A Cluster Randomized Trial Evaluating the Efficacy of Patient Navigation in Improving Quality of Diagnostic Care for Patients with Breast or Colorectal Cancer Abnormalities

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Abstract

Background: This study examines efficacy of a lay patient navigation (PN) program aimed to reduce time between a cancer abnormality and definitive diagnosis among racially/ethnically diverse and medically underserved populations of Tampa Bay, Florida.

Methods: Using a cluster randomized design, the study consisted of 11 clinics (six navigated; five control). Patients were navigated from time of a breast or colorectal abnormality to diagnostic resolution, and to completion of cancer treatment. Using a generalized mixed-effects model to assess intervention effects, we examined: (i) length of time between abnormality and definitive diagnosis, and (ii) receipt of definitive diagnosis within the 6-month minimum follow-up period.

Results: A total of 1,267 patients participated (588 navigated; 679 control). We also included data from an additional 309 chart abstractions (139 navigated arm; 170 control arm) that assessed outcomes at baseline. PN did not have a significant effect on time to diagnostic resolution in multivariable analysis that adjusted for race-ethnicity, language, insurance status, marital status, and cancer site ($P = 0.16$). Although more navigated patients achieved diagnostic resolution by 180 days, results were not statistically significant (74.5% navigated vs. 68.5% control, $P = 0.07$).

Conclusions: PN did not impact the overall time to completion of diagnostic care or the number of patients who reached diagnostic resolution of a cancer abnormality. Further evaluation of PN programs applied to other patient populations across the cancer continuum is necessary to gain a better perspective on its effectiveness.

Impact: PN programs may not impact timely resolution of an abnormality suspicious of breast or colorectal cancer. *Cancer Epidemiol Biomarkers Prev; 21(10); 1664–72. ©2012 AACR.*

Introduction

Medically underserved populations experience delays in breast and colorectal cancer diagnoses and treatment, more late-stage breast and colorectal cancer diagnoses, and higher breast and colorectal cancer–related mortality and morbidity (1–8). Obtaining timely diagnostic care following a screening abnormality or symptom of breast or colorectal cancer can be hampered by personal, logistic, and health system barriers (9–12). Patient navigation (PN) is a model of health care coordination that focuses on reducing barriers to a health care outcome (13–21). Many PN programs have been created to improve outcomes related to breast or colorectal cancer (14–16, 18, 20, 22–58). Of 8 studies focused on either reducing number of patients lost to follow-up following a breast cancer screening abnormality or reducing time from an abnormal screening mammogram or symptom of breast cancer to diagnostic resolution of breast cancer (22, 27, 30, 31, 33, 47, 55, 58), 6 indicate PN is a promising strategy (22, 30, 31, 33, 47, 55). For colorectal cancer, few studies have used PN to improve outcomes related to diagnostic care following identification of a colorectal cancer screening abnormality or symptom. Most studies used patient navigators to improve rates of colorectal cancer screening (25, 26, 40, 43–45, 48, 49, 52, 53). Some studies had methodologic problems that precluded drawing conclusions from their results, such as a lack of concurrent control group and randomization, and small sample sizes (22, 27, 30, 33, 55).

The Moffitt Cancer Center Patient Navigation Research Program (Moffitt PNRP) is one of 10 Patient Navigation Research Program (PNRP) sites funded by the National Cancer Institute's (NCI) Center to Reduce Cancer Health Disparities (CRCHD) and American Cancer Society (ACS; ref. 59). This article presents outcomes of Moffitt PNRP, a cluster randomized trial evaluating efficacy of PN in improving outcomes related to diagnostic resolution of a breast or colorectal cancer abnormality. It

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was hypothesized that participants presenting with a breast or colorectal cancer–related abnormality and receiving care at 1 of 7 clinics randomized to PN would be more likely to receive diagnostic resolution and would resolve the abnormality in less time than participants receiving care at 1 of 5 clinics randomized to usual care.

Methods

Moffitt PNRP used a cluster randomized design in which clinics were randomized to either intervention (navigation) or control (usual care; Fig. 1).

Clinic recruitment and randomization

Project investigators approached 7 Tampa Bay health care organizations with primary care clinics serving populations affected by health disparities in both urban and rural areas. Five health care organizations that included 12 clinics agreed to participate. The study statistician randomized clinics using PLAN in SAS (60). As clinics within each health care organization were homogeneous, randomization took place within these strata (health care organizations). For 3 organizations that had 2 primary care clinics, the study statistician randomly assigned 1 clinic to PN, whereas the other served as a control. For the

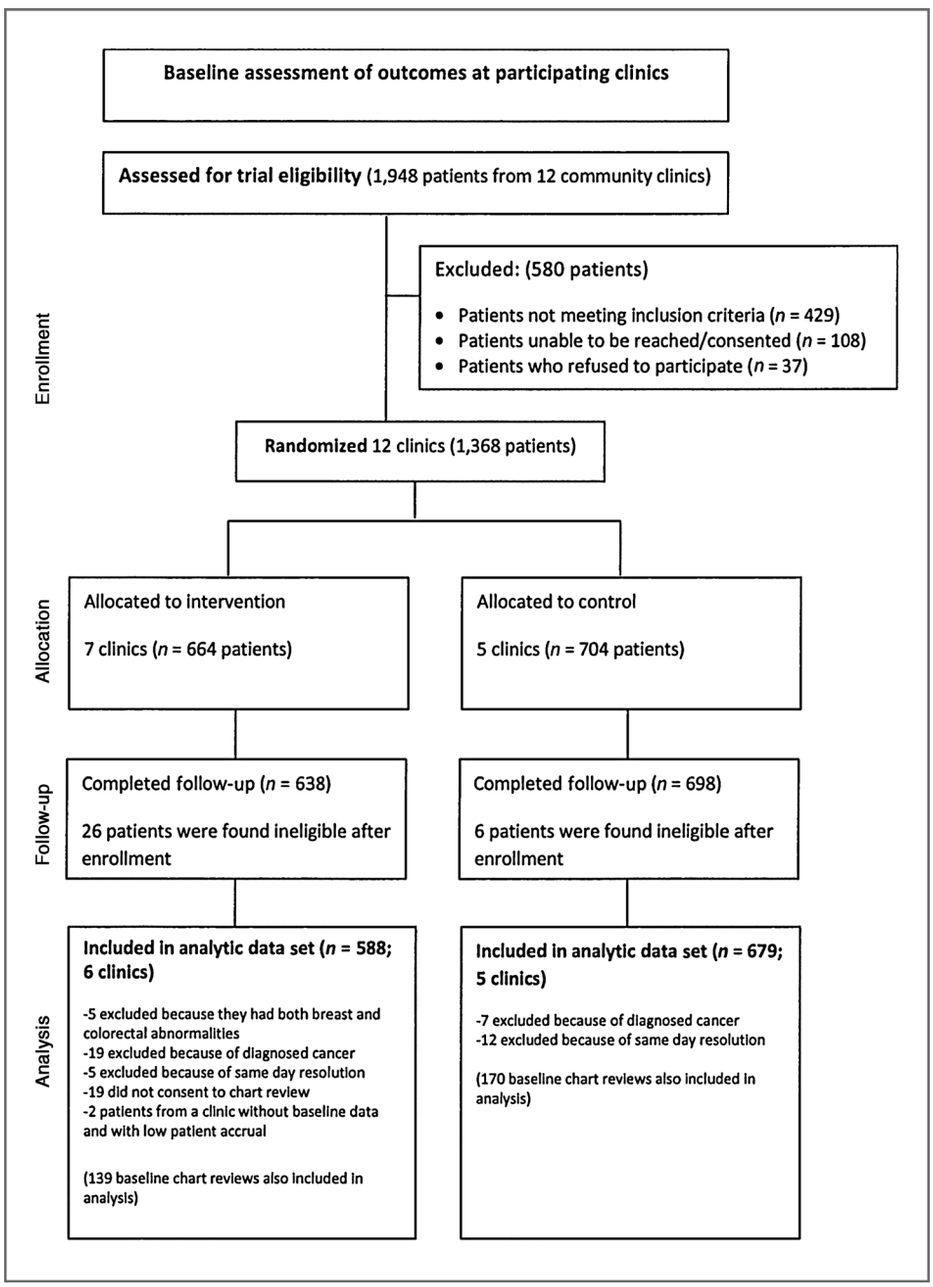

Figure 1. Tampa PNRP flow of participants.

2 organizations that had 3 clinics, 2 were randomized to PN. For these organizations, 1 clinic was randomly chosen as the control site with the remaining 2 clinics receiving PN. With this strategy, 7 clinics were randomly assigned PN, and 5 clinics served as controls. It was not possible to blind clinics or participants to study group assignment.

Participant population and sample

Populations served by the 12 primary care clinics were mostly Hispanic, African-American, and White, which reflects demographic characteristics of the Tampa Bay region (61). Most clinics provided off-site referrals for cancer diagnostic and treatment services. Patients were eligible for the Moffitt PNRP if they had an abnormality that could indicate a potential breast or colorectal cancer. Participants were also eligible if they had pathologically confirmed newly diagnosed breast or colorectal cancer but had not yet undergone initial treatment. Because of the small sample size, patients with cancer were not analyzed in the present Moffitt PNRP analysis. Patients were excluded if they were cognitively impaired, institutionalized, less than 18 years old, diagnosed with a previous cancer (excluding nonmelanoma skin cancer) within the past 5 years, currently undergoing cancer treatment, or had previously received PN.

Participant identification and recruitment

Participating clinics regularly searched for eligible patients using mammography/FOBT screening logs, information from referral coordinators, identification/referral from clinical staff, and computer searches of diagnostic codes. For navigated participants, there was a further stipulation that patients receive a written referral into the PN program from their health care provider. Once received, navigators contacted potential participants to explain the study and invite participation. For those interested, navigators confirmed eligibility and obtained written informed consent. When the study began, control participants were also contacted in person and required to complete an informed consent. However, due to low recruitment of control participants, the study was modified so that participation of control participants was limited to medical record abstraction for which written informed consent was waived.

Patient navigation intervention

As described in more detail (57), the Moffitt PNRP PN intervention was designed to be culturally competent, created through formative research, and guided by a Community Advisory Board. Three full-time and 2 part-time paid lay navigators provided PN during the Moffitt PNRP. Navigators were provided standardized annual in-person 3-day training sessions (62) and ongoing local educational updates. The Moffitt PNRP project manager and a registered nurse supervised all Moffitt PNRP navigators. The registered nurse observed each patient navigator biannually to evaluate adherence to the Moffitt PNRP intervention protocol.

Following consent and an intake assessment, navigators worked to overcome identified barriers to care (57). Patients were navigated from initial breast or colorectal abnormality to diagnostic resolution, and for patients diagnosed with cancer, through end of cancer treatment. We report here on the time period until diagnosis.

Control

Patients receiving care in clinics randomized to control condition were provided usual health care, which could include some form of care coordination and referrals for cancer diagnostic or treatment services, but did not include navigation-like services.

Data collection

Trained research assistants abstracted medical records of study participants using a standardized medical record abstraction form. Data elements were defined in a data dictionary developed by the PNRP (59). Medical records were abstracted at least 6 months after the initial cancer-related abnormality until diagnostic resolution, conclusion of cancer treatment, or study conclusion. Reliability of data abstraction was verified by having research assistants each independently abstract data and subsequently comparing data abstracted.

Study outcomes

The Moffitt PNRP had 2 primary outcomes. Among participants who achieved diagnostic resolution of the cancer-related abnormality, the first outcome (T1) was length of time (in days) between initial abnormality and date of definitive diagnosis or date of last follow-up. Definitive diagnosis could result from biopsy, additional imaging, or other diagnostic tests, or by clinical assessment of a medical specialist. The second dichotomous outcome was whether participants received a definitive diagnosis within the minimum follow-up period of 6 months.

Sample size

Sample size of 1,400 eligible participants was calculated *a priori*. We expected a participation rate of 95% with a mean sample size of 111 patients per clinic. Assuming a 90% follow-up rate, the planned 1,200 patients were estimated to provide power of at least 80% to detect a difference between navigation and control groups for T1 of 5 days (SD: 12 days; $\alpha = 2.5\%$, 2-sided), assuming an intracluster correlation (ICC) of 0.01 (63).

Analytic sample

Baseline data collection. To control for potential baseline differences in outcomes by clinic, we identified eligible participants during the year before clinics participated in Moffitt PNRP. Trained research assistants abstracted charts of patients meeting eligibility criteria in the 12-month period before the clinic began formal study participation and recorded information in standardized medical record abstraction forms. Medical

records were abstracted for 322 patients allowing baseline estimates of demographic characteristics and clinical outcomes for participating clinics, and 309 met inclusion criteria.

Intervention data collection. After the Moffitt PNRP began, there were 1,368 patients who received care at clinics allocated either to receive PN ($n = 664$) or to receive usual care ($n = 704$; Fig. 1). Thirty-two patients were found to be ineligible after chart reviews. We excluded: patients who had both breast and colorectal abnormalities simultaneously ($n = 5$), patients who were eligible because of diagnosed cancer ($n = 26$), patients whose cancer-related abnormality resolved on the day of their initial abnormality and had no opportunity to be navigated ($n = 17$), and patients who did not provide consent to have their chart reviewed ($n = 19$). Finally, despite multiple visits from project staff and patient navigators to promote the program, one health care organization (having 3 clinics) had one intervention clinic that referred only 2 patients and no baseline data. It was therefore dropped from the analysis. The 2 control clinics were retained.

For the combined baseline and postintervention samples, we were able to ascertain whether participants had achieved definitive diagnosis for 1,569/1,576 participants (99.6%). For 36 participants, we were unable to calculate T1 because either the exact date of eligibility ($n = 28$) or exact date of resolution ($n = 8$) could not be determined. Forty-one participants did not reach definitive diagnosis but had less than the minimum 180 days of follow-up specified in our protocol. These participants were not excluded but instead classified as not having achieved resolution at 180 days. BI-RADS III abnormalities call for additional imaging in 6 months. For these participants ($n = 10$), we subtracted 180 days from time to diagnostic resolution.

Because it was required that patients receiving care at a clinic allocated to PN had to be referred by a health care provider, we assessed whether patients referred for PN were representative of all clinic patients eligible for the study. We compared sociodemographic characteristics and clinical outcomes between clinic patients referred and those eligible but not referred.

Statistical analysis

Our analytic approach was based on the cluster randomized design. We used general (continuous outcome) or generalized (binary outcome) linear-mixed effects models to conduct comparisons between navigated and control groups and to assess intervention effects (PN effect). To account for the positive expected intraclass correlation among patients within a clinic nested within groups, the variables of clinic and the combination of clinic and time were included as random effects, whereas time (baseline vs. postintervention), intervention (navigated vs. control), their interaction term, and covariates were fixed effects. Random effects were assumed to be independent and distributed as normal. We included the following available covariates as potential confounders in all multivariable models; race-ethnicity (white non-Hispanic, black non-Hispanic, Hispanic, other), language (English, non-English), marital status (married, not married), insurance (some form of health insurance, uninsured), and cancer site (breast, colorectal). Time to definitive resolution (T1) was not normally distributed and was therefore log transformed. Percentage of patients achieving resolution is summarized with its 95% confidence interval based on exact binomial distribution.

We assessed intervention effects using the interaction term between study group allocation and time. This term indicated if changes between baseline and postintervention measures differed between navigated and control groups. We also created "survival" curves to visually depict time to resolution for participants who were navigated compared with control participants receiving usual care. Participants who had not achieved definitive diagnosis were censored at time of last medical record abstraction. Finally, we examined effects of PN among persons at higher risk of delayed diagnosis (uninsured or non-English speaking) and examined timeliness of provider referral as a determinant of navigator effects. Analyses were conducted using SAS software version 9.2 (60).

Results

Most participants were female (94.2%); Hispanic (57.8%); non-English speakers (52.8%); not married (51.5%); referred for a breast cancer abnormality (84.0%); and had no health insurance coverage (51.9%), not completed high school (53.5%), and an annual household income of less than $20,000 (88.0%). After intervention, navigated patients were more likely to be married (57.2%) compared with control patients (40.9%; $P = 0.03$; Table 1).

Among participants presenting with a breast cancer abnormality ($n = 1,294$), 68.4% were eligible because of an abnormal clinical examination, and 30.1% had an abnormal screening mammogram. The required definitive diagnostic test was generally either additional imaging [ultrasound (48.6%), diagnostic mammography (28.5%), or breast biopsy (19.7%)]. Of 282 participants with a colorectal abnormality, most experienced rectal bleeding (62.1%) or abnormal FOBT (32.6%). The definitive diagnostic test required was most often colonoscopy (85.3%). Among all participants, persons with colorectal abnormalities were less likely to achieve diagnostic resolution at 180 days (51.4% colorectal vs. 86.9% breast, $P < 0.0001$) and had longer times to definitive diagnosis (median T1: 74.5 days colorectal vs. 48 days breast, $P < 0.001$).

Median time to diagnostic resolution was essentially unchanged in control clinics from baseline (38 days) to postintervention (42 days; Table 2). In clinics that received navigation, there was an increase in median time to diagnosis from 42 days at baseline to 61 days postintervention. PN did not have a statistically significant effect on time to diagnostic resolution in multivariable analysis that

Table 1. Demographic comparison between control and navigated patients, postintervention ($n = 1,267$ patients)

	Control group ($n = 679$ patients)	Navigation group ($n = 588$ patients)	*P* value
Age at diagnosis in years (minimum, 25th percentile, median, 75th percentile, maximum)	(18,40,48,58,88)	(18,33,42,50,89)	0.56
Gender (%)			
Female	625 (92.3%)	567 (96.4%)	0.43
Male	52 (7.7%)	21 (3.6%)	
Race/ethnicity (%)			
Black, non-Hispanic	104 (16.2%)	39 (6.7%)	0.40
White, non-Hispanic	224 (34.8%)	109 (18.7%)	
Hispanic/Latin(a/o)	279 (43.4%)	430 (73.8%)	
Mixed/other non-Hispanic	36 (5.6%)	5 (0.9%)	
Language (%)			
English	405 (60.9%)	184 (31.6%)	0.32
Non-English	260 (39.1%)	399 (68.4%)	
Marital status (%)			
Married	241 (40.9%)	299 (57.2%)	0.03
Not married	349 (59.2%)	224 (42.8%)	
Education level of residence (%)			
8th grade or less	59 (22.1%)	175 (46.3%)	0.37
Some high school	45 (16.9%)	66 (17.5%)	
High school diploma(including equivalency)	89 (33.3%)	92 (24.3%)	
Some college/vocational after high school or Associate degree or College graduate	74 (27.7%)	45 (11.9%)	
Income (%)			
Less than $10,000	216 (58.5%)	176 (40.4%)	0.10
$10,000 to $19,999	119 (32.3%)	197 (45.2%)	
$20,000 to $29,999	23 (6.2%)	54 (12.4%)	
$30,000 or more	11 (3.0%)	9 (2.1%)	
Employment (%)			
Employed full time	115 (24.2%)	145 (30.4%)	0.77
Not employed full time	361 (75.8%)	332 (69.6%)	
Insurance status (%)			
Private insurance	50 (7.5%)	21 (3.6%)	0.20
Medicaid (no private or Medicare)	107 (16.0%)	40 (6.9%)	
Medicare (no private)	75 (11.2%)	21 (3.6%)	
Other government insurance	196 (29.3%)	89 (15.4%)	
Uninsured	241 (36.0%)	406 (70.4%)	
Family history of breast or colorectal cancer (%)			
Yes	540 (79.5%)	501 (85.2%)	0.63
No	139 (20.5%)	87 (14.8%)	
Charlson Comorbidity Index score (%)			
0	534 (78.7%)	506 (86.1%)	0.92
1	104 (15.3%)	69 (11.7%)	
>1	41 (6.0%)	13 (2.2%)	
Cancer site (%)			0.75
Breast	556 (81.9%)	508 (86.4%)	
Colorectal	123 (18.1%)	80 (13.6%)	

adjusted for race-ethnicity, language, insurance status, marital status, and cancer site ($P = 0.16$ for intervention effect comparing change in T1 log values over time between navigated vs. control participants, ICC = 0.10; Fig. 2). Data analysis indicated there was a difference between the 2 groups of 12 days; however, the SD was larger than estimated (108 days) and reduced statistical power for detecting differences between groups to 18% (63).

Table 2. Summary of major outcomes at baseline and postintervention for control and navigated groups

	Control		Navigated	
Outcome	**Baseline ($n = 170$)**	**Postintervention ($n = 679$)**	**Baseline ($n = 139$)**	**Postintervention ($n = 588$)**
T1[a] days mean (SD)[b]	92 (140)	85 (118)	83 (119)	97 (98)
T1 days median (lower–upper quartile)	38 (18–93)	42 (20–95)	42 (16–89)	61 (37–116)
Patients reaching resolution by 180 days (%)[c]	68.2	68.5	61.9	74.5

[a]T1 = time from abnormality to definitive diagnosis

[b]$P = 0.16$ [F test with degrees of freedom (df) = 9] for intervention effect comparing change in T1 log values over time between navigated versus control participants, while adjusting for cancer site, race, language, insurance, and marital status.

[c]$P = 0.07$ (F test with $df = 9$) for intervention effect comparing change in odds of diagnostic resolution over time between navigated versus control participants, while adjusting for cancer site, race, language, insurance, and marital status.

Percentage of participants that reached diagnostic resolution by 180 days was unchanged in the control group (68.2%–68.5%) but increased in the PN group (61.9%–74.5%) between baseline and postintervention (Table 2). In multivariable analysis controlling for race-ethnicity, language, cancer site, insurance status, and marital status, PN did not increase likelihood of achieving diagnostic resolution by 180 days ($P = 0.07$ for intervention effect comparing change in odds of diagnostic resolution over time between navigated vs. control participants, ICC = 0.02). We found with a sample size of 588 in the navigated group and 679 in control group, there was only 30% power to detect a difference of 7 percentage points between groups (63).

There was no statistically significant difference in time to diagnostic resolution (log of T1) among subgroups of patients defined by insurance status or language. We also examined likelihood of resolution by 180 days in the navigated group among patients who were insured and English speaking (percent resolved; baseline: 63%, postintervention: 69%, Fisher exact test $P = 0.45$) and among those who were uninsured and non-English speaking (percent resolved; baseline: 50%, postintervention: 75%, Fisher exact test $P = 0.03$).

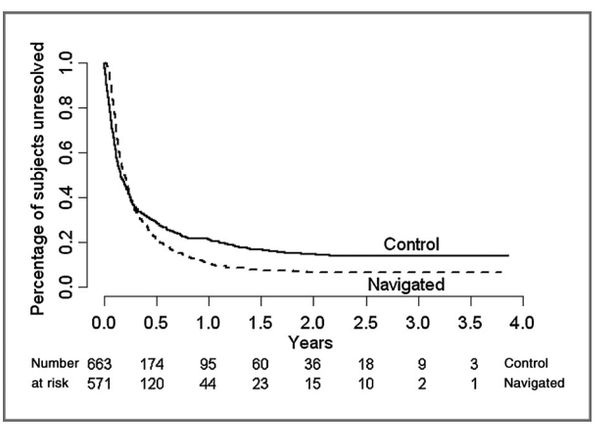

Figure 2. Diagnostic resolution over time for navigated and control participants.

Navigation referral patterns

Median time from discovery of abnormality until patient consent and entry into PN was 19 days (mean: 44 days, SD: 91 days). Median time to resolution for patients with timely PN (starting within 30 days of abnormality) was 48 days and was 95 days when PN started more than 30 days after initial abnormality. Among patients starting PN within 30 days, 77% reached diagnostic resolution within 180 days. Among patients starting PN more than 30 days after initial abnormality, 66% reached resolution by 180 days.

In 3 clinics, we identified 254 patients who met eligibility criteria and could have been referred for PN in addition to 576 patients actually referred for PN. Patients referred for PN were younger (mean age 42 vs. 53 years, $P < 0.0001$), and more likely to be female (95% vs. 86%, $P < 0.0001$), Hispanic ethnicity (74% vs. 25%, $P < 0.0001$), non-English speaking (70% vs. 26%, $P < 0.0001$), and uninsured (71% vs. 15%, $P < 0.0001$) compared with patients who were eligible but not referred. Patients referred for PN were more likely to achieve diagnostic resolution by 180 days (71% vs. 53%, $P < 0.0001$), but tended toward longer times to diagnostic resolution (median 60 vs. 47 days, $P = 0.01$) compared with those who were eligible but not referred.

Discussion

This PNRP study examined whether PN was effective in increasing proportion of patients who reached clinical resolution within 180 days, and for those who resolved, the number of days from a cancer abnormality until diagnostic resolution. Participants who received PN were no more likely to achieve timely diagnostic resolution when compared with participants who received usual care. This result differs from 6 previous studies (22, 30, 31, 33, 47, 55), but is similar to 2 studies which found PN had no effect on timely diagnostic resolution of a breast cancer abnormality (27, 58).

Participants with a breast abnormality were more likely to achieve diagnostic resolution than those with an abnormality suspicious for colorectal cancer. Of those who did get diagnostic resolution of a breast abnormality, on

average, did so within 48 days. Reducing delays between identification of a symptom of breast cancer and its treatment is critical as a delay of 3 months or more can reduce survival (64).

The present study represents one of the first studies to evaluate efficacy of PN to improve adherence to colorectal cancer diagnostic recommendations. Most studies of the efficacy of PN in improving outcomes related to colorectal cancer focus on colorectal cancer screening (25, 26, 40, 43–45, 49, 52, 53). Compared with patients with a breast cancer symptom, patients who had colorectal cancer abnormalities had a more difficult time achieving diagnostic resolution of the abnormality, with 61.4% resolving the abnormality. These difficulties may be related to lack of affordable diagnostic services in our community, lack of programs to offset costs, and high cost of a diagnostic colonoscopy. Overall, there were more programs to assist patients with breast diagnostic care, which was also less costly than colorectal diagnostic care if a patient did not qualify for services. However, the overall rate of resolution of a colorectal cancer symptom found in our study is higher than previous research has documented (65). Currently, it is not known whether delays in colorectal cancer treatment are linked to increased mortality or late-stage cancer (66, 67).

One study limitation was the difference in ways that control participants and navigated participants were referred to the study. Although identified in similar ways, patients at primary care clinics assigned to PN were referred by a health care provider. Data indicate patients from vulnerable populations, defined by lack of English proficiency and health insurance, were more likely to be referred to the PN arm. The significant differences between control and navigator groups may have reduced impact of PN on time to resolution of an abnormality as navigated patients, who presented with more barriers related to insurance and communication, needed more time to resolve the cancer abnormality. Also, there were delays of 1 month or more in consenting one-third of navigated participants. Delays were likely related to the fact that patients had to be called after the visit where the abnormality was detected and subsequently consented. When patients were referred early to PN, this resulted in more rapid diagnostic resolution. Both referral bias and consent delays may have biased findings toward a null effect. Future research should identify control and navigated patients in the same way and should consent participants immediately after identification of the abnormality by embedding navigators or research staff in the clinic. Also, when final analyses were conducted, there was low power to detect differences in time to diagnostic resolution between control and treatment groups due to a higher than estimated ICC and large variation in number of days to diagnostic resolution, making the sample size inadequate for detecting a difference between navigated and control participants. Although methodologic limitations reduce the ability of the study to detect quantifiable improved care for navigated patients, several indicators suggested benefit from PN.

Although the study was designed to evaluate efficacy of a PN intervention, it was implemented in several "real world" settings where cancer care is delivered. Adjustments were made to study design to complete the study and to comply with requirements of clinic leadership. As a result, the study more closely represents a study of effectiveness than efficacy of PN.

In conclusion, the Moffitt PNRP, a cluster randomized trial evaluating effectiveness of PN in improving adherence and timely diagnostic care in patients with either a breast or colorectal cancer abnormality, found patients provided PN were as likely to achieve diagnostic resolution of an abnormality suspicious for cancer as those provided usual care. PN services did not reduce overall time from abnormality to diagnostic resolution. Further evaluation of PN programs applied to other patient populations across the cancer continuum is necessary to gain a better perspective on its effectiveness.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Authors' Contributions

Conception and design: J.-H. Lee, C. Meade, M. Rivera, R.G. Roetzheim
Development of methodology: J.-H. Lee, M. Rivera, R.G. Roetzheim
Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): J.-H. Lee, C. Meade, W. Fulp, R.G. Roetzheim
Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): K.J. Wells, R.G. Roetzheim
Writing, review, and/or revision of the manuscript: K.J. Wells, J.-H. Lee, C. Meade, M. Rivera, W. Fulp, R.G. Roetzheim
Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases): K.J. Wells, E.R. Calcano
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