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ORIGINAL ARTICLE

Effects of a culturally tailored patient navigation program on unmet supportive care needs in Hispanic/Latino cancer survivors: A randomized controlled trial

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Abstract

Background: Patient navigation (PN) is a promising yet underused approach to address Hispanic/Latino (H/L) cancer survivors' unmet supportive care needs. The authors conducted a randomized trial to evaluate the effect of a culturally tailored PN program with the LIVESTRONG Foundation's Cancer Navigation Services (PN-LCNS) on reducing unmet needs in H/L survivors.

Methods: From 2012 to 2015 at two US sites, 288 H/L survivors diagnosed with breast, prostate, or colorectal cancer were randomized to a PN-LCNS program or to standard PN. Participants assigned to the PN-LCNS program received 3-month PN services; access to phone-based, bilingual, one-on-one support; and additional resources (i.e., guidebook, health journal, and care plan). Participants completed assessments at baseline and at 3, 9, and 15 months post-baseline. The Supportive Care Needs Survey was used to assess unmet needs across five domains: psychological, health system and information, physical and daily living, patient care and support, and sexuality. Intervention effects were tested by using separate multilevel growth models for women and men.

Results: Women randomized to the PN-LCNS program, relative to those who received standard PN, had a statistically significant reduction in unmet needs (i.e., overall and for the health systems and information, physical and daily living, and patient care and support domains). Among men, younger age was associated with greater unmet needs at baseline. Prostate cancer survivors reported greater unmet sexual health needs compared with colorectal cancer survivors. There was no significant change in unmet needs among H/L men.

Conclusions: A culturally tailored PN program can reduce unmet supportive care needs among H/L women cancer survivors. However, interventions specifically

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targeting unmet needs in H/L men and sexual health are still necessary (ClinicalTrials.gov identifier NCT02275754).

Plain Language Summary

- Hispanic/Latino (H/L) cancer survivors often report concerns or needs that are not adequately addressed by the health care team, which could be related to psychological, health system and information, patient care and support, physical and daily living, and sexuality issues.
- In this randomized controlled trial of 288 H/L survivors diagnosed with breast, prostate, or colorectal cancer, women assigned to a culturally tailored patient navigation program experienced a reduction in unmet needs compared with those who received standard patient navigation.
- H/L men did not experience a change in unmet needs.

KEYWORDS
cancer survivorship, Hispanic or Latino, patient navigation, supportive care, unmet need

INTRODUCTION

A diagnosis of cancer and its associated treatment have a significant impact on an individual's physical and psychosocial well-being. Providing supportive care, or the necessary services to those living with cancer, aims to meet their physical, psychosocial, informational, spiritual, and practical needs across the cancer care continuum.[1] There is a growing body of literature that suggests an association between unmet supportive care needs and poor health outcomes among people living with cancer.[2,3] For example, unmet supportive care needs in cancer survivors are associated with high symptom burden and psychological distress as well as lower physical and cognitive functioning.[4–6] Thus unmet supportive care needs should be considered as modifiable factors/targets for interventions designed to improve the health-related quality of life of cancer survivors.

Notably, little attention has been paid to the supportive care needs of ethnic minority groups, particularly Hispanics/Latinos (H/Ls), who are expected to see a 142% increase in cancer incidence in the upcoming years.[7] H/L cancer survivors report greater unmet supportive care needs compared with previously published norms in non-Hispanic White samples.[8–10] For example, among H/L breast and colon cancer survivors, the most prevalent unmet supportive care needs were psychological (e.g., fears about cancer spreading, uncertainty about the future), which were also associated with greater symptom burden and lower patient–provider communication self-efficacy and satisfaction with cancer care.[8] Importantly, interventions that assist cancer survivors to satisfy their supportive care needs may reduce adverse cancer outcomes (e.g., unplanned hospitalizations, emergency room visits), improve treatment adherence and survival, and reduce health care-related costs.[10–12]

An underused approach to address H/L cancer survivors' unmet supportive care needs is patient navigation (PN). A patient navigator can be a professional (e.g., psychologist, social worker) or a lay health worker (e.g., community health workers or *promotores de salud*), who helps patients navigate through the health care system and overcome barriers to care.[13] PN has been effective at improving cancer screening rates as well as reducing delays in diagnostic resolution and initiation of cancer treatment among racially/ethnically diverse populations.[14–16] However, a small body of work has looked at the effects of PN on cancer treatment and survivorship outcomes.[16–18] Furthermore, the large majority of these studies focused on the effect of PN on a single cancer site (e.g., breast or colon cancer) among a predominantly non-Hispanic White sample.[16] In addition, few studies have examined the efficacy of PN in connecting H/L cancer survivors with supportive care services.[18] Therefore, the purpose of this study was to evaluate the effect of a culturally tailored, community-based, participatory research-informed PN program on reducing unmet supportive care needs among H/L cancer survivors.

MATERIALS AND METHODS

Study design

The current study is a secondary analysis of a randomized controlled trial examining the efficacy of a culturally tailored PN program for improving general and disease-specific health-related quality of life and treatment follow-up compliance in H/L cancer survivors (ClinicalTrials.gov identifier: NCT02275754). This study took place at two major tertiary medical centers in Chicago, Illinois, and San Antonio, Texas. The study procedures and primary outcome results have been described in detail elsewhere.[19,20] In brief, the purpose of this project was two-fold: first, to engage community partners using a community-based, participatory research approach, which involved providing feedback on recruitment strategies, assessment materials, and the overall utility of the program, creating a resource directory to connect survivors with necessary services, and receiving training on cancer survivorship and PN. Second, the project aimed to evaluate the efficacy of a culturally tailored PN program in improving general and disease-specific quality-of-life and treatment follow-up compliance among breast, colorectal, and prostate H/L cancer survivors. The Institutional Review Boards of Northwestern University and the University of Texas Health San Antonio reviewed and approved the study protocol before initiation.

Participants

Eligible patients were adults who (1) self-identified as H/L; (2) had a primary diagnosis of breast, prostate, or colorectal cancer; (3) completed active treatment within the past 15 months; and (4) were fluent in Spanish or English. Participants were excluded if they (1) had evidence of distant metastatic disease, (2) reported active substance dependence problems within the past year, or (3) had current severe mental illness (e.g., psychosis) or active suicidal ideation.

Study procedures

Potential participants were identified from a medical chart review and contacted by phone to complete a preliminary phone screen survey and determine whether the patient met the general inclusion criteria for the study. Preliminary eligible patients were then invited to complete a formal screening interview and were assessed for cognitive impairment, psychotic disorder, and substance dependence. After determining their eligibility for the study, participants provided written informed consent and completed baseline questionnaires (T1) in English or Spanish based on their language of choice. Later, participants were randomized 1:1 to either the culturally tailored PN program or a standard PN control group. To guarantee equivalence of cancer types across conditions, randomization by disease site was done when two participants in the same disease type were identified at each study site. In addition, randomization was further stratified by sex among colorectal cancer survivors to ensure equal balance across conditions. Participants completed follow-up assessments at 3 months (T2), 9 months (T3), and 15 months (T4) postbaseline and were compensated $25 for completion of an assessment.

Study interventions

Intervention details have been published elsewhere.[19] Briefly, the culturally tailored PN program (PN-LCNS) was developed in partnership with the LIVESTRONG Foundation's Cancer Navigation Services as well as community-based leaders, service providers, and organizations from Chicago, Illinois, and San Antonio, Texas, known to provide services to H/L cancer survivors. Bilingual lay individuals from the community were recruited to serve as PNs They received training from the project research staff on patient outreach, as well as HIPAA (Health Insurance Portability and Accountability Act) and ethics training to handle confidential patient information appropriately. Equipped with a list of identified community resources, patient navigators helped connect patients with social services (e.g., finances, transportation, and childcare). Participants assigned to the PN-LCNS program received PN services for 3 months, which included working closely with patient navigators to identify barriers to cancer care, schedule medical appointments, and get access to community resources. In addition, participants received educational materials available in English and Spanish, such as the LIVESTRONG Guidebook, the LIVESTRONG Health Journal, and the LIVESTRONG Care Plan. They also had access to the phone-based, bilingual LIVESTRONG Foundation's services for the entire study, which helped to address emotional and financial concerns and provided education on cancer, treatment options, and fertility services.

Participants assigned to the standard PN condition received the standard follow-up treatment and usual access to the traditional PN services available at each institution. Cancer survivors were provided with a business card that had the name of the patient navigator employed by the cancer center at the time and were advised to reach out whenever they needed assistance. The cancer center patient navigator was assigned to assist all patients at their institution as needed. In addition, print materials relevant to breast, colorectal, or prostate cancer survivorship from organizations such as the American Cancer Society and the National Cancer Institute were made available to all participants.

Measures

Supportive care needs

Cancer survivors' unmet needs were assessed by using the Supportive Care Needs Survey.[21] This 34-item instrument assesses unmet needs across five domains: psychological, health system and information, physical and daily living, patient care and support, and sexuality. For each item, participants indicated their level of need over the past month (1 = not applicable, 2 = satisfied, 3 = low need, 4 = moderate need, and 5 = high need). We calculated a standardized sum score for each domain, with possible values ranging from zero to 100,[22] wherein higher scores indicate greater unmet supportive care needs (Cronbach α = .97).

Sociodemographic and medical characteristics

Participants self-reported sociodemographic characteristics, including age, sex, marital status, education, household annual income, language of preference, and country of origin. Acculturation was measured with the Short Acculturation Scale for Hispanics,[23] a 12-item instrument used to assess US acculturation (e.g., English language use, English language media, and social relations). Items are rated on a 5-point Likert scale, and the responses are summed up to obtain a total score and three subscores, wherein higher scores indicate greater acculturation to US culture (Cronbach α = .93).

Data on cancer diagnosis, stage of disease, treatment type, and months since diagnosis and treatment completion were extracted from the electronic medical records. Medical comorbidities were assessed with the Charlson comorbidity index.[24] The total score is a weighted sum of the number of existing conditions, wherein higher scores indicate greater medical comorbidity.

Statistical analysis

Given the high collinearity among sex and cancer type, as expected, we tested the intervention effects on overall unmet needs and the five domains in separate multilevel growth curve models for men and women. Multilevel growth curve models are a type of statistical model for repeated measures in which assessments (or time points) are nested within participants. At level 1, time was treated as a continuous variable (0, 3, 9, 15). Person-level predictors (level 2) included intervention assignment (dummy coded; 1 = PN-LCNS, 0 = PN-only) and sociodemographic characteristics, including age, cancer type (reference, colon cancer), stage (reference, stage I), comorbidities, income (reference, <$15,000), and acculturation. In all analyses, continuous variables (i.e., age, comorbidities, and acculturation) were grand mean centered before modeling. Modeling took place in a stepwise approach. First, we estimated an unconditional model (intercept-only model) to calculate the intraclass correlation. Then, we identified the optimal functional form of the trajectory over time (e.g., linear vs. quadratic curve). In step 3, we added the random effect of time and assessed whether it was needed. In model 4, we added the main effect of the person-level predictors. In step 5, the final step, we added cross-level interactions (e.g., time * intervention). Interaction terms were removed using a backward stepwise selection strategy by starting with the most complex model and removing the term with the largest *p* value > .05 using unrestricted maximum likelihood estimations. Moreover, a likelihood-ratio test was performed to compare nested models and determine which model was a better fit for the data. The Akaike information criterion and Bayesian information criterion were used for comparing non-nested models. Better model fit is indicated by lower values for the Akaike and Bayesian information criteria. Statistical analyses were performed in RStudio (version 2023.06.1, R-base version 4.3.1; R Foundation for Statistical Computing). The *p* values were adjusted using the Benjamini and Hochberg method (false-discovery rate correction) to account for multiple comparisons.[25]

RESULTS

Participant characteristics

Baseline sociodemographic and medical characteristics are shown in Tables 1 and 2. Overall, the mean age of participants was 56.1 years (standard error, 0.6 years). The majority were married or living with a partner (62%) and reported a high school education or less (69%). Almost one half of the participants had an annual household income < $25,000 (49%). Most participants were foreign-born (59%), Mexican or Mexico-descendent (81%), and monolingual Spanish-speaking (54%) or English–Spanish bilingual (26%). Regarding medical characteristics, participants were diagnosed with either breast (44%), prostate (31%), or colorectal (24%) cancer. The majority had either stage II or III disease (67%). In addition, participants had a mean Charlson comorbidity index of 3.5 (standard error, 0.1). Compared with H/L men, H/L women were significantly younger; lived fewer years in the United States; were more likely to have stage 0 or I cancer; received adjuvant chemotherapy, hormone therapy, immunotherapy, and surgery; and reported fewer comorbidities. In addition, H/L women reported greater overall unmet needs and across all domains except the sexual health domain relative to H/L men (Table 3).

Multilevel growth curve models on unmet supportive care needs among H/L women cancer survivors

The intraclass correlations ranged from 0.283 to 0.583, indicating that between 28% and 58% of the variance in the supportive care needs variables were attributable to the between-person level. Therefore, it was appropriate to consider a multilevel model to account for clustering effects. Table 4 displays the final model for total unmet supportive care needs and the five unmet needs domains for H/L women cancer survivors. At baseline, younger H/L women experienced greater overall unmet needs across all domains except the psychological domain. Women randomized to the PN-LCNS condition, relative to those in standard PN, showed a statistically significant reduction across overall unmet needs and specific domains (i.e., health systems and information, physical and daily living, patient care and support). Moreover, older age at baseline was significantly associated with an increase in overall unmet needs and in the physical and daily living and patient care and support domains over time.

Multilevel growth curve models on unmet supportive care needs among H/L men cancer survivors

Based on intraclass correlations ranging from 0.234 to 0.474, we determined that multilevel modeling was appropriate for data analysis. Among H/L men, younger age was associated with greater overall, psychological, and health system and information unmet needs at baseline (Table 5). Prostate cancer survivors reported greater unmet sexual health needs at baseline compared with male colorectal cancer survivors. No other demographic or medical covariate was significantly associated with unmet supportive care needs at baseline. There was not a significant change over time in unmet needs among H/L men.

DISCUSSION

The purpose of this study was to examine the efficacy of a culturally tailored, community-based, participatory research-informed PN program on reducing unmet supportive care needs among H/L cancer

TABLE 1 Sociodemographic characteristics.

	Mean ± SE or No. (%)			
	Total, $N = 288$	**Men, $N = 133$**	**Women, $N = 155$**	**p[a]**
Age, years	56.1 ± 0.61	60.5 ± 0.81	52.1 ± 0.77	< .001[b]
Intervention group				.7
PN only	144 (50.0)	65 (48.9)	79 (51.0)	
PN-LCNS	144 (50.0)	68 (51.1)	76 (49.0)	
Marital status				.2
Married or in an equivalent relationship	177 (61.5)	91 (68.4)	86 (55.5)	
Single, never married	33 (11.5)	15 (11.3)	18 (11.6)	
Dating	1 (0.3)	0 (0.0)	1 (0.6)	
Separated	16 (5.6)	6 (4.5)	10 (6.5)	
Divorced	39 (13.5)	16 (12.0)	23 (14.8)	
Widowed	14 (4.9)	3 (2.3)	11 (7.1)	
Missing	8 (2.8)	2 (1.5)	6 (3.9)	
Preferred language				.15
Spanish only	156 (54.2)	80 (60.2)	76 (49.0)	
English only	49 (17.0)	23 (17.3)	26 (16.8)	
Bilingual: English and Spanish	75 (26.0)	28 (21.1)	47 (30.3)	
Missing	8 (2.8)	2 (1.5)	6 (3.9)	
Country of origin				.5
Mexico	234 (81.3)	112 (84.2)	122 (78.7)	
Central America and Caribbean	22 (7.6)	8 (6.0)	14 (9.0)	
South America	19 (6.6)	9 (6.8)	10 (6.5)	
Missing	13 (4.5)	4 (3.0)	9 (5.8)	
US born	109 (38.9)	48 (36.6)	61 (40.9)	.5
Years living in the United States	28.7 ± 1.09	32.9 ± 1.45	24.5 ± 1.49	< .001[b]
Acculturation score	28.6 ± 0.74	27.7 ± 1.04	29.4 ± 1.03	.3
Income				.7
<$12,000	64 (22.2)	27 (20.3)	37 (23.9)	
$12,000–$24,999	77 (26.7)	37 (27.8)	40 (25.8)	
$25,000–$49,999	56 (19.4)	24 (18.0)	32 (20.6)	
≥$50,000	44 (15.3)	24 (18.0)	20 (12.9)	
Missing	47 (16.3)	21 (15.8)	26 (16.8)	
Education				.007[b]
Less than high school	111 (38.5)	62 (46.6)	49 (31.6)	
High school diploma	82 (28.5)	40 (30.1)	42 (27.1)	
Associate/bachelor's degree	46 (16.0)	19 (14.3)	27 (17.4)	
Master/doctorate/professional	18 (6.3)	5 (3.8)	13 (8.4)	
Missing	31 (10.8)	7 (5.3)	24 (15.5)	
Insurance	236 (81.9)	107 (80.5)	129 (83.2)	.5

Abbreviations: PN only, standard patient navigation; PN-LCNS, enhanced patient navigation; SE, standard error.

[a] Wilcoxon rank-sum test, Pearson χ^2 test, or Fisher exact test.

[b] These *p* values indicate a significant difference.

TABLE 2 Medical Characteristics.

	No. (%) or Mean ± SE			
	Total, *N* = 288	**Men, *N* = 133**	**Women, *N* = 155**	***p***[a]
Cancer diagnosis				< .001[b]
Breast	128 (44.4)	0 (0.0)	128 (82.6)	
Prostate	90 (31.3)	90 (67.7)	0 (0.0)	
Colon	70 (24.3)	43 (32.3)	27 (17.4)	
Stage				< .001[b]
0 or I	64 (22.2)	14 (10.5)	50 (32.3)	
II	102 (35.4)	49 (36.8)	53 (34.2)	
III	72 (25.0)	38 (28.6)	34 (21.9)	
Missing	50 (17.4)	32 (24.1)	18 (11.6)	
Time since treatment, months	5.0 ± 0.28	5.7 ± 0.46	4.4 ± 0.34	.056
Time since diagnosis, months	12.0 ± 0.35	12.4 ± 0.58	11.7 ± 0.44	.5
Surgery	243 (88.0)	95 (77.9)	148 (96.1)	< .001[b]
Neoadjuvant chemotherapy	46 (18.0)	13 (11.3)	33 (23.4)	.012[b]
Adjuvant chemotherapy	90 (36.1)	25 (21.0)	65 (50.0)	< .001[b]
Radiotherapy	163 (60.1)	72 (58.1)	91 (61.9)	.5
Hormone therapy	135 (51.5)	38 (31.7)	97 (68.3)	< .001[b]
Immunotherapy	22 (8.8)	1 (0.8)	21 (16.4)	< .001[b]
Comorbidity Charlson score	3.5 ± 0.12	3.9 ± 0.18	3.1 ± 0.15	< .001[b]

Abbreviation: SE, standard error.

[a] Pearson χ^2 test or Wilcoxon-rank sum test.

[b] These *p* values indicate a significant difference.

TABLE 3 Baseline unmet supportive care needs.

	Mean ± SE			
	Total, *N* = 288[a]	**Men, *N* = 133**	**Women, *N* = 155**	***p***[a]
Total unmet needs	27.2 ± 1.32	20.4 ± 1.72	33.1 ± 1.85	< .001[b]
Psychological	32.0 ± 1.64	24.6 ± 2.32	38.7 ± 2.18	< .001[b]
Health system and information	28.5 ± 1.56	19.9 ± 2.01	36.0 ± 2.16	< .001[b]
Patient care and support	21.9 ± 1.44	12.4 ± 1.62	30.5 ± 2.07	< .001[b]
Physical and daily living	22.0 ± 1.45	12.4 ± 1.62	30.4 ± 2.09	< .001[b]
Sexuality	31.3 ± 1.97	32.9 ± 2.80	29.7 ± 2.76	.2

Abbreviation: SE, standard error.

[a] Wilcoxon rank sum test.

[b] These *p* values indicate a significant difference.

survivors. H/L women assigned to the PN-LCNS program experienced a statistically significant reduction on overall unmet needs and across all domains except the psychological and sexuality domains compared with those in the standard PN program. Previous studies have demonstrated that PN programs improve cancer screening adherence and quality of life in H/L individuals.[26–28] Our findings suggest an added value of the intervention and support the idea that culturally tailored PN interventions had significantly stronger effects on health outcomes in H/L women than nontailored interventions. Several factors could explain the beneficial observations including, but not limited to, incorporating cultural beliefs and values into the intervention, translating materials into a specific language, and involving people from the community to serve as patient navigators. These strategies may remove linguistic barriers, enhance patient

TABLE 4 Hierarchical linear model results examining the effects of condition, time, covariates, and their interactions on unmet supportive care needs among Hispanic/Latina women.

	SCN			PSY			HSI			PCS			PDL			SXN		
Predictor	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE[a]**	***p*[a]**
Intercept	26	6.32	< .001[b]	31	8.61	.003[b]	28	7.18	.002[b]	25	6.87	**.005**[b]	25	6.87	.007[b]	22	8.66	.077
Time	−1.7	0.498	.004[b]	−2.0	0.541	.003[b]	−2.0	0.638	.010[b]	−1.6	0.685	.059	−1.5	0.689	.073	−1.2	0.695	.2
Intervention group																		
PN only	—	—		—	—		—	—		—	—		—	—		—	—	
PN-LCNS	3.4	3.10	.4	3.0	4.05	.8	6.4	3.61	.2	5.3	3.58	.2	5.6	3.59	.2	−6.4	4.28	.3
Age	−0.74	0.213	.004[b]	−0.43	0.284	.3	−0.38	0.223	.2	−0.77	0.239	.011[b]	−0.79	0.240	.009[b]	−0.86	0.270	.026[b]
Marital status																		
Other	—	—		—	—		—	—		—	—		—	—		—	—	
Married	0.82	2.74	.8	−3.5	3.75	.6	−1.5	3.10	.7	0.68	2.96	.8	1.0	2.96	.7	8.5	3.76	.10
Income																		
<$25,000	—	—		—	—		—	—		—	—		—	—		—	—	
≥$25,000 and greater	−4.8	2.93	.2	2.0	4.01	.8	−4.6	3.32	.3	−6.1	3.17	.12	−5.9	3.17	.14	−8.9	4.02	.10
Acculturation score	0.12	0.144	.6	0.22	0.196	.6	0.11	0.163	.7	0.11	0.155	.7	0.10	0.155	.7	0.16	0.198	.5
US born																		
No	—	—		—	—		—	—		—	—		—	—		—	—	
Yes	0.03	3.72	> .9	−1.5	5.08	.8	−2.3	4.21	.7	1.2	4.02	.8	1.7	4.02	.7	−0.92	5.13	.9
Comorbidity Charlson score	1.6	0.986	.2	0.57	1.35	.8	1.7	1.12	.2	1.9	1.06	.2	1.9	1.07	.15	1.8	1.35	.3
Cancer diagnosis																		
Colon	—	—		—	—		—	—		—	—		—	—		—	—	
Breast	9.7	4.04	.044[b]	11	5.52	.2	9.8	4.58	.12	9.4	4.37	.082	9.6	4.37	.073	10	5.54	.2
Stage																		
III	—	—		—	—		—	—		—	—		—	—		—	—	
II	−2.0	3.87	.7	−1.6	5.28	.8	0.98	4.38	.9	−2.6	4.18	.7	−3.1	4.19	.6	−5.3	5.30	.4
0 or I	−2.1	4.16	.7	−1.3	5.67	.8	−0.10	4.71	> .9	−1.7	4.50	.8	−2.2	4.50	.7	−6.3	5.69	.4
Months since diagnosis	−0.19	0.269	.6	−0.11	0.369	.8	−0.26	0.304	.6	−0.39	0.290	.3	−0.38	0.290	.3	0.14	0.368	.8
Time * intervention group																		
Time * PN-LCNS	−2.3	0.698	.004[b]	−1.9	0.758	.065	−2.5	0.889	.026[b]	−2.7	0.958	.017[b]	−2.8	0.966	.015[b]	−0.80	0.974	.5
Time * age	0.11	0.036	.008[b]	0.07	0.040	.2				0.14	0.050	.017[b]	0.15	0.051	.015[b]			

Abbreviations: HSI, health system and information; PCS, patient care and support; PDL, physical and daily living; PN only, standard patient navigation; PN-LCNS, enhanced patient navigation; PSY, psychological; SCN, supportive care needs; SE, standard error; SXN, sexuality.

[a] False discovery rate correction for multiple testing.

[b] These *p* values indicate a significant difference.

navigators' understanding of patients' needs, and empower H/L women to better articulate their needs as well as improve their disease knowledge, treatment adherence, self-efficacy, and access to timely care. Notably, by using a lay patient navigator model, we were able to minimize costs compared with employing nurse navigators. With new potential reimbursement mechanisms being established, we are optimistic that more cancer centers will begin using this model. Nonetheless, future implementation studies should evaluate

TABLE 5 Hierarchical linear model results examining the effects of condition, time, covariates, and their interactions on unmet supportive care needs among Hispanic/Latino Men.

	SC			PSY			HSI			PCS			PDL			SXN		
Predictor	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**	**Beta**	**SE**	***p*[a]**
Intercept	15	6.47	.2	24	8.42	.040[b]	15	6.50	.11	9.0	5.73	.5	9.3	5.72	.5	15	11.5	.5
Time	−0.24	0.691	> .9	−0.34	0.795	.8	−0.81	0.819	.6	−0.54	0.728	.8	−0.61	0.724	.8	0.86	1.07	.8
Intervention group																		
PN only	—	—		—	—		—	—		—	—		—	—		—	—	
PN-LCNS	−1.4	3.55	> .9	−4.3	4.48	.7	−1.3	3.76	.9	0.21	3.32	> .9	0.17	3.31	> .9	−1.5	6.09	.8
Age	−0.80	0.245	.022[b]	−1.2	0.321	.004[b]	−0.81	0.244	.019[b]	−0.50	0.214	.2	−0.50	0.214	.2	−0.98	0.438	.13
Marital status																		
Other	—	—		—	—		—	—		—	—		—	—		—	—	
Married	1.1	3.38	> .9	−2.8	4.43	.8	2.0	3.36	.8	1.8	2.95	.8	1.7	2.95	.8	2.8	6.04	.8
Income																		
<$25,000	—	—		—	—		—	—		—	—		—	—		—	—	
≥$25,000	−2.6	3.30	.9	−5.6	4.33	.6	−3.3	3.27	.6	0.06	2.88	> .9	−0.07	2.88	> .9	−3.9	5.90	.8
Acculturation score	−0.11	0.184	> .9	−0.23	0.241	.7	−0.25	0.182	.5	−0.13	0.160	.8	−0.12	0.160	.8	0.18	0.328	.8
US born																		
No	—	—		—	—		—	—		—	—		—	—		—	—	
Yes	8.9	4.30	.2	11	5.65	.2	11	4.26	.068	10	3.75	.10	10	3.75	.10	1.5	7.70	.8
Comorbidity Charlson score	1.9	0.976	.2	3.0	1.28	.10	1.7	0.968	.3	0.47	0.851	.8	0.48	0.851	.8	4.2	1.75	.13
Cancer diagnosis																		
Colon	—	—		—	—		—	—		—	—		—	—		—	—	
Prostate	4.5	3.59	.5	−0.08	4.71	> .9	1.2	3.57	.9	0.99	3.14	.9	0.85	3.14	> .9	20	6.42	.043[b]
Stage2b																		
III	—	—		—	—		—	—		—	—		—	—		—	—	
II	−0.73	3.50	> .9	1.9	4.59	.8	−1.8	3.47	.8	−2.7	3.05	.8	−2.6	3.05	.8	1.3	6.25	.8
0 or I	6.7	4.75	.5	5.1	6.24	.7	5.4	4.69	.6	5.4	4.13	.7	5.4	4.13	.7	12	8.51	.5
Months since diagnosis	0.03	0.286	> .9	0.11	0.375	.8	0.02	0.283	> .9	−0.14	0.249	.8	−0.15	0.249	.8	0.36	0.512	.8
Time * intervention group																		
Time * PN-LCNS	−0.28	0.957	> .9	−0.53	1.10	.8	0.07	1.14	> .9	0.42	1.01	.9	0.49	1.00	.8	−1.6	1.49	.6

Abbreviations: HSI, health system and information; PCS, patient care and support; PDL, physical and daily living; PN-LCNS, enhanced patient navigation; PSY, psychological; SCN, supportive care needs; SE, standard error; SXN, sexuality.

[a] False discovery rate correction for multiple testing.

[b] These *p* values indicate a significant difference.

the cost-effectiveness and sustainability of lay navigation programs and assess their impact on cancer outcomes across the cancer care continuum.

Regardless of condition, H/L women survivors reported a significant reduction in unmet psychological needs. The observed improvements over time in both conditions could be attributed to several factors. For instance, patient navigators may help patients cope with the emotional burden associated with cancer by providing emotional and tangible support, coordinating care, and linking patients to community resources, support groups, or counseling services.[29] Conversely, H/L women survivors did not report a reduction in unmet sexual health needs. Possible explanations for the absence of an effect may include the lack of training on sexual health/needs or referral options. In addition, the topic is often considered a cultural taboo, and health professionals may make assumptions about patient sexuality based on age, sex, marital status, or culture.[30–32] Survivors may also be reluctant to talk about their sexual concerns because of shyness, embarrassment, or stigma.[31,33] Further work is needed to better understand sexual concerns in the context of cancer care and develop culturally appropriate interventions to address this gap for H/L cancer survivors. These interventions should incorporate cultural beliefs and values, provide information in the preferred language, and involve community members who understand the cultural context. This approach allows for respectful and effective addressing of sexual health concerns. Moreover, health care providers should receive training to recognize and address sexual health issues in a culturally sensitive manner by understanding the cultural nuances that may influence patients' willingness to discuss sexual concerns and providing a safe and supportive environment for these discussions.

Contrary to our hypotheses, there were no significant differences over time in unmet needs between H/L men in the PN-LCNS and standard PN programs. In our study, H/L men reported fewer overall unmet care needs and across all domains except the sexuality domain compared with H/L women. This may help explain the lack of significant findings among men because these low baseline levels of unmet needs likely diminished the opportunity for improvement. In addition, machismo, a cultural value that represents a set of traditional masculine norms and behaviors,[34] can affect the ability of Hispanic men to express their care needs. This value emphasizes qualities such as strength, honor, and dominance and men, adhering to this mindset may hesitate to seek help and express their care needs, fearing it will undermine their masculine identity.[35] H/L men are underrepresented in the survivorship literature[36]; therefore, it is critical to better understand the supportive care needs of this group to properly develop or adapt interventions relevant to H/L men survivors. Future research should focus on exploring the unique supportive care needs of H/L men, considering the influence of H/L cultural values such as machismo. It should also aim to develop culturally tailored interventions that encourage H/L men to express their care needs and seek help without compromising their sense of identity.

Similar to previous research examining unmet supportive care needs in cancer survivors, we observed that younger age was associated with greater unmet supportive care needs at baseline among H/L male and female cancer survivors.[37–39] Younger cancer survivors often face unique challenges related to physical, emotional, and social aspects of cancer survivorship. These needs may include fertility preservation, body image concerns, self-esteem issues, interruptions in education or career plans, social isolation because of missing school or work.[40,41] Furthermore, we also observed that the unmet needs scores of older patients increased over time compared with younger patients. Older patients may find it difficult to cope with any level of unmet needs because of poor overall health (e.g., increased prevalence of comorbidities, cognitive impairment, mobility issues), low social support (e.g., loss of loved ones and peers), and financial toxicity.[42,43] Our findings emphasize the importance of developing age-appropriate interventions and support services.

STRENGTHS AND LIMITATIONS

Our research study has notable strengths, including that, to our knowledge, it is the first randomized controlled trial of a culturally tailored PN program in H/L cancer survivors. In addition, our study features a relatively large and distinctive sample of US H/L cancer survivors diagnosed with breast, prostate, and colorectal cancer. The majority were either monolingual Spanish-speaking or bilingual, with low levels of education and income. However, the generalizability of our findings should be further explored. Future research should include H/L cancer survivors with different primary disease sites beyond breast, prostate, and colorectal, with the full spectrum of disease severity (from stages 0 to IV). This study was conducted at two major tertiary medical centers in Chicago, Illinois, and San Antonio, Texas. Therefore, our results may not be generalizable to other geographic locations or clinical settings. Finally, this randomized clinical trial was specifically powered to detect differences in primary outcomes. Therefore, the sample size may not have had sufficient statistical power to detect differences in supportive care needs.

CONCLUSIONS

The current study contributes to the increasing body of evidence highlighting the importance of developing culturally tailored interventions for underserved racial-ethnic minority groups. Our findings support the use of a culturally tailored PN program to reduce the unmet supportive care needs of H/L women diagnosed with breast and colon cancer. Future studies should evaluate PN programs that target unmet supportive care needs in H/L men and sexual health.

AUTHOR CONTRIBUTIONS

Blanca S. Noriega Esquives: Writing–original draft preparation (lead), data curation, and formal analysis. **Patricia I. Moreno**: Writing–original draft and writing–review and editing. **Edgar Munoz**: Data curation and writing–review and editing. **Thomas E. Lad**: Writing–review and editing. **Courtney M. P. Hollowell**: Writing–review and editing. **Roberto M. Benzo**: Writing–review and editing. **Amelie G. Ramirez**: Conceptualization, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, and writing–review and editing. **Frank J. Penedo**: Conceptualization, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, and writing–review and editing. All authors read and approved the final version.

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CONFLICT OF INTEREST STATEMENT

Frank J. Penedo reports personal/consulting fees from Blue Note Therapeutics outside the submitted work. The remaining authors disclosed no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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