

Assessing the Effect of Patient Navigator Assistance for Psychosocial Support Services on Health-Related Quality of Life in a Randomized Clinical Trial in Latino Breast, Prostate, and Colorectal Cancer Survivors

Amelie G. Ramirez, DrPH ¹; Byeong Yeob Choi, PhD ²; Edgar Munoz, MS ¹; Arely Perez, MS ¹; Kipling J. Gallion, MA¹; Patricia I. Moreno, PhD ³; and Frank J. Penedo, PhD^{4,5}

BACKGROUND: After a diagnosis of prostate, breast, or colorectal cancer, Latinos experience higher mortality rates and lower health-related quality of life (HRQOL) in comparison with other ethnic/racial groups. Patient navigation (PN) and lay community health workers or *promotores* are effective in increasing cancer screening and early-stage diagnosis among Latinos. However, little is known about the effect of PN on HRQOL among Latino cancer survivors. **METHODS:** Latinos previously diagnosed with breast, prostate, or colorectal cancer (n = 288) were randomized to 1 of 2 conditions: 1) the Patient Navigator LIVESTRONG Cancer Navigation Services (PN-LCNS) survivor care program or 2) PN only. HRQOL was measured with the Functional Assessment of Cancer Therapy-General, and cancer-specific HRQOL was measured with the Functional Assessment of Cancer Therapy-Breast, the Functional Assessment of Cancer Therapy-Prostate, and the Functional Assessment of Cancer Therapy-Colorectal for breast, prostate, and colorectal cancer survivors, respectively, at the baseline and at 3 follow-up time points. Generalized estimating equation analyses were conducted to estimate the effect of condition on HRQOL with adjustments for covariates and baseline HRQOL. **RESULTS:** PN-LCNS demonstrated a significant improvement in HRQOL in comparison with PN only for colorectal cancer survivors but not for breast and prostate cancer survivors. **CONCLUSIONS:** Enhanced PN improves HRQOL among Latino colorectal cancer survivors. Future research should identify the best strategies for engaging Latino survivors in PN programs. PN programs should also be adapted to address HRQOL concerns among Latina breast cancer survivors. *Cancer* 2019;0:1-12. © 2019 The Authors. *Cancer* published by Wiley Periodicals, Inc. on behalf of American Cancer Society. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

KEYWORDS: breast cancer, colorectal cancer, health-related quality of life, Hispanic, Latino, patient navigation, *promotores*, prostate cancer, survivorship.

INTRODUCTION

There are currently approximately 15.5 million cancer survivors living in the United States.¹ Recent advances in prevention, screening, and treatment have resulted in longer survival for cancer survivors, particularly those diagnosed with early-stage disease.^{2,3} However, a significant proportion of these survivors continue to experience decrements to health-related quality of life (HRQOL) even years after the completion of their cancer treatment,⁴⁻⁹ including chronic pain, fatigue, sexual dysfunction, and psychosocial concerns such as depression, anxiety, and decreased social support.^{3,10-20} Compared with non-Latino whites (NLWs), Latinos face disproportionately higher mortality and worse HRQOL after the diagnosis and treatment of the 3 most common nonskin cancers: prostate, breast, and colorectal cancer.²¹⁻²⁶ Latinos are also more likely to have less educational attainment, live below the federal poverty level, and lack both health insurance and a primary care provider in comparison with NLWs.²⁷⁻³¹ Therefore, more research is needed to identify viable interventions to improve outcomes among Latinos living beyond a cancer diagnosis.

Corresponding Author: Amelie G. Ramirez, DrPH, Institute for Health Promotion Research, Department of Epidemiology and Biostatistics, Long School of Medicine, University of Texas Health San Antonio, 7411 John Smith Dr, Ste 1000, San Antonio, TX 78229 (ramirezag@uthscsa.edu).

¹Institute for Health Promotion Research, Department of Epidemiology and Biostatistics, Long School of Medicine, University of Texas Health San Antonio, San Antonio, Texas; ²Department of Epidemiology and Biostatistics, Long School of Medicine, University of Texas Health San Antonio, San Antonio, Texas; ³Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, Illinois; ⁴Department of Medicine, Miller School of Medicine and College of Arts and Sciences, University of Miami, Miami, Florida; ⁵Department of Psychology, Miller School of Medicine and College of Arts and Sciences, University of Miami, Miami, Florida

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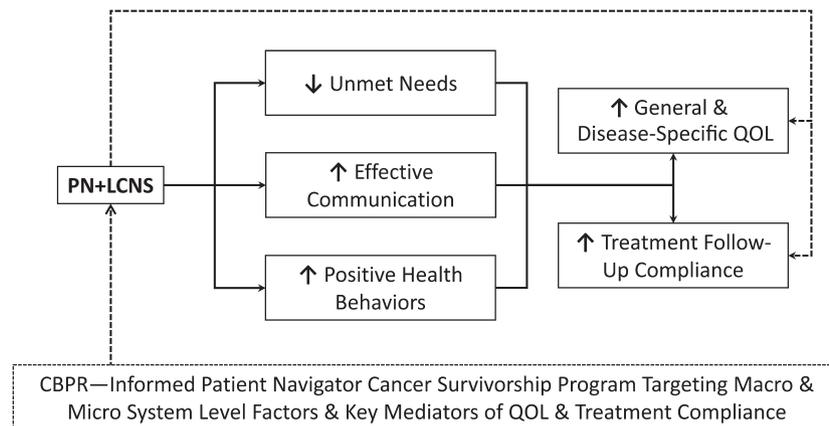


Figure 1. The conceptual model of the current randomized controlled trial proposes that in comparison with PN only, Latino cancer survivors who are randomized to enhanced PN (PN-LCNS) will demonstrate greater health-related QOL and treatment compliance. Broken lines between PN-LCNS and key outcomes suggest that reducing unmet needs, improving communication, and increasing positive health behaviors are mechanisms that may explain the effects of PN-LCNS (not tested). CBPR indicates community-based participatory research; LCNS, LIVESTRONG Cancer Navigation Services; QOL, quality of life; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services.

Patient navigators and lay community health workers or *promotores* are trained to promote better health and health care service utilization. Previous research has demonstrated that patient navigators and *promotores* are effective in increasing cancer screening and early-stage diagnosis.³²⁻³⁶ However, little is known about the impact of patient navigation (PN) on HRQOL among Latino cancer survivors. Previous studies have demonstrated that PN is effective in increasing cancer screening and reducing the delay between abnormal screening results and diagnosis.³⁷⁻³⁹ Furthermore, studies examining cancer survivors who are newly diagnosed or currently in treatment suggest that PN may improve HRQOL⁴⁰⁻⁴²; however, results are inconsistent.^{43,44} To the authors' knowledge, there are no previous randomized controlled trials examining the effects of PN in Latino cancer survivors after the completion of primary treatment.

LIVESTRONG Cancer Navigation Services (LCNS) is a community-delivered intervention developed with community-based participatory research methods to address the unique needs of individuals affected by cancer, including Latino cancer survivors, by drawing on theoretical frameworks such as social cognitive theory,⁴⁵⁻⁴⁷ stress and coping theory,^{48,49} and health behavior change theory.⁵⁰⁻⁵² The current randomized controlled trial is based on a conceptual model (see Fig. 1). PN commonly addresses both macrolevel factors (eg, socioeconomic status, cultural processes, and contextual barriers to care) and microlevel factors (eg, access to psychosocial resources and increased knowledge) that affect health through direct contact with

patient navigators or *promotores*. The Patient Navigator LIVESTRONG Cancer Navigation Services (PN-LCNS) program was developed to enhance PN by incorporating additional multimodal resources (eg, phone calls and online and written materials) and increasing access to patient navigators or *promotores* in comparison with PN only. Therefore, the primary aim of the current randomized controlled trial was to examine the effects of enhanced PN through the PN-LCNS program (vs PN only) on both general and disease-specific HRQOL in Latino breast, prostate, and colorectal cancer survivors after primary treatment completion. We hypothesized that cancer survivors randomized to PN-LCNS would demonstrate greater general and disease-specific HRQOL than those randomized to PN only.

MATERIALS AND METHODS

Participants

Potential participants were identified from chart review data from major tertiary medical centers in Chicago, Illinois, and San Antonio, Texas. The trial enrolled 288 participants (see Fig. 2 for the Consolidated Standards of Reporting Trials flow diagram). Study eligibility criteria included the following: primary diagnosis of breast, colorectal, or prostate cancer; completion of primary cancer treatment within the past 15 months; no ongoing adjuvant therapy (chemotherapy or radiation); and self-identification with Hispanic/Latino ethnicity with verbal fluency in English or Spanish. Exclusion criteria included the following: evidence of distant metastatic

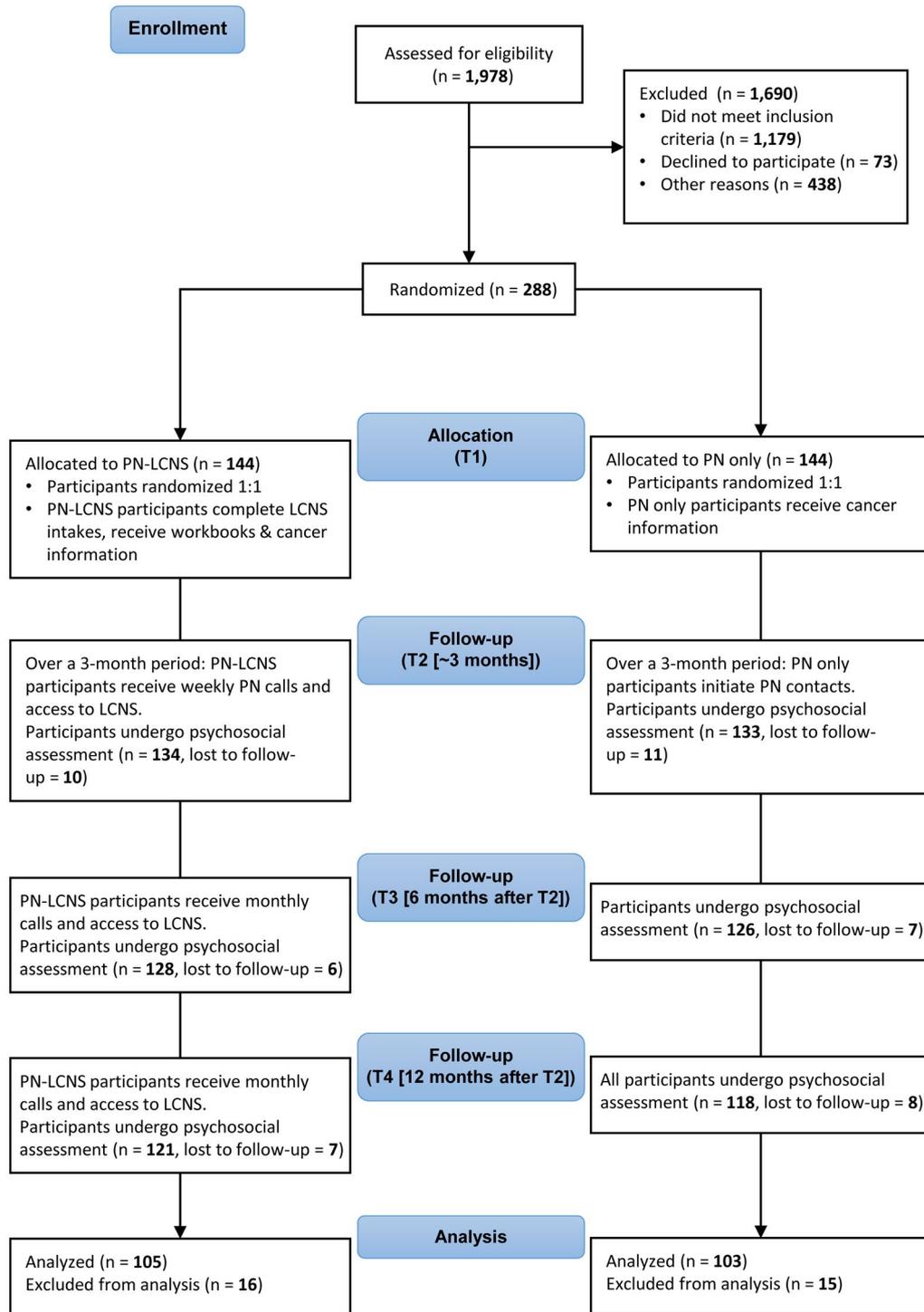


Figure 2. Consolidated Standards of Reporting Trials flow diagram. LCNS indicates LIVESTRONG Cancer Navigation Services; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services.

disease, current severe mental illness (eg, psychosis), substance dependence within the past year, and any active suicidal ideation.

Procedures

Potential participants identified from the chart review were contacted to assess interest and, if interested, to

complete a preliminary phone screen survey to determine eligibility criteria for the study. The preliminary phone screen was used to determine whether individuals met the inclusion criteria for the study. If individuals were eligible, formal screening interviews (the Short Portable Mental Status Questionnaire [SPMSQ] and the Structured Clinical Interview for *DSM-IV* [SCID]) and the baseline (T1) assessment were administered. The SPMSQ was administered to assess participants for cognitive impairment. Participants who did not meet the requisite cutoff of ≥ 3 for the SPMSQ were excluded because such impairment could interfere with participation in the intervention, understanding of assessment materials, and so forth. Then, the screening items from the SCID for psychotic disorders from the psychosis module as well as screener items for substance dependence (from the SCID-II) were administered. All excluded participants were handed English or Spanish materials on breast, colorectal, or prostate cancer survivorship from the National Cancer Institute, the American Cancer Society, and other groups and were referred to appropriate and relevant services.

Baseline questionnaires were completed after the formal screening interviews. The T1 assessment (duration of approximately 90 minutes) was completed after informed consent had been received. Participants had the option of completing the baseline assessment in their language of choice (English or Spanish) and were compensated \$25 for completion of the baseline assessment as well as subsequent assessments (~3 months [T2], ~6 months after T2 [T3], and ~12 months after T2 [T4]). All screening forms and assessments were conducted by the patient navigators. Patient navigators were not blinded to the intervention assignment. Informed consent was approved by the institutional review boards at Northwestern University and University of Texas Health San Antonio.

After completing the T1 baseline assessment, participants were randomized 1:1 to the PN-LCNS or PN-only condition to reduce potential bias. Among colorectal cancer survivors, randomization was further stratified by sex to ensure equal balance across intervention groups. Once a cohort of 2 participants in the same disease type were identified (eg, 2 completed breast cancer T1 assessments) at each site (Chicago and San Antonio), randomization by disease type was performed to ensure the equivalence of cancer types across the PN-LCNS and PN conditions.

PN-LCNS Program (Intervention)

PN-LCNS participants were assigned patient navigators who provided PN services for 3 months (from T1 to T2) and facilitated participation in the phone-based PN-LCNS

program for cancer survivors. The PN-LCNS program was available to participants randomized to this condition for the entire study (from T1 to T4). Once participants were randomized to the PN-LCNS condition, patient navigators worked closely with them over the intervention period to 1) present the PN-LCNS program; 2) promote usage of PN-LCNS services; 3) help to address and overcome barriers to using the PN-LCNS program; 4) orient participants to the availability of community resources, such as social work and psychosocial services referrals, child/elder care, transportation, and financial services available at local community clinics; and 5) assist with accessing and planning future medical appointments for treatment follow-up. The LCNS program provided free, professional, phone- or online-based, one-on-one support in English and Spanish to anyone affected by cancer. Provided services included the following: 1) coping with emotional concerns; 2) understanding one's cancer type and treatment options; 3) helping to address financial and insurance concerns, including applying for benefit programs; 4) matching people to clinical trials of new treatments in development; and 5) providing education about risks to fertility, preservation options, and access to discounted fertility services. On the basis of the call and the participant's needs, the LCNS navigation coordinator provided services and resources from his or her partner organizations: Psychosocial Navigators, the Patient Advocate Foundation, EmergingMed, and the Sharing Hope program. Specifically, community feedback from the community-based participatory research helped to update the list of community referrals for wide-ranging services for Latino cancer survivors.

The LCNS also offered additional English/Spanish tools to the current study's PN-LCNS participants, including a guidebook, health journal, and care plan. The guidebook was a navigational tool written in English with information, resources, organizational worksheets, and journal spaces to help survivors to address the physical, emotional, and practical concerns that many have during the cancer journey. The health journal, written in Spanish, was a tool used by health care providers to help people affected by cancer to document and organize information about their health providers, insurance, and treatment in one place. The care plan was a survivorship care plan detailing the medical concerns that a survivor might face.

PN Only (Control)

The inclusion of a PN-only control group maximized the ability to observe an intervention effect relative to a condition that reflects the standard follow-up treatment available for Latino cancer survivors in combination with

traditional PN services without the PN-LCNS component. Participants in the PN-only condition had limited access to PN services (but no access to PN-LCNS) for a maximum of 6 participant-initiated phone calls to the PN at each study site to seek out information on cancer survivorship or available community services and be provided print materials relevant to breast, colorectal, and prostate cancer survivorship from organizations such as the National Cancer Institute and the American Cancer Society. Information was also available on cancer survivorship and available community services, and there were print materials relevant to breast, colorectal, or prostate cancer survivorship.

Measures

Sociodemographic characteristics

Sociodemographic characteristics, including age, marital status, nativity, education, language, and household income, were collected.

Medical comorbidities and health records

Noncancer medical conditions were assessed with the Charlson Comorbidity Index.⁵³ In addition, a review of the medical health records provided information on the date of diagnosis, state of disease, treatment type, and treatment completion.

Primary outcome (HRQOL)

The 27-item Functional Assessment of Cancer Therapy–General (FACT-G) scale^{54,55} was administered at T1 through T4 to assess HRQOL, including facets of physical, functional, social, and emotional well-being on a Likert-type scale ranging from 0 (not at all) to 4 (very much). Sample items included the following: “I am bothered by side effects of treatment” (physical, reverse-coded), “I am able to work” (functional), “I am satisfied with family communication about my illness” (social), and “I worry about dying” (emotional, reverse-coded). Furthermore, cancer-specific Functional Assessment of Cancer Therapy symptom burden subscales were administered at T1 through T4 to capture cancer-specific HRQOL in breast cancer survivors (Functional Assessment of Cancer Therapy–Breast⁵⁶; $n = 128$), colorectal cancer survivors (Functional Assessment of Cancer Therapy–Colorectal⁵⁷; $n = 70$), and prostate cancer survivors (Functional Assessment of Cancer Therapy–Prostate⁵⁸; $n = 90$).

Sample Size and Power Analysis

There were no or very limited psychosocial intervention studies in Latino cancer survivorship that tested the effects of PN and a phone-based program (eg, LCNS) on HRQOL among breast, colorectal, and prostate cancer survivors by

the time that the current study was designed. Therefore, using G*Power 3 software,⁵⁹ the research team conducted conservative power calculations based on a final sample of 280 to 300 participants (140-150 in each condition) repeatedly measured at 4 time points to detect a significant group \times time interaction ($\alpha = .05$) of a small to medium effect size ($f = .08$). Estimations showed that a minimum power of 0.90 could be achieved with this design.

Randomization

A randomized schedule for 288 participants (144 pairs) stratified by disease type to ensure equal balance across breast, colorectal, and prostate cancer survivors was generated with SAS PROC PLAN software (version 9.2; SAS Institute, Inc, Cary, North Carolina) by a statistician not involved in the project. Sequentially numbered, concealed envelopes containing the assigned group for each participant were prepared and distributed to each study site by a team member not involved in the analysis of data or in the administration of the experimental condition. After a preliminary phone screen interview to assess participant eligibility and a baseline assessment (T1; described previously), participants were randomized to 1 of 2 conditions (PN-LCNS or PN only). The assessors were individuals not administering the PN-LCNS experimental condition.

Statistical Analysis

The primary endpoints included changes in the FACT-G score and the cancer-specific subscale score from the baseline at 3 follow-up times (T2, T3, and T4). The cancer-specific subscale score was scaled to lie between 0 and 1, with each subscale score being divided by its full score (40 for breast and prostate cancers and 28 for colorectal cancer) to account for different ranges by cancer type. To account for the correlations between 3 follow-up times within subjects, generalized estimating equation (GEE) models with an identity link and an unstructured correlation matrix were used. The goal of these analyses was to examine whether the PN-LCNS program improved HRQOL for each cancer type at 3 follow-up times. The research team identified the following 4 cancer groups: female colorectal cancer, male colorectal cancer, breast cancer, and prostate cancer.

With intent-to-treat samples, cancer-specific and time-dependent effects of the PN-LCNS program (vs PN only) on HRQOL, as measured by FACT-G and the cancer-specific score, were estimated through GEE models. Specifically, the models included the intervention, cancer type, time, and 2-way and 3-way interactions between the intervention, cancer type, and time. The research team

conducted 2 GEE analyses: one adjusted for the outcome at the baseline and the stage of cancer at diagnosis and the other one additionally adjusted for education and income. The analyses gave similar results for the effects of the PN-LCNS program, but the second GEE analysis used fewer observations because of more missing values. Thus, the research team presented and discussed only the intervention effects from the first GEE analysis. The GEE model equations are described in detail and all regression parameter estimates are presented in the supporting information.

The effects of sex and cancer type on the change in HRQOL from the baseline were estimated in the following ways. Because breast and prostate cancer survivors included only females and males, respectively, a sex effect could not be identified among these survivors. Thus, a sex effect was identified with a comparison of female and male colorectal cancer survivors in the PN-only group. Through the comparison of breast and female colorectal cancer survivors in the PN-only group, the difference in the change in HRQOL between breast and colorectal cancers was estimated. Through the comparison of prostate and male colorectal cancer survivors in the PN-only group, the difference in the change in HRQOL between prostate and colorectal cancers was estimated. The comparison of breast and prostate cancers was conducted by taking a difference of the parameter estimates for the aforementioned pairwise comparisons. These effects of sex and cancer type on the change in HRQOL were estimated under the assumption that they were approximately consistent across follow-up times.

All cancer-specific and time-dependent effects of the PN-LCNS program were identified with linear functions of the regression parameters for the intervention group, cancer type, and time in the GEE models. A total of 288 survivors provided 753 data points for the GEE models. With the exclusion of observations lost to follow-up and missing values, 587 observations were used for FACT-G and 669 observations were used for the cancer-specific subscale score in the first GEE analysis; 454 observations were used for FACT-G and 507 observations were used for the cancer-specific subscale score in the second GEE analysis. The threshold for statistical significance was a 2-sided P value of .05.

RESULTS

Table 1 displays sociodemographic and medical characteristics of the eligible study participants by the randomization groups. Participant characteristics did not significantly differ between the PN-only (control) group and the PN-LCNS group. Survivors were on average 56 years old (standard deviation, 10.20 years). More than half

were married or cohabitating with partners (61.5%) and reported a high school education or less (68.8%) and a combined household income less than \$50,000 (84.7%). Most survivors were either monolingual (Spanish-speaking; 54.2%) or bilingual (English- and Spanish-speaking; 26.0%). Survivors in the PN-LCNS group accessed the standard services (PN-only services) 2.70 times on average (median, 2; range, 1-9) and the LCNS services about twice on average (median, 2; range, 0-16). PN-only survivors accessed the PN-only services on average 2.69 times (median, 2; range, 1-11), and there were 3 PN-only survivors who accessed the LCNS services (2, 3, and 9 times).

Table 2 and Figure 3 present the mean differences in the changes in FACT-G from the baseline between the PN-only and PN-LCNS groups at 3 follow-up times for all cancer types. Male colorectal cancer survivors randomized to PN-LCNS demonstrated significantly greater HRQOL improvement as measured by FACT-G than those randomized to PN only at T2 (β , 10.074; 95% confidence interval [CI], 2.030-18.119; $P = .014$). However, breast cancer survivors randomized to PN-LCNS demonstrated significantly worse HRQOL than those randomized to PN only at T2 (β , -5.054; 95% CI, -9.059 to -1.049; $P = .013$). Greater baseline HRQOL was associated with a smaller change in HRQOL from the baseline (β , -0.321; 95% CI, -0.397 to -0.244; $P < .001$).

Table 3 and Figure 4 present the mean differences in the changes in the scaled cancer-specific subscale score from the baseline between the PN-only and PN-LCNS groups at 3 follow-up times for all cancer types. Female colorectal cancer survivors randomized to PN-LCNS demonstrated significantly greater HRQOL improvement as measured by the cancer-specific subscale score than those randomized to PN only at T2, T3, and T4 (β for T2, 0.168; 95% CI, 0.030-0.305; $P = .017$; β for T3, 0.147; 95% CI, 0.001-0.293; $P = .049$; β for T4, 0.171; 95% CI, 0.025-0.317; $P = .021$). Greater baseline HRQOL was associated with a smaller change in HRQOL from the baseline (β , -0.322; 95% CI, -0.438 to -0.205; $P < .001$).

Tables 4 and 5 report the main effects of sex and cancer type on the changes in the FACT-G score and the scaled cancer-specific subscale score from the baseline, as estimated from the first GEE analysis. No effects were statistically significant.

The effects of education and income on HRQOL were estimated from the second GEE analysis. Cancer survivors who had an education level of junior college or higher demonstrated greater HRQOL improvement (FACT-G) than those with an education level of high school (β , 3.808; 95% CI, 0.064-7.553; $P = .046$).

TABLE 1. Baseline Characteristics by Intervention Groups

Characteristic	Overall (n = 288)	PN Only (n = 144)	PN-LCNS (n = 144)	P
Months since treatment, mean (SD)	8.32 (15.43)	9.43 (19.28)	7.22 (10.17)	.232
Age, mean (SD), y	56.05 (10.20)	55.76 (10.38)	56.35 (10.03)	.631
Study site: San Antonio, No. (%)	171 (59.4)	85 (59.0)	86 (59.7)	1
Religion, No. (%)				.166
Other	67 (23.3)	40 (27.8)	27 (18.8)	
Roman Catholic	213 (74.0)	101 (70.1)	112 (77.8)	
NA	8 (2.8)	3 (2.1)	5 (3.5)	
Income, No. (%)				.765
<\$12,000	64 (22.2)	32 (22.2)	32 (22.2)	
\$12,000-\$24,999	77 (26.7)	42 (29.2)	35 (24.3)	
\$25,000-\$49,999	56 (19.4)	27 (18.8)	29 (20.1)	
≥\$50,000	44 (15.3)	23 (16.0)	21 (14.6)	
NA	47 (16.3)	20 (13.9)	27 (18.8)	
Country/territory of origin, No. (%)				.637
Mexico	232 (80.6)	119 (82.6)	113 (78.5)	
Central America	4 (1.4)	3 (2.1)	1 (0.7)	
South America	13 (4.5)	4 (2.8)	9 (6.2)	
Caribbean	2 (0.7)	1 (0.7)	1 (0.7)	
Other	10 (3.5)	5 (3.5)	5 (3.5)	
NA	27 (9.4)	12 (8.3)	15 (10.4)	
Language, No. (%)				.345
English and Spanish	75 (26.0)	36 (25.0)	39 (27.1)	
English only	49 (17.0)	30 (20.8)	19 (13.2)	
Spanish only	156 (54.2)	75 (52.1)	81 (56.2)	
NA	8 (2.8)	3 (2.1)	5 (3.5)	
Highest education, No. (%)				.986
Less than high school	122 (42.4)	60 (41.7)	62 (43.1)	
High school	76 (26.4)	38 (26.4)	38 (26.4)	
Junior college or more	54 (18.8)	27 (18.8)	27 (18.8)	
NA	36 (12.5)	19 (13.2)	17 (11.8)	
Sex: male, No. (%)	133 (46.2)	65 (45.1)	68 (47.2)	.813
Relationship status, No. (%)				.612
Single	33 (11.5)	19 (13.2)	14 (9.7)	
Married or living with partner	177 (61.5)	90 (62.5)	87 (60.4)	
Dating	1 (0.3)	1 (0.7)	0 (0.0)	
Separated	16 (5.6)	6 (4.2)	10 (6.9)	
Divorced	39 (13.5)	20 (13.9)	19 (13.2)	
Widowed	14 (4.9)	5 (3.5)	9 (6.2)	
NA	8 (2.8)	3 (2.1)	5 (3.5)	
Cancer type, No. (%)				.963
Breast	128 (44.4)	65 (45.1)	63 (43.8)	
Colorectal	70 (24.3)	35 (24.3)	35 (24.3)	
Prostate	90 (31.2)	44 (30.6)	46 (31.9)	
Stage of cancer, No. (%)				.168
0	6 (2.1)	5 (3.5)	1 (0.7)	
I	58 (20.1)	33 (22.9)	25 (17.4)	
II	102 (35.4)	47 (32.6)	55 (38.2)	
III	72 (25.0)	31 (21.5)	41 (28.5)	
IV	1 (0.3)	0 (0.0)	1 (0.7)	
NA	49 (17.0)	28 (19.4)	21 (14.6)	
Charlson Comorbidity Index, mean (SD)	3.47 (1.96)	3.39 (1.89)	3.56 (2.03)	.455

Abbreviations: NA, not available; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services; SD, standard deviation.

but not a statistically different HRQOL improvement (β , 1.516; 95% CI, -2.133 to 5.165; $P = .416$). Income did not affect significantly HRQOL improvement in terms of both FACT-G and cancer-specific subscale scores.

DISCUSSION

The primary aim of this randomized controlled trial was to examine the benefits of enhanced PN through a comparison of the effects of the PN-LCNS program and

standard PN only on both general HRQOL and cancer-specific HRQOL among Latino cancer survivors previously treated for the 3 most common nonskin cancers: breast, prostate, and colorectal cancer. Intent-to-treat analyses demonstrated that male colorectal cancer participants randomized to PN-LCNS demonstrated greater general HRQOL at a 3-month follow-up than those randomized to PN only. Similarly, female colorectal cancer survivors randomized to PN-LCNS demonstrated greater

TABLE 2. Cancer-Specific and Time-Dependent Effects of PN-LCNS on Health-Related Quality of Life Measured by FACT-G in Comparison With PN Only

Cancer	Time	Estimate	Standard Error	Z	Lower Bound	Upper Bound	P
Colorectal (female)	T2	-0.306	5.115	-0.060	-10.332	9.719	.952
	T3	-0.473	4.296	-0.110	-8.894	7.947	.912
	T4	2.956	4.440	0.666	-5.747	11.659	.506
Colorectal (male)	T2	10.074	4.104	2.454	2.030	18.119	.014
	T3	6.877	6.439	1.068	-5.745	19.498	.286
	T4	7.654	5.146	1.487	-2.433	17.741	.137
Breast	T2	-5.054	2.043	-2.473	-9.059	-1.049	.013
	T3	-3.209	5.082	-0.631	-13.170	6.753	.528
	T4	-2.630	3.470	-0.758	-9.431	4.171	.448
Prostate	T2	-3.786	2.390	-1.584	-8.471	0.898	.113
	T3	-2.153	5.388	-0.400	-12.714	8.408	.690
	T4	-3.195	3.794	-0.842	-10.630	4.241	.400

Abbreviations: FACT-G, Functional Assessment of Cancer Therapy–General; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services; T2, ~3 months; T3, ~6 months after T2; T4, ~12 months after T2.

Mean differences are shown in the changes in FACT-G from the baseline between the PN-LCNS and PN-only groups.

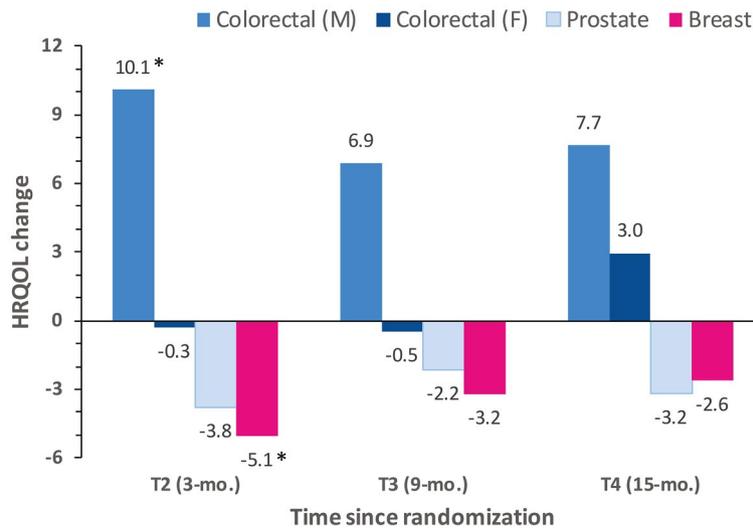


Figure 3. Cancer-specific and time-dependent effects of PN-LCNS on HRQOL as measured by FACT-G in comparison with PN only (mean differences in the changes in FACT-G from the baseline between the PN-LCNS and PN-only groups). **P* < .05. F indicates female; FACT-G, Functional Assessment of Cancer Therapy–General; HRQOL, health-related quality of life; M, male; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services.

TABLE 3. Cancer-Specific and Time-Dependent Effects of PN-LCNS on Health-Related Quality of Life Measured by the Cancer-Specific Subscale Score in Comparison With PN Only

Cancer	Time	Estimate	Standard Error	Z	Lower Bound	Upper Bound	P
Colorectal (female)	T2	0.168	0.070	2.382	0.030	0.305	.017
	T3	0.147	0.075	1.967	0.001	0.293	.049
	T4	0.171	0.074	2.300	0.025	0.317	.021
Colorectal (male)	T2	0.027	0.093	0.285	-0.156	0.209	.775
	T3	0.050	0.107	0.467	-0.160	0.260	.641
	T4	-0.036	0.114	-0.315	-0.259	0.187	.753
Breast	T2	-0.024	0.030	-0.810	-0.082	0.034	.418
	T3	0.013	0.046	0.288	-0.076	0.103	.773
	T4	0.011	0.053	0.203	-0.093	0.115	.839
Prostate	T2	0.044	0.042	1.038	-0.039	0.126	.299
	T3	0.108	0.056	1.923	-0.002	0.219	.054
	T4	0.022	0.075	0.294	-0.126	0.170	.769

Abbreviations: PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services; T2, ~3 months; T3, ~6 months after T2; T4, ~12 months after T2.

Mean differences are shown in the changes in the scaled cancer-specific subscale score from the baseline between the PN-LCNS and PN-only groups.

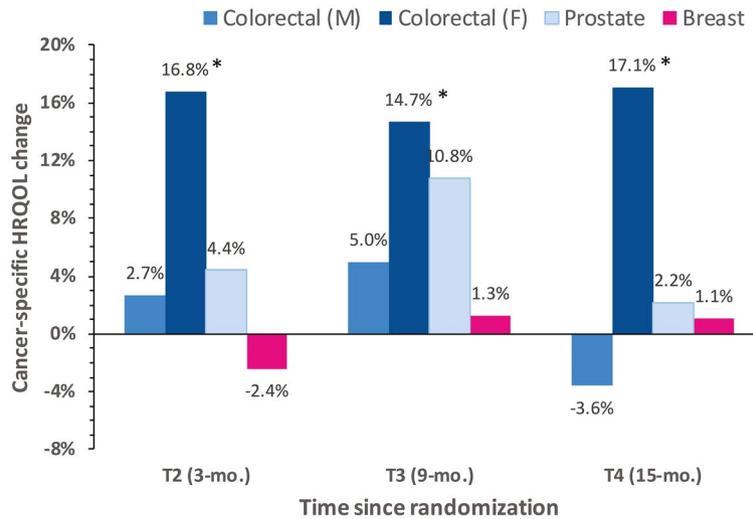


Figure 4. Cancer-specific and time-dependent effects of PN-LCNS on HRQOL as measured by the cancer-specific subscale score in comparison with PN only (mean differences in the changes in the cancer-specific subscale score from the baseline between the PN-LCNS and PN-only groups). **P* < .05. F indicates female; HRQOL, health-related quality of life; M, male; PN, patient navigation; PN-LCNS, Patient Navigator LIVESTRONG Cancer Navigation Services.

TABLE 4. Effects of Sex and Cancer Type on FACT-G in the Generalized Estimating Equation Model

Covariate Effect	Estimate	Standard Error	Z	Lower Bound	Upper Bound	<i>P</i>
Male vs female	-6.751	4.698	-1.437	-15.960	2.458	.151
Breast vs colorectal	-0.025	3.987	-0.006	-7.840	7.789	.995
Prostate vs colorectal	6.020	3.274	1.839	-0.398	12.437	.066
Breast vs prostate	-6.045	5.170	-1.169	-16.178	4.089	.242

Abbreviation: FACT-G, Functional Assessment of Cancer Therapy–General. Mean differences are shown in the changes in FACT-G by sex and cancer type.

TABLE 5. Effects of Sex and Cancer Type on the Cancer-Specific Subscale Score in the Generalized Estimating Equation Model

Covariate Effect	Estimate	Standard Error	Z	Lower Bound	Upper Bound	<i>P</i>
Male vs female	-0.029	0.091	-0.317	-0.208	0.150	.751
Breast vs colorectal	0.060	0.068	0.880	-0.074	0.194	.379
Prostate vs colorectal	0.080	0.076	1.046	-0.070	0.229	.296
Breast vs prostate	-0.019	0.102	-0.189	-0.220	0.181	.850

Mean differences are shown in the changes in the scaled cancer-specific subscale score by sex and cancer type.

cancer-specific HRQOL at 3-, 6-, and 15-month follow-ups than those randomized to PN only.

Although PN aims to facilitate access to care services across the cancer continuum, most studies have examined the effects of PN on increasing cancer screening and reducing the delay between abnormal screening results and diagnostic evaluation.³⁷⁻³⁹ However, there is a paucity of research examining the effects of PN after the diagnosis of cancer during primary treatment or after the completion of treatment during the survivorship phase.^{37,38} Furthermore, very few studies have examined effects on

patient-reported outcomes and HRQOL. Available studies examining survivors who are newly diagnosed or currently receiving cancer treatment demonstrate that PN may increase satisfaction with care and HRQOL,⁴⁰⁻⁴² but there are mixed and null results.^{43,44}

Many cancer survivors become “lost in transition” because of a fragmented health care system that fails to guide cancer survivors from primary treatment to post-treatment, and this results in inadequate or poorly coordinated care and leaves survivors without knowledge of their increased risks and a follow-up plan of action.⁶⁰⁻⁶²

However, to the research team's knowledge, there have been no previous randomized controlled studies examining the effects of PN on the HRQOL of Latino cancer survivors after the completion of primary treatment. The current study also builds on previous research demonstrating that PN is effective in improving cancer screening and diagnosis among Latinos,^{32-36,40} and it extends this work to cancer survivorship and demonstrates that the enhanced PN may have superior effects in comparison with standard PN on HRQOL among Latino colorectal cancer survivors. The enhanced PN, however, did not show any positive or negative effects on HRQOL among Latino prostate cancer survivors.

Importantly, breast cancer survivors did not appear to derive greater HRQOL benefits from the PN-LCNS program versus PN only and demonstrated significantly lower HRQOL when they were randomized to PN-LCNS rather than PN only. The pattern of results is similar to those of a previous study⁴² that found that colorectal cancer survivors undergoing primary cancer treatment and randomized to PN demonstrated greater HRQOL (specifically emotional well-being) than controls but found no effect of PN on HRQOL among breast cancer survivors undergoing primary cancer treatment. Previous research has also demonstrated that Latina breast cancer survivors after primary treatment completion specifically report greater unmet supportive care needs and lower HRQOL and self-efficacy in comparison with both Latino prostate and colorectal survivors.^{63,64}

Therefore, because of their vulnerability in comparison with not only NLWs but also Latino survivors diagnosed with the 2 other common cancers, it is crucial that future research be focused on specifically identifying efficacious interventions that improve HRQOL among both Latina breast cancer survivors and Latino prostate cancer survivors.

Strengths and Limitations

This unique sample of Latino breast, prostate, and colorectal cancer survivors who have a high school education or less and are primarily either monolingual (Spanish-speaking) or bilingual (Spanish- and English-speaking) is a strength of this study. Furthermore, to the research team's knowledge, this is the first randomized controlled trial of enhanced or standard PN in Latino cancer survivors after the completion of primary treatment. A limitation of this study was the exclusion of a true control condition, which would have allowed for the examination of the benefits of both PN-LCNS and PN only versus standard care without PN. However, the inclusion of

this control condition would have required an increase in the sample size by one-third to achieve adequate power. Furthermore, the primary interest was to examine the effects of enhanced PN like the PN-LCNS program versus PN only because of the existing research supporting the efficacy of standard PN services for quality of care among cancer survivors. Lastly, the analyses focused solely on complete cases and included only participants with no missing data. Excluding missing values induces unbalanced data, with subjects not having the same number of repeated measures, and it limits the use of standard statistical methods such as repeated measures analysis of variance. This problem was overcome with GEE models, which can accommodate imbalanced designs well. Through GEE models, the within-subject correlations among the repeated measures from different follow-up times were also accounted for.

In conclusion, although previous studies have demonstrated that PN may improve cancer screening and diagnosis among vulnerable populations, more research is needed to examine the effects of PN on HRQOL during the transition from the completion of primary cancer treatment to the survivorship phase.³⁷⁻³⁹ The current study suggests that Latino colorectal cancer survivors may derive HRQOL benefits from enhanced PN, and this may support the use of PN programs that incorporate multimodal resources (eg, phone calls and online and written materials) for this patient population. Nevertheless, these results should be interpreted with caution because they are limited in generalizability (ie, primarily foreign born, Spanish-speaking Mexican American cancer survivors diagnosed with nonmetastatic colorectal disease). Future research should examine the effects of PN on HRQOL in a sample of Latino cancer survivors with diverse primary sites of disease and diagnoses that span the full spectrum of disease stages. Because mixed and null effects were observed in Latino prostate and breast cancer survivors, studies should particularly focus on developing and testing PN programs aimed at improving HRQOL among these survivors.

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CONFLICT OF INTEREST DISCLOSURES

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AUTHOR CONTRIBUTIONS

Amelie G. Ramirez: Conceptualization, funding acquisition, investigation, methodology, project, project administration, resources, supervision, validation, writing—original draft, and writing—review and editing. **Byeong Yeob Choi:** Conceptualization, data curation, formal analysis, project, software, validation, writing—original draft, and writing—review and editing. **Edgar Munoz:** Conceptualization, data curation, formal analysis, investigation, software, validation, writing—original draft, and writing—review and editing. **Arely Perez:** Data curation, investigation, project administration, writing—original draft, and writing—review and editing. **Kipling J. Gallion:** Investigation and writing—original draft. **Patricia I. Moreno:** Validation, writing—original draft, and writing—review and editing. **Frank J. Penedo:** Conceptualization, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, writing—original draft, and writing—review and editing.

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