Parkinson's (PwP) n=121*		Partners /Carers (Controls) n=54*		Significant difference PwP vs Controls
		n	%	n	%	
How often do you currently suffer from constipation?	Always/v often	32	26.5	1	1.9	Always/very often vs rest p = <.001
	Quite often	19	15.7	2	3.7	
	Sometimes	31	25.6	12	22.2	
	Never / rarely	39	32.2	39	72.2	
To what extent is constipation a cause of concern?	A lot	28	23.1	4	7.4	A lot vs little, not at all p = .013
	A little	43	35.5	5	9.3	
	Not at all	50	41.3	45	83.3	
Over your adult life, how often has constipation been a cause of concern?	Always/v often	5	4.1	3	5.6	Always, quite often vs sometimes, never: p = .809
	Quite often	10	8.3	3	5.6	
	Sometimes	17	14.1	7	13.0	
	Never / rarely	89	73.6	41	75.9	
How often do you open your bowels on a typical day?	Mean number of times per day	0.96 (n=120)	SD= 0.72	1.36 (n=52)	SD= 0.77	p=.002
Rome criterion: for at least a quarter of the time during the last 3 months have you had:	to strain when opening your bowels? Yes	84 (n=120)	70.0	13 (n=52)	25.0	p<.001
	lumpy or hard stools? Yes	78	64.5	12 (n=49)	24.5	p<.001
	sensation of incomplete evacuation? Yes	67	55.4	16 (n=50)	32.0	p=.005
	2 or fewer bowel movements / week? Yes	32 (n=120)	26.7	3 (n=49)	6.1	p=.003
	Mean number of symptoms. (Range 0-4)	2.17 (n=119)	SD= 1.28	0.88 (n=49)	SD= 1.20	p<.001
Constipated by Rome criterion	Yes to >=2 symptoms	87 (n=119)	73.1	12 (n=49)	24.5	>=2 vs <2 p<.001
In the last 7 days, have you taken:	laxatives prescribed by Doctor? [1] Yes	25 (n=120)	20.8	4	7.4	Yes vs No p=.028
In the last 7 days, have you taken	laxatives you bought from a chemist?[2] Yes	24 (n=120)	20.0	4	7.4	Yes vs No p=.036
In the last 7 days, have you taken	any laxatives? Yes	42[3] (n=119)	35.3	6[3]	11.1	Yes vs No p=.001
In the last 7 days, have you tried any of the following (self help) means of dealing with constipation?	Increased fluid intake? Yes	22 (n=119)	18.5	4 (n=46)	8.7	p=.122
	Increased fibre intake? Yes	26 (n=119)	21.9	4 (n=45)	8.9	p=.055
	Increased exercise? Yes	16 (n=119)	13.5	1 (n=46)	2.2	p=.033
	Eaten more fruit/vegetables? Yes	43 (n=119)	36.1	7 (n=46)	15.2	p=.009
	Eaten/ avoided certain food? Yes	19 (n=118)	16.1	2 (n=45)	4.4	p=.047
At least a quarter of the time, do you	have pain opening your bowels? Yes	22 (n=120)	18.3	6 (n=48)	12.5	p=.359
Do you use finger to help empty bowels?	Always/ Often	4	3.4	1	1.7	Always, often vs sometimes, never p = .606
	Sometimes	8	6.6	0	0	
	Never / rarely	109	90.1	53	98.3	
Do you get soiling after opening your bowels?	Always/ Often	9	7.5	1	1.7	Always, often vs sometimes, never p = .141
	Sometimes	16	13.2	5	9.3	
	Never / rarely	96	79.3	48	88.9	

Do you wear	protection for bowel incontinence? Yes	11	9.1	2	3.7	p=.209
In the past 6 months, have you	had haemorrhoids (piles) or bleeding from back passage?[5] Yes	23 (n=118)	19.5	12 (n=52)	23.1	p=0.594
	used suppositories for constipation? Yes	12 (n=106)	11.3	2 (n=32)	6.3	p=0.405
	had an enema for constipation? Yes	3 (n=103)	2.9	1 (n=29)	3.5	p large
	used any CAM for constipation? [4] Yes	4 (n=103)	3.9	1 (n=28)	3.6	p large
Have you ever	been hospitalised for constipation? Yes	5 (n=116)	4.3	1	1.9	p=.419

Key: * Missing observations for some variables; SD: Standard Deviation

Notes: [1] Prescribed laxatives mentioned: Movicol, senna, dioctyl, manevec, fybogel, lactulose

[2] Laxatives reported purchased 'over-the-counter': senna, fybogel, lactulose, exlax, fruit cubes, dulcolax, syrup of figs, Epsom salts, ortisan

[3] Of the 42 people with Parkinson's (6 controls) who took any laxative, 6 (2) took both prescribed and laxatives purchased from chemist

[4] CAMs (Complementary or Alternative Medicine) reported: ortisan, reiki

[5] Any reports of bleeding were referred to the doctor

TABLE 4: Associations between measures of constipation in the baseline questionnaires

Measures of constipation	Patients		Carers	
	Odds ratio	95% CI	Odds ratio	95% CI
Now of concern vs Rome	13.95	1.74 to 112.13	7.20*	0.56 to 92.37
Now of concern v any laxative	8.26	3.02 to 22.60	11.50	1.21 to 109.69
Now of concern v any self help	1.97*	0.80 to 4.81	11.67*	0.86 to 157.70
Rome v any laxative	12.72	2.77 to 58.39	5.83*	0.80 to 39.24
Rome v any self help	3.49	1.41 to 8.64	22.50	3.20 to 158.05
Any laxative v any self help	2.59	1.16 to 5.81	11.67*	0.86 to 157.70

Key: * Not significant

Notes: Subjective measure: Constipation is currently a cause for concern (a lot vs not a lot)

Objective measure: Meets Rome criterion (reports ≥ 2 symptoms)

Behavioural measures: in the last 7 days, taken any laxative; taken any self help measure

TABLE 5: Bowel activity reporting: comparison of people with Parkinson's and partner / carer (controls) from 28 day diaries.

	People with Parkinson's (PwP) n=106*					Partner / Carer (Controls) n = 43*					Significant difference PwP vsControls
	Mean	SD	Min.	Median	Max.	Mean	SD	Min.	Median	Max.	
Mean number of bowel movements / day	.95	.41	.21	.92	2.4	1.19	.42	.5	1.07	2.75	p=.003
Mean strain level (0 none – 3 severe)	.94	.63	0	.93	2.7	.39	.43	0	.23	1.4	p<.001
% bowel movements with straining	62.0	33.6	0	79.3	100	30.9	30.4	0	23.3	100	p<.001
Mean consistency (1 very hard – 7 liquid) ^{\$}	3.4	1.1	.5	3.4	5.7	3.7	.74	2.0	3.7	5.9	p=.034
% bowel movements hard stools (1,2) ^{\$}	26.6	31.0	0	11.6	100	11.3	18.2	0	5.9	92.3	p<.001
% bowel movements soft stools (6,7) ^{\$}	7.2	15.0	0	0	87.5	4.4	10.1	0	0	55.1	p=.18
% bowel movements not felt empty	35.7	33.2	0	26.6	100	12.3	16.8	0	7.1	83.3	p<.001
Mean time spent (minutes)	3.7	3.8	.12	2.6	25.8	2.1	2.4	.16	1.2	11.1	p=.002
% of days laxatives taken	13.4	27.5	0	0	100	2.5	14.3	0	0	92.9	p=.002
% of days use self help measure	2.3	9.6	0	0	75.0	0	0	0	0	0	
Meet Rome criterion for constipation [#]	n = 37 (34.9%)					n = 3 (7.0%)					p<.001

* There was minimal missing information. Most participants completed the full 28 days of record keeping (people with Parkinson's: mean 25.8 days; SD 4.5; median 28; range 2 - 30; partners / carers: mean 27.2 days; SD 1.8; median 28; range 20 - 28).

\$ From Bristol Stool Form Chart [21]

To meet the Rome criterion: for at least a quarter of the time any two of the following symptoms must be present: straining when opening bowels (defined as a mean straining score >1 from diary entries); lumpy or hard stools (mean Bristol stool score <3); sensation of incomplete evacuation (report not feeling bowels empty > 33% of bowel movements); <3 bowel movements per week (mean of < 3/7 = 0.43).