Randomized Controlled Trial of Patient Navigation for Newly Diagnosed Cancer Patients: Effects on Quality of Life

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Abstract

Background—Patient navigation (PN) is a promising intervention to ameliorate cancer health disparities. This study objective was to measure PN effects on cancer-specific quality of life (QOL) among newly diagnosed cancer patients.

Methods—A randomized, controlled trial of PN was conducted in Rochester, New York. Breast cancer and colorectal cancer patients were randomly assigned to receive a PN intervention or usual care. QOL was measured at baseline and four subsequent time points, using the validated Functional Assessment of Cancer Therapy (FACT-B, FACT-C) instruments.

Results—Among 319 randomized patients (165 PN, 154 control), median age was 57 years and 32.5% were from minority race/ethnicity groups. PN and control groups were comparable on baseline factors, except home ownership v. renting (more home ownership among controls, p=0.05) and race (more whites among controls, p=0.05). Total and subscale FACT scores did not differ between groups when analyzed as a change from baseline to 3 months, or at various time points. The emotional well-being subscale change from baseline approached significance (better change among PN group, p=0.05). Time trends of QOL measures did not differ significantly between groups. Adjustment for baseline patient factors did not reveal a benefit of PN on QOL.

Conclusions—In this randomized trial of PN, there was no statistically significant effect on disease-specific QOL.

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Conflicts of Interests: None of the authors report any.

Impact—These results suggest that PN may not affect QOL during cancer treatment, that social/ medical support are adequate in this study's setting, or that the trial failed to target patients likely to experience QOL benefit from PN.

Introduction

In the United States, poor and minority patients have poorer cancer survival than majority populations. This multifactorial phenomenon is likely due to a lack of access to timely and high-quality medical care, communication barriers, and lack of social support and other resources.(1) Pioneered in in the 1990's in Harlem by cancer surgeon Harold P. Freeman, patient navigation (PN) is an intervention to provide support to disadvantaged cancer screening and diagnosed cancer patients, to address barriers to and delays in care.(2, 3) In an effort to rigorously test the effects of PN on cancer health disparities, the National Cancer Institute and the American Cancer Society sponsored a nationwide group of trials to test the effectiveness of patient navigation, including effects on timeliness of care, patient satisfaction, and disease-specific quality of life.(4)

Cancer patients experience decreased quality of life (QOL) during and after treatment, and multiple studies of cancer survivors and of non-cancer populations have shown that low socioeconomic status is associated with poorer quality of life, including domains of psychological functioning, social functioning and physical functioning.(5–8) Therefore, quality of life is important to consider among cancer patients' outcomes, including of patient navigation interventions. There is a theoretical basis for the hypothesis that patient navigation might improve cancer patients' quality of life, in addition to their timeliness of care.(9) Numerous studies have shown that increased social support improves cancer patients' quality of life, mainly in the setting of cancer support groups.(10–13) Because a primary focus of the PN role is providing social support, similar QOL effects might be seen to support groups. There are also some non-randomized data suggesting that PN may be associated with improved QOL.(14) These studies support the hypothesis that PN might improve cancer patients' QOL and/or decrease disparities in QOL.

In this context, the current randomized controlled trial tests the effect of an intensive PN intervention on disease-specific QOL, among newly-diagnosed patients with breast and colorectal cancer.

Methods

Research Setting

This randomized trial was part of the National Cancer Institute-sponsored Patient Navigation Research Program.(15) It focused on the impact of PN on newly-diagnosed breast and colorectal cancer patients; details of the study protocol have been previously described.(16) The trial was approved by the Institutional Review Board of the University of Rochester, and informed consent was provided by each participating patient. Patients were recruited from thirteen oncology and primary care practices serving disadvantaged patients in Rochester, New York and the surrounding suburbs. Most patients were referred by three large hospital-based oncology practices.

Patient eligibility was defined as adult patients with definitively-diagnosed breast cancer or colorectal cancer treated at a participating practice. Patients were excluded if they were institutionalized, had dementia, or had prior cancer (except for non-melanoma skin cancer). During the study, 928 patients were referred for possible enrollment; 337 declined to participate, 145 were ineligible, and 122 were unable to be contacted. The remaining 324 were enrolled in the study, of which 319 were diagnosed cancer patients who were

administered the FACT quality of life questionnaire (the remaining patients were patients with a positive cancer screening test but not diagnosed cancer; these were excluded from the current analysis because the FACT instruments are not relevant to these patients).

Intervention

Prior to randomization, participating patients completed research-assistant-administered questionnaires, and chart reviews were also performed to abstract disease and treatment information. Race-ethnicity classifications were obtained directly from patients. After the initial interview, eligible patients were randomized to intervention or usual care by a study statistician using computer-generated numbers. Randomization was stratified by site of enrollment, in blocks of four patients. Assignments were placed in sealed envelopes and opened by the research assistant following confirmation of eligibility.

Patient navigation (including multiple in-person and telephone interactions) was provided by trained, nonmedical personnel housed in the research offices of the University of Rochester, Department of Family Medicine. An intensive training process completed by navigators and their supervision and evaluation has been previously described.(16) The navigators interacted with patients via in-person and telephone meetings, and used a semi-structured interview procedure to determine barriers that each cancer patient may be facing. Barriers had standardized definitions, and included financial, social, logistical, language, medical and mental health comorbidities, attitudes such as fear and mistrust, and communication barriers. These were addressed by the patient navigators in various ways, including appointment scheduling, reminders, arranging transportation, accompanying patients to appointments when requested, and helping patients to make list of questions and take notes to improve communication.

Outcomes

The objective of the present study was assessment of the cancer-specific quality of life (QOL), which was the pre-specified secondary outcome for this randomized, controlled trial. The validated Functional Assessment of Cancer Treatment (FACT-G) general instrument, as well as breast- and colorectal cancer-specific modules (FACT-B and FACT-C, respectively), were self-administered at baseline and at 3, 6, 9, and 12 months.(17) For Spanish-speaking patients, the FACT was administered in a (translated and back-translated) Spanish version. These scales yield a total score and 5 subscale scores: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, Functional Well-Being, and Additional Concerns (cancer type-specific questions). There are 36 questions, scored on a 5-point Likert scale (0=not at all, 4=very much). The FACT scales have been rigorously validated and used in numerous cancer trials and studies.(9, 17–21) Text of questions is included in Tables 3 and 4.

Statistical Analysis

Patient baseline characteristics were compared between randomized groups to assess whether the groups were balanced on key characteristics after randomization, using Chi-square tests and Fisher's exact tests as appropriate. The numerical data of the FACT instruments were compared with t-tests. The primary analysis involved comparing the change in QOL scores from baseline to 3 months between randomized groups, with and without stratification by cancer type (breast versus colorectal cancer). This was calculated by subtracting the FACT (total and subscale) scores at baseline from the scores at three months. The potential benefits of PN would be expected to be seen most prominently during this time frame because newly diagnosed patients would be expected to have greatest difficulty "navigating" the complex cancer treatment system. Over time, patients would be expected to develop more familiarity with the system and require less logistical assistance.

However, because cancer patients' quality of life scores fluctuate with treatment and over time, additional analyses were conducted to compare QOL scores between randomized groups at the later time points, as well.(22) The scores on subscales were also compared between groups at the various time points, and QOL trends over time were also compared between randomized groups. Finally, a repeated-measures linear regression model was used to test for association between navigation and QOL, while adjusting for differences in baseline characteristics. SAS 9.2 for Windows was used for analysis.

Results

Three hundred nineteen newly-diagnosed cancer patients were enrolled in the study, 270 with breast cancer and 49 with colorectal cancer. Of these, 165 were randomized to PN and 154 to the control group; 299 patients answered the FACT questionnaire at both baseline and 3 months. Characteristics of the patients are shown in Table 1. The median age was 57 years and 32.5% were from minority race/ethnicity groups. The two groups were generally well-matched; however, they differed marginally on home ownership status (more renting and less home ownership among patients randomized to navigation, p=0.05) and race. (p=0.05), with more minority patients in the navigated group.

The primary analysis compared the change in QOL scores (total and subscale) from baseline to 3 months (Table 2), for all patients and for breast and colorectal cancer patients separately. These results show no statistically-significant differences, although the Emotional Well-Being subscale scores were marginally significant, with the trend favoring the navigation group (p=0.05).

Unadjusted FACT total and subscale scores at the 3, 6, 9 and 12 month time points were compared between randomized navigation versus control groups (3-month timepoint shown in Tables 3 and 4). There was no significant difference in scores between groups at any time points. Analysis of the time-trends of FACT total and subscale scores also did not show any significant differences, for total score or subscale scores.

Finally, analyses were performed to test for interactions between patient factors and quality of life scores based on greater hypothesized benefit for more socially disadvantaged patients. The *a priori* analysis plan was to test the following factors for interactions: race/ethnicity, income, insurance, and language. These analyses revealed significant interactions between quality of life scores over time and the baseline patient factors of gender and housing status. Because of these interactions and the possibility that the navigated patients represented a more disadvantaged group (Table 1), we then conducted a multivariable model to test the association between PN and overall quality of life scores, adjusting for age, gender, race/ethnicity, income and housing status. This analysis also failed to show improved quality of life score associated with patient navigation over time.

Discussion

This study revealed that patient navigation did not affect disease-specific quality of life scores among cancer patients undergoing primary treatment. There was no difference in the overall score or among subscales potentially more sensitive to PN, such as social or emotional well-being (although the association between PN and emotional well-being was marginally statistically-significant). These results are particularly striking, given that this study utilized an intensive intervention that included multiple in-person plus telephone supports. Furthermore, quality of life was measured using well-validated instruments with demonstrated sensitivity to change.(18, 21)

Multiple studies have documented that a cancer diagnosis---and cancer treatment---have negative effects on quality of life.(20, 23, 24) For breast and colorectal cancer patients, effects on physical, emotional, and functional quality of life are seen both during active treatment, and in some cases during survivorship.(20) At the outset of this trial of PN to address cancer disparities, we hypothesized that particular aspects of quality of life would be modifiable with PN. For example, the physical effects of pain and nausea during treatment might be better controlled if the navigator helped patients to communicate these concerns more effectively to providers; or worry and uncertainty might be reduced through social support and improved, culturally-sensitive information. In our study, QOL was relatively stable over time in both the navigated and control groups, but failed to show differences between these groups.

Why was PN not associated with overall improved quality of life? There are both study-specific and theoretical explanations for the failure of this study to support our hypothesis. First, this study targeted cancer centers and other practices that serve socioeconomically-disadvantaged cancer patients, but these centers also serve higher-income cancer patients. As such, participating patients included both patients of lower and higher participants, some of whom may not benefit from the help of a patient navigator. However, we observed no interaction between PN and disadvantage.

Second, the majority of participants were recruited from two multidisciplinary cancer centers, in which the problem of cancer health disparities has become recognized. Patients in these centers have had increasing access to help from social workers and volunteer cancer survivors, who may have contaminated the study by providing similar supports to patients in the control group. Also, the majority of study patients were breast cancer patients, who have been shown in prior studies to utilize support group services more frequently than other cancer patients.(25) As such, our findings might not be generalizable to other cancers in which the social support offered by navigation might make a greater difference (because it is otherwise lacking). Another possible source of contamination was our research assistants, who administered questionnaires to both control and PN-randomized patients quarterly. While they were trained to limit their interactions to collection of survey data, their inherently empathetic and engaging personalities may have been an unintended source of social support for participants, some of whom reported these interactions as supportive.

In addition to these study-specific reasons, patient navigation may have difficulty achieving an improvement in quality of life due to a threshold effect of social support on distress. Mallinckrodt and colleagues published a study in which social support had an effect on breast cancer patients' distress only among the lowest quartile of social support, supporting a threshold effect.(26) In support of this hypothesis, we observed an impact on emotional well-being that was marginally significant. Also, quality of life in the active phase of cancer treatment may simply be dominated by the relatively immutable (to a navigator or other support person) factors of treatment side effects and the variable process of learning to live with a cancer diagnosis. Finally, it is reasonable to speculate that cancer care providers have become increasingly aware of the importance of patient-centered outcomes over time, and that their care is in general more supportive of patients' quality of life.

The implications of this study for cancer quality improvement and disparities reduction are that patient navigation may not have an appreciable effect on QOL, at least in treatment settings similar to the setting of this study. Quality of life may be improved via providers' effective symptom management, use of minimally-invasive therapies when possible, and fitness programs,(27) but perhaps not via patient navigation programs (at least for breast cancer patients). The big picture is that while certain cancer treatments such as surgery, chemotherapy and hormonal therapy have negative effects on quality of life, particularly in

the short-term, the most significant factor in long-term quality of life for most cancer patients is freedom from recurrence.(28) As such the thoughtful counsel of cancer providers in balancing long-and short-term quality of life remains of greatest importance.

While this randomized trial has several methodological strengths compared to prior studies, it has the limitations of being a single-center study that may not be generalizable to other cancer treatment settings or cancer types. Also, the inclusion of patients of higher socioeconomic status may have limited the ability of this study to show an effect of patient navigation on outcomes although we did not observe effects for more disadvantaged participants

In conclusion, an intensive patient navigation intervention had no effect on disease-specific quality of life, among breast and colorectal cancer patients undergoing primary cancer treatment. These results may reflect this trial's patient selection, the baseline care in this research setting, or simply that quality of life during cancer treatment is insensitive to social and instrumental support interventions. Future studies will focus on other possible effects of patient navigation for patients undergoing cancer treatment and confirm the potential effect on patient emotional well-being.

Acknowledgments

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Table 1

Patient Characteristics

Independent Variable	ALL (*n* = 319)	Control (*n* = 154)	Navigated (*n* = 165)	*p*-value (Chi- square)
Gender				0.66
Female	92.2% (294)	92.9% (143)	91.5% (151)	
Male	7.8% (25)	7.1% (11)	8.5% (14)	
Age Categorized				0.11
1: < 40	6.3% (20)	3.2% (5)	9.1% (15)	
2: 40–< 49	20.4% (65)	18.8% (29)	21.8% (36)	
3: 50–< 60	33.8% (108)	37.7% (58)	30.3% (50)	
4: 60+	39.5% (126)	40.3% (62)	38.8% (64)	
Charlson Comorbidity				0.41
0	22.5% (64)	19.1% (26)	25.6% (38)	
1	25.7% (73)	27.9% (38)	23.6% (35)	
2	21.5% (61)	19.9% (27)	23.0% (34)	
3+	30.3% (86)	33.1% (45)	27.7% (41)	
Final Race/Ethnicity				0.051
Black	20.8% (66)	18.4% (28)	23.0% (38)	
White	67.5% (214)	72.4% (110)	63.0% (104)	
Hispanic	6.0% (19)	2.6% (4)	9.1% (15)	
Other	5.7% (18)	6.6% (10)	4.9% (8)	
Primary Language				0.34
English	95.6% (305)	96.8% (149)	94.6% (156)	
Other	4.4% (14)	5.4% (5)	5.4% (9)	
Education				0.16
Less than high school	14.8% (47)	120.3% (19)	17.1% (28)	
High school diploma	25.8% (82)	31.2% (48)	20.7% (34)	
Some college/vocational	33.6% (107)	31.2% (48)	36.0% (59)	
College graduate/Graduate	25.8% (82)	25.3% (39)	26.2% (43)	
Median Household Income by ZIP				0.16
Less than $30,000	18.4% (58)	17.0% (26)	19.7% (32)	
$30,000 to $39,999	23.2% (73)	19.0% (29)	27.2% (44)	
$40,000 to $49,999	20.9% (66)	20.9% (32)	21.0% (34)	
$50,000 or more	37.5% (118)	43.1% (66)	32.1% (52)	
Insurance Status				0.36
Uninsured	5.3% (17)	3.9% (6)	6.7% (11)	
Public	27.3% (87)	25.3% (39)	29.1% (48)	
Private	67.4% (215)	70.8% (109)	64.2% (106)	
Patient's Employment Status At Time Of Enrollment				0.91
No current employment	60.5% (193)	61.7% (95)	59.4% (98)	
Part-time employment	11.0% (35)	10.4% (16)	11.5% (19)	
Full-time employment	28.5% (991)	27.9% (43)	29.1% (48)	

Independent Variable	ALL ($n = 319$)	Control ($n = 154$)	Navigated ($n = 165$)	p-value (Chi- square)
Housing Status				**0.048**
Renting	29.0% (92)	24.2% (37)	33.5% (55)	
Own	63.1% (200)	69.9% (107)	56.7% (93)	
Other	7.9% (25)	5.9% (9)	9.8%(16)	
Dependents				0.18
0	57.4% (183)	57.1% (88)	57.6% (95)	
1	23.5% (75)	20.1% (31)	26.7% (44)	
2 or more	19.1% (61)	22.7% (35)	15.7% (26)	
Cancer Type				0.68
Breast	84.6% (270)	83.8% (129)	85.5% (141)	
Colorectal	15.4% (49)	16.2% (25)	14.5% (24)	
Stage				0.92
Stage 0	8.1% (26)	7.9% (13)	8.4% (13)	
Stage 1	32.3% (103)	32.7% (49)	31.8% (54)	
Stage 2	34.8% (111)	36.4% (51)	33.1% (60)	
Stage 3	21.3% (68)	19.4% (36)	23.4% (32)	
Stage 4	3.5% (11)	3.6% (5)	3.3% (6)	

NOTE: Column percentages reported.

Table 2

FACT Quality of Life Scores: Difference Between Baseline and 3-Month Time Points

	All Subjects			Breast Cancer Subjects			Colorectal Cancer Subjects		
	Control [mean (SD)] n=144	Navigated [mean (SD)] n=155	p-value	Control [mean (SD)] n=119	Navigated [mean (SD)] n=134	p-value	Control [mean (SD)] n=25	Navigated [mean (SD)] n=21	p-value
Total Score (FACT-G)	−1.23 (14.3)	−0.32 (14.44)	0.58	−1.67 (13.85)	−1.21 (13.14)	0.79	0.85 (20.45)	5.4 (16.41)	0.42
Physical Well-Being Subscale	−2.38 (6.5)	−2.38 (6.85)	1.00	−2.79 (6.57)	−2.66 (6.61)	0.88	−0.33 (8.19)	−0.64 (5.85)	0.89
Social/Family Well-Being Subscale	−0.11 (4.24)	0.34 (4.61)	0.38	−0.11 (3.77)	0.31 (4.86)	0.44	−0.1 (2.51)	0.53 (6.1)	0.64
Emotional Well-Being Subscale	1.4 (4.09)	2.36 (4.51)	0.053	1.45 (3.99)	2.07 (4.23)	0.22	1.2 (5.78)	4.14 (4.62)	0.06
Functional Well-Being Subscale	−0.38 (6.52)	−0.65 (5.85)	0.70	−0.47 (6.33)	−1.08 (5.14)	0.40	0.08 (8.81)	2.05 (7.52)	0.42
Additional Concerns Subscale	−0.26 (5.4)	−1.01 (5.72)	0.24	−0.63 (5.39)	−1.14 (5.71)	0.45	1.55 (5.85)	−0.16 (5.18)	0.30

NOTE: A positive difference indicates improvement over time in quality of life score, while negative value indicates a decrease in quality of life score.

Table 3

FACT-B Scores for Navigated and Control Patients at 3 Months (n=259)

Subscale	Questions	Control [mean (SD)]	Navigated [mean (SD)]	p-value (t-test)
PHYSICAL WELL-BEING		**20.2 (6.81)**	**19.7 (6.38)**	**0.51**
	I have a lack of energy	1.8 (1.31)	1.9 (1.31)	0.53
	I have nausea	0.6 (1.09)	0.7 (1.16)	0.51
	Because of my physical condition, I have trouble meeting the needs of my family	1.0 (1.35)	1.1 (1.24)	0.79
	I have pain	1.1 (1.35)	1.2 (1.31)	0.25
	I am bothered by side effects of treatment	1.5 (1.46)	1.5 (1.40)	0.88
	I feel ill	1.0 (1.38)	1.0 (1.30)	0.95
	I am forced to spend time in bed	0.8 (1.21)	0.9 (1.28)	0.50
SOCIAL/FAMILY WELL-BEING		**24.0 (5.10)**	**23.0 (5.28)**	**0.12**
	I feel close to my friends	3.4 (1.06)	3.3 (1.07)	0.28
	I get emotional support from my family	3.6 (0.95)	3.4 (1.07)	0.16
	I get support from my friends	3.5 (0.95)	3.4 (1.01)	0.37
	My family has accepted my illness	3.6 (0.79)	3.4 (0.88)	0.14
	I am satisfied with family communication about my illness	3.5 (1.09)	3.4 (0.94)	0.49
	I feel close to my partner (or the person who is my main support)	3.7 (0.90)	3.4 (1.18)	**0.03**
	I am satisfied with my sex life	2.5 (1.67)	2.4 (1.60)	0.52
EMOTIONAL WELL-BEING		**19.4 (4.69)**	**19.0 (4.37)**	**0.49**
	I feel sad	1.1 (1.13)	1.1 (1.12)	0.58
	I am satisfied with how I am coping with my illness	3.3 (1.04)	3.2 (1.08)	0.35
	I am losing hope in the fight against my illness	0.2 (0.65)	0.2 (0.65)	0.92
	I feel nervous	1.0 (1.20)	1.1 (1.20)	0.67
	I worry about dying	0.6 (1.02)	0.7 (1.06)	0.40
	I worry that my condition will get worse	1.0 (1.17)	1.0 (1.13)	0.91
FUNCTIONAL WELL-BEING		**19.8 (6.35)**	**18.5 (6.23)**	**0.10**
	I am able to work (include work at home)	2.8 (1.34)	2.6 (1.32)	0.34
	My work (include work at home) is fulfilling	2.8 (1.34)	2.6 (1.28)	0.26
	I am able to enjoy life	3.1 (1.11)	3.0 (1.16)	0.39
	I have accepted my illness	3.5 (0.91)	3.4 (0.95)	0.68
	I am sleeping well	2.4 (1.29)	2.1 (1.46)	0.10
	I am enjoying the things I usually do for fun	2.7 (1.34)	2.3 (1.42)	**0.04**

Subscale	Questions	Control [mean (SD)]	Navigated [mean (SD)]	p-value (t-test)
	I am content with the quality of my life right now	2.6 (1.36)	2.5 (1.30)	0.40
ADDITIONAL CONCERNS		**24.5 (6.68)**	**23.7 (6.36)**	**0.33**
	I have been short of breath	0.8 (1.20)	0.7 (1.04)	0.70
	I am self-conscious about the way I dress	0.9 (1.27)	0.9 (1.27)	0.92
	One or both of my arms are swollen or tender	0.8 (1.21)	0.7 (1.18)	0.37
	I feel sexually attractive	1.6 (1.43)	1.5 (1.34)	0.40
	I am bothered by hair loss	1.0 (1.43)	1.3 (1.59)	0.13
	I worry about the risk of cancer in other family members	1.9 (1.49)	2.0 (1.49)	0.37
	I worry about the effect of stress on my illness	1.6 (1.52)	1.9 (1.48)	0.17
	I am bothered by a change in weight	1.0 (1.39)	1.1 (1.50)	0.63
	I am able to feel like a woman	2.8 (1.29)	2.8 (1.28)	0.92
TOTAL SCORE		**83.7 (18.01)**	**80.4 (16.93)**	**0.13**

NOTE: t-test uses Satterthwaite method with unequal variances; otherwise uses the pooled method.

Table 4

FACT-C Scores for Navigated and Control Patients at 3 Months (n=46)

Subscale	Questions	Control [mean (SD)]	Navigated [mean (SD)]	p-value t-test
PHYSICAL WELL-BEING		**23.4 (6.54)**	**21.9 (5.59)**	**0.42**
	I have a lack of energy	1.2 (1.22)	1.6 (1.30)	0.35
	I have nausea	0.4 (0.91)	1.0 (1.23)	0.06
	Because of my physical condition, I have trouble meeting the needs of my family	0.6 (0.96)	0.8 (1.15)	0.58
	I have pain	0.7 (1.11)	0.8 (1.22)	0.69
	I am bothered by side effects of treatment	0.8 (1.28)	0.6 (1.01)	0.47
	I feel ill	0.4 (1.04)	0.7 (0.99)	0.28
	I am forced to spend time in bed	0.6 (1.26)	0.7 (1.04)	0.72
SOCIAL/FAMILY WELL-BEING		**23.5 (5.28)**	**25.4 (2.97)**	**0.15**
	I feel close to my friends	3.4 (1.08)	3.6 (0.90)	0.51
	I get emotional support from my family	3.6 (1.00)	3.9 (0.48)	0.20
	I get support from my friends	3.4 (1.11)	3.9 (0.47)	**0.047**
	My family has accepted my illness	3.4 (0.81)	3.7 (0.90)	0.17
	I am satisfied with family communication about my illness	3.3 (1.17)	3.6 (0.75)	0.31
	I feel close to my partner (or the person who is my main support)	3.7 (0.56)	3.8 (0.70)	0.66
	I am satisfied with my sex life	2.5 (1.66)	2.7 (1.16)	0.69
EMOTIONAL WELL-BEING		**20.7 (3.74)**	**20.8 (3.17)**	**0.89**
	I feel sad	0.8 (1.27)	0.7 (0.94)	0.92
	I am satisfied with how I am coping with my illness	3.3 (1.14)	3.7 (0.55)	0.12
	I am losing hope in the fight against my illness	0.2 (0.88)	0.0 (0.00)	0.19
	I feel nervous	0.6 (1.00)	0.6 (0.96)	0.85
	I worry about dying	0.5 (0.96)	0.7 (1.03)	0.40
	I worry that my condition will get worse	0.6 (0.87)	0.9 (1.23)	0.26
FUNCTIONAL WELL-BEING		**19.9 (5.38)**	**21.4 (4.87)**	**0.32**
	I am able to work (include work at home)	2.7 (1.28)	2.8 (1.27)	0.84
	My work (include work at home) is fulfilling	2.7 (1.30)	3.2 (1.04)	0.14
	I am able to enjoy life	3.3 (1.14)	3.2 (0.87)	0.86
	I have accepted my illness	3.6 (1.04)	3.8 (0.39)	0.26
	I am sleeping well	2.5 (1.33)	2.7 (1.29)	0.60
	I am enjoying the things I usually do for fun	2.6 (1.50)	2.8 (1.15)	0.59
	I am content with the quality of my life right now	2.7 (1.25)	3.0 (0.93)	0.33

Subscale	Questions	Control [mean (SD)]	Navigated [mean (SD)]	p-value t-test
ADDITIONAL CONCERNS		**21.9 (5.36)**	**21.9 (4.02)**	**0.97**
	I have swelling or crampsin my stomach area	0.4 (0.81)	0.6 (1.10)	0.41
	I am losing weight	0.5 (1.05)	0.2 (0.53)	0.23
	I have control of my bowels	3.1 (1.25)	2.5 (1.74)	0.20
	I can digest my food well	3.3 (1.18)	3.3 (1.20)	0.89
	I have diarrhea	0.8 (1.34)	0.7 (1.13)	0.67
	I have a good appetite	2.8 (1.47)	3.3 (0.94)	0.19
	I like the appearance of my body	2.4 (1.04)	2.3 (1.53)	0.78
	I am embarrassed by my ostomy appliance	0.0 (0.00)	2.5 (1.91)	0.08
	Caring for my ostomy appliance is difficult	0.0 (0.00)	1.8 (1.71)	0.14
TOTAL SCORE		**87.5 (15.33)**	**89.6 (11.75)**	**0.61**

NOTE: *t*-test uses Satterthwaite method with unequal variances; otherwise uses the pooled method.