

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

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### Abstract

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

**Methods:** A randomized controlled trial of patient navigation was conducted in Rochester, NY. Patients with breast cancer and colorectal cancer were randomly assigned to receive a patient navigation 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 patient navigation, 154 control), median age was 57 years and 32.5% were from minority race/ethnicity groups. Patient navigation and control groups were comparable on baseline factors, except home ownership versus 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 patient navigation 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 patient navigation on QOL.

**Conclusions:** In this randomized trial of patient navigation, there was no statistically significant effect on disease-specific QOL.

**Impact:** These results suggest that patient navigation 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 patient navigation. *Cancer Epidemiol Biomarkers Prev*; 21(10);1682–90. ©2012 AACR.

### 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 the 1990's in Harlem by cancer surgeon Harold P. Freeman, patient navigation 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 patient navigation 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).

Patients with cancer experience decreased quality of life (QOL) during and after treatment, and multiple studies of cancer survivors and of noncancer populations have shown that low socioeconomic status is associated with poorer quality of life, including domains of psychologic functioning, social functioning, and physical functioning (5–8). Therefore, QOL 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 QOL in patients with cancer, in addition to their timeliness of care (9). Numerous studies have shown that increased social support improves QOL in patients with cancer, mainly in the setting of cancer support groups (10–13). Because a primary focus of the patient navigation role is providing social support, similar QOL effects might be seen to support groups. There are also some

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nonrandomized data suggesting that patient navigation may be associated with improved QOL (14). These studies support the hypothesis that patient navigation might improve QOL in patients with cancer and/or decrease disparities in QOL.

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

## Materials and 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 patient navigation on patients with newly diagnosed breast and colorectal cancer; details of the study protocol have been previously described. (16) The trial was approved by the Institutional Review Board of the University of Rochester (Rochester, NY), and informed consent was provided by each participating patient. Patients were recruited from 13 oncology and primary care practices serving disadvantaged patients in Rochester, New York and the surrounding suburbs. Most patients were referred by 3 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 nonmelanoma 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

Before randomization, participating patients completed research-assistant-administered questionnaires, and chart reviews were also conducted 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 the site of enrollment, in blocks of 4 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, non-medical personnel housed in the research offices of the Department of Family Medicine, University of Rochester. 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 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 vs. colorectal cancer). This was calculated by subtracting the FACT (total and subscale) scores at baseline from the scores at 3 months. The potential benefits of patient navigation 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' QOL 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

**Table 1.** Patient characteristics

<b>Independent Variable</b>	<b>All (n = 319)</b>	<b>Control (n = 154)</b>	<b>Navigated (n = 165)</b>	<b><math>p(\chi^2)</math></b>
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 the 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% (91)	27.9% (43)	29.1% (48)	
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)	

*(Continued on the following page)*

**Table 1.** Patient characteristics (Cont'd)

Independent Variable	All (n = 319)	Control (n = 154)	Navigated (n = 165)	<i>p</i> ( $\chi^2$ )
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.

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 patients with newly diagnosed cancer were enrolled in the study, 270 with breast cancer and 49 with colorectal cancer. Of these, 165 were randomized to patient navigation 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 2 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 patients with breast and colorectal cancer 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 time-point 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 conducted to test for interactions between patient factors and QOL 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 QOL 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 patient navigation and overall QOL scores, adjusting for age, gender, race/ethnicity, income and housing status. This analysis also failed to show improved QOL score associated with patient navigation over time.

## Discussion

This study revealed that patient navigation did not affect disease-specific QOL scores among patients with cancer undergoing primary treatment. There was no difference in the overall score or among subscales potentially more sensitive to patient navigation, such as social or emotional well-being (although the association between patient navigation and emotional well-being was marginally statistically significant). These results are particularly striking, given that this study used an intensive intervention that included multiple in-person plus telephone supports. Furthermore, QOL 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 the QOL (20, 23, 24). For patients with breast and colorectal cancer, effects on physical, emotional, and functional QOL are seen both during active treatment, and in some cases during survivorship (20). At the outset of this trial of patient navigation, to address cancer disparities, we hypothesized that particular aspects of QOL would be modifiable with patient navigation. 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 patient navigation not associated with overall improved QOL? There are both study-specific and theoretical explanations for the failure of this study to



**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	Control mean (SD) n = 119	Navigated mean (SD) n = 134	p	Control mean (SD) n = 25	Navigated mean (SD) n = 21	p
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 (4.2)	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 (6.5)	-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, whereas negative value indicates a decrease in quality of life score.

support our hypothesis. First, this study targeted cancer centers and other practices that serve socioeconomically disadvantaged patients with cancer, but these centers also serve higher-income patients with cancer. 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 patient navigation 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 patients with breast cancer, who have been shown in prior studies to use 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 patient navigation-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 QOL due to a threshold effect of social support on distress. Mallinckrodt and colleagues published a study in which social support had an effect on patients with breast cancer' 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, QOL 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. QOL 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

**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		<b>20.2 (6.81)</b>	<b>19.7 (6.38)</b>	<b>0.51</b>
	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		<b>24.0 (5.10)</b>	<b>23.0 (5.28)</b>	<b>0.12</b>
	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		<b>19.4 (4.69)</b>	<b>19.0 (4.37)</b>	<b>0.49</b>
	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		<b>19.8 (6.35)</b>	<b>18.5 (6.23)</b>	<b>0.10</b>
	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
	I am content with the quality of my life right now	2.6 (1.36)	2.5 (1.30)	0.40
Additional concerns		<b>24.5 (6.68)</b>	<b>23.7 (6.36)</b>	<b>0.33</b>
	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		<b>83.7 (18.01)</b>	<b>80.4 (16.93)</b>	<b>0.13</b>

NOTE: *t* Test uses Satterthwaite method with unequal variances; otherwise uses the pooled methods.

**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		<b>23.4 (6.54)</b>	<b>21.9 (5.59)</b>	<b>0.42</b>
	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 well-being		<b>23.5 (5.28)</b>	<b>25.4 (2.97)</b>	<b>0.15</b>
	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
Emotional well-being		<b>20.7 (3.74)</b>	<b>20.8 (3.17)</b>	<b>0.89</b>
	I am satisfied with my sex life	2.5 (1.66)	2.7 (1.16)	0.69
	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
Functional well-being		<b>19.9 (5.38)</b>	<b>21.4 (4.87)</b>	<b>0.32</b>
	I worry that my condition will get worse	0.6 (0.87)	0.9 (1.23)	0.26
	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
Additional concerns		<b>21.9 (5.36)</b>	<b>21.9 (4.02)</b>	<b>0.97</b>
	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
	I have swelling or cramps in 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
Total score		<b>87.5 (15.33)</b>	<b>89.6 (11.75)</b>	<b>0.61</b>
	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

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

patients with breast cancer). The big picture is that while certain cancer treatments such as surgery, chemotherapy, and hormonal therapy have negative effects on QOL, particularly in the short-term, the most significant factor

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

While this randomized trial has several methodological strengths compared with 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 QOL, among patients with breast and colorectal cancer undergoing primary cancer treatment. These results may reflect this trial's patient selection, the baseline care in this research setting, or simply that the QOL 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.

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## Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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