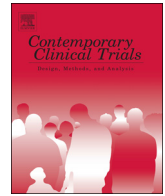




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Improving quality of life among latino cancer survivors: Design of a randomized trial of patient navigation



Amelie G. Ramirez^{a,*}, Kipling J. Gallion^a, Arely Perez^a, Edgar Munoz^a, Dorothy Long Parma^a, Patricia I. Moreno^b, Frank J. Penedo^c

^a Institute for Health Promotion Research, Mays Cancer Center, University of Texas Health San Antonio, San Antonio, TX, USA

^b Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

^c Department of Medicine, Division of Population Health and Computational Medicine, University of Miami at the Miller School of Medicine, Miami, FL, USA

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ABSTRACT

Latino cancer survivors have lower survival rates for most cancers relative to non-Latino whites, including, colorectal, prostate, and breast. In addition, Latinos experience health disparities in both access to care and quality of care. Experts recommend providing psychosocial services as an integral part of quality cancer care; however, there continues to be a paucity of information on the efficacy of Patient Navigators (PNs) in linking Latino cancer survivors to appropriate psychosocial services. *Redes En Acción*: The National Latino Cancer Research Network partnered with LIVESTRONG Cancer Navigation Services Patient Navigation program (PN-LCNS) to provide an intervention to improve wellness and increase access to psychosocial services among non-metastatic Latino cancer survivors from Texas and Chicago using trained bilingual, bicultural PNs. The study design involved a mixed-methods approach in two phases. Phase I used a Community-Based Participatory Research (CBPR) approach wherein PNs engaged community partners who provide services to breast, colorectal and prostate Latino cancer survivors. Phase II was a randomized controlled trial (RCT) that evaluated the efficacy of combining PN-facilitated interventions with the culturally tailored and CBPR-informed PN-LCNS in 300 breast, prostate and colorectal Latino cancer survivors. Outcomes investigated were improvements in: 1) quality of life (QOL), both general and disease-specific, and; 2) treatment follow-up compliance. While limited work has addressed the psychosocial needs of Latino cancer survivors, culturally-competent interventions using PNs have potential to address these needs and significantly improve Latino cancer survivorship.

1. Introduction

As the largest and one of the fastest-growing minority populations in the nation [1], Latinos are expected to comprise 28.6% of the total population by 2060 [2]. Cancer is the leading cause of morbidity and mortality in Latinos [1]. Although Latinos have lower incidence rates than Non-Latino Whites (NLWs) for all cancers combined and the most common cancers (prostate, female breast, colorectal and lung), their mortality rates are higher for the most common cancers [1,3]. It is also well-documented in the literature that Latino cancer survivors face quality of life (QOL) disparities [4–7].

Improvements in public cancer awareness and advances in early detection and treatment have yielded nearly 15.5 million U.S. cancer survivors [8]. Survivorship encompasses the time of diagnosis to end of life [9,10]. Underinsured or uninsured individuals are more likely to be

diagnosed with later-stage cancer, and have worse treatment outcomes and lower survival rates [11–15]. Latinos are more likely to be poorer, have lower education levels, no health insurance, and no source of primary care compared to NLWs [16]. Lower Latino cancer survival rates, even after accounting for differences in age and stage distribution, may reflect disparities in both access to care and timely, high-quality treatment [1,3] [12,15,17].

Research demonstrates that most newly diagnosed cancer survivors adjust well, and their overall QOL returns to levels comparable to the general population soon after treatment completion [18–20]. However, a proportion of cancer survivors continue experiencing physical, emotional, and social problems, often persisting for years after treatment ends [18–27]. Physiological problems that develop during treatment may become chronic [20], including pain and fatigue [28–32], sleep disorders [33–35], lymphedema [36–38], cognitive deficits [39,40],

* Corresponding author at: UT Health San Antonio, School of Medicine, Department of Epidemiology and Biostatistics, Institute for Health Promotion Research, 7411 John Smith Drive, Suite 1000, San Antonio, TX 78229, USA.

E-mail address: ramirezag@uthscsa.edu (A.G. Ramirez).

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urinary or bowel dysfunction [41,42], premature menopause [43,44], sexual dysfunction [45–47], and infertility [48,49]. Emotional and psychosocial concerns include anxiety, depression, fear of recurrence sense of loss and vulnerability, decreased social support, and issues around sexuality parenting, and relationships with the treatment team [25,50–53].

Promotores, lay Community Health Workers trained in health promotion, and Patient Navigators (PNs), who help patients navigate through the health-care system, have proven effective in increasing cancer screening and early-stage diagnosis [54–58]. However, evidence remains insufficient on PNs' efficacy in linking Latinos survivors to appropriate psychosocial services following diagnosis. This two-phase study seeks to bridge this evidence gap. For Phase I, the study used PNs in a Community-Based Participatory Research (CBPR) [59] approach to engage community-based partners that provide services to breast, colorectal and prostate Latino cancer survivors. For Phase II, we conducted a randomized clinical trial (RCT) comparing PN-facilitated intervention plus the culturally tailored and CBPR-informed LIVESTRONG Cancer Navigation Services Patient Navigator program (PN-LCNS) on improving QOL, both general and disease-specific, and treatment follow-up compliance among Latino breast, colorectal and prostate cancer survivors.

This paper details the study design of a two-phase mixed-methods intervention utilizing PNs and culturally tailored survivor services among Latino breast, colorectal and prostate cancer survivors in San Antonio and Chicago.

2. Methods

2.1. Study design

Phase I consisted of a CBPR approach to engage community-based partners in the implementation and dissemination of a randomized clinical trial (in Phase II), in which the efficacy of the PN-LCNS program compared to patient navigation only on improving QOL and treatment follow-up compliance among Latino breast, colorectal and prostate cancer survivors was tested over a 12-month follow-up in both Chicago, IL and San Antonio, TX. Phase I occurred over the first 3 months of the study period and brought together community-based leaders, service providers, organizations, and key informants from San Antonio and Chicago known to provide services to Latino cancer survivors. Four meetings were held at each location to: 1) introduce project staff; 2) present the RCT design; 3) present the PN-LCNS program (e.g., materials for training the PNs, topics addressed, cancer survivorship and cultural issues addressed in training, the LIVESTRONG Foundation Cancer Survivor's Health Journal, etc.); 4) present recruitment and assessment materials in English and Spanish; 5) discuss the utility of the program and the potential efficacy in improving QOL and treatment compliance; 6) establish or confirm RCT recruitment channels; and 7) offer LIVESTRONG Foundation curriculum training to community-based partners and PNs. In this phase, PNs were educated on the PN-LCNS program. The LIVESTRONG Foundation developed a *Promotores* Cancer Survivorship Training Curriculum to provide survivorship care for Latino cancer survivors and facilitate access and utilization of the LIVESTRONG SurvivorCare (LSSC) PN by English- and Spanish-speaking communities. The 5-session curriculum provided the knowledge, skills and motivation for *promotores* to promote the LSSC PN services and encourage Latino cancer survivors to access the services, as well as provided the skills for *promotores* to adequately address the many needs of Latino cancer survivors [60]. Feedback from community partners was integrated into multiple aspects of our study. It helped establish all advertising and recruitment activities, updated a list of community referrals for wide-ranging services for Latino cancer survivors, spurred recommendations of print materials for the PN-LCNS program and PN only conditions, and highlighted specific survivorship concerns that may have not been fully addressed by the PN-LCNS

program. In addition, the community partners helped strategize and discuss the potential burden of response for all eligibility assessments.

The CBPR interaction between community partners who provided services to breast, colorectal and prostate Latino cancer survivors and the research team also resulted in the creation of a resource directory. PNs utilized this resource directory to make connections and generate a clear understanding of what each resource partner offered. For example, community partners considered that the main needs of our local cancer survivors include financial support, transportation to and from the medical clinics to avoid missing medical appointments, and survivorship guidance, such as nutrition and exercise. Survivors also needed support and education about what cancer is, demystifying it, and becoming aware of available resources within the community. These specific survivorship concerns were addressed by stressing the importance of a bilingual PN and review of Spanish questionnaire for comprehension.

Phase II evaluated the efficacy of the PN-LCNS in improving treatment follow-up compliance and QOL among Latino breast, colorectal and prostate cancer survivors and the extent to which intervention-associated improvements in these outcomes are mediated by targets of the PN-LCNS program (e.g., communication with medical team, meeting unmet needs, improving health behaviors, reducing psychological distress, improving self-efficacy, etc.). The study involved a 2×4 randomized repeated measures design with experimental condition (combined patient navigation over 3 months with access to services provided by the PN-LCNS program [PN-LCNS] versus patient navigation only [PN]) as the between-groups factor, and time-point (baseline/pre-randomization [T1]; post-PN [\sim 3-months post-T1; T2], and \sim 6- [T3] and \sim 12-months [T4] follow-up post-T2) as the within-groups factor. The CONSORT flow diagram for Phase II is shown in Fig. 1.

The purpose of Phase II's RCT was to compare the effects of the PN-LCNS and PN only conditions on both general and disease-specific QOL and treatment follow-up compliance in 300 breast, colorectal and prostate Latino cancer survivors with no evidence of metastatic disease. To understand the mechanisms through which the PN-LCNS condition significantly impacts QOL and treatment compliance outcomes, we also examined the extent to which participation in the PN-LCNS (vs. PN only) led to significant changes in unmet cancer needs, better communication with the medical team, reduced negative health behaviors, psychological distress and worry, and improvements in coping and general self-efficacy as potential mediators of the intervention effects.

3. The PN-LCNS program

PN-LCNS participants were assigned PNs who provided patient navigation 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 (T1 to T4). Once participants were randomized to the PN-LCNS condition, PNs worked closely with them over the intervention period to: 1) present the PN-LCNS program; 2) promote usage of PN-LCNS services; 3) help address and overcome barriers to using the PN-LCNS program; 4) orient participants to 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 access and planning future medical appointments for treatment follow-up. Although PNs only worked with participants randomized to the PN-LCNS program from baseline (T1) to about 3-months post-baseline (T3), participants were encouraged to continue the use of the LIVESTRONG Foundation's LCNS program 1–800 number over the course of the study. The LIVESTRONG Foundation's LCNS program [60] provided free, professional, phone-or online-based, one-on-one support in English and Spanish to anyone affected by cancer, starting from the moment of diagnosis through the entire cancer experience, and health care professionals. Services provided include: 1) coping with emotional concerns; 2)

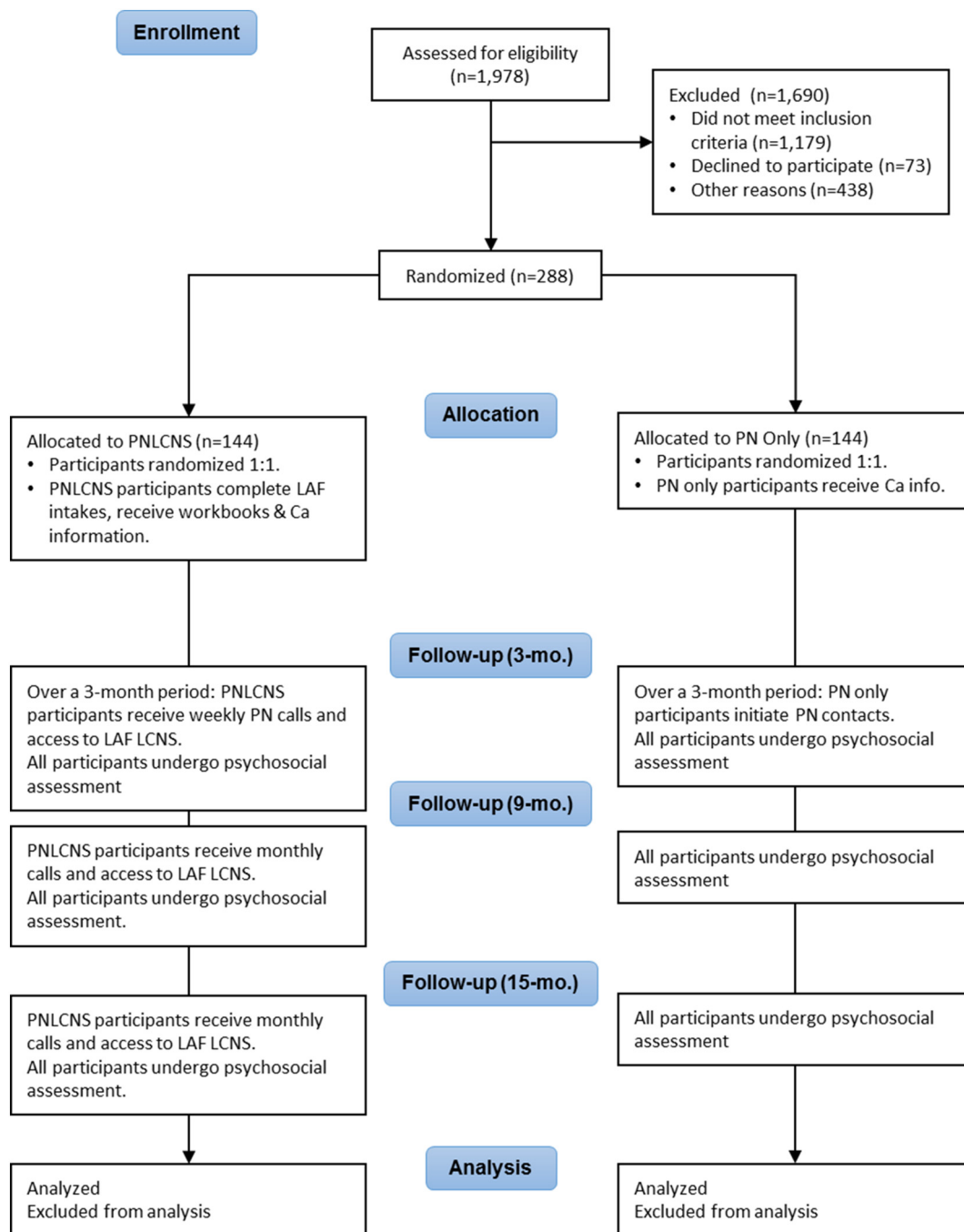


Fig. 1. CONSORT flow diagram.

understanding one's cancer type and treatment options; 3) help addressing financial and insurance concerns, including applying for benefit programs; 4) matching people to clinical trials of new treatments in development; and 5) education about risks to fertility, preservation options and access to discounted fertility services. The LCNS also offered additional English/Spanish tools to our PN-LCNS participants, including the LIVESTRONG Guidebook, Health Journal and Care Plan. The LIVESTRONG Guidebook, designed to help cancer survivors, their loved ones and caregivers, is a two-volume navigational tool written in English that provides information, resources, organizational worksheets and journal spaces to help survivors address the physical, emotional and practical concerns that many have during the cancer journey. The LIVESTRONG Health Journal, written in Spanish, is a tool used by healthcare providers to help people affected by cancer document and

organize information about their health providers, insurance and treatment in one place. The LIVESTRONG Care Plan focused on a “survivorship care plan” detailing the medical consequences a survivor may face. This document was individualized and based on the answers the survivor provided in a brief questionnaire. This care plan is designed to provide a summary that the survivor can review and discuss with his or her healthcare team.

4. Patient navigator only condition

Including a PN only control group allowed us to establish the efficacy of the PN-LCNS program among Latino breast, colorectal and prostate cancer survivors. The control group maximized the ability to observe an intervention effect relative to a condition that reflects the

Table 1
Description of scales/measures.

Scales/measures	Description
Demographics	Consists of a range of socio-demographic variables (SES, race/ethnicity, age, gender, country of origin, marital status, living arrangement and household size, and language preference/fluency).
MacArthur Foundation's Sociodemographic Ladder	This instrument from the MacArthur Foundation's Research Network on Socioeconomic Status and Health [61] allows respondents to indicate their perceptions of their social standing in their community.
Short Acculturation Scale for Hispanics (SASH)	In this 12-item instrument [62], items are rated on a 5-item Likert scale to assess multiple cultural domains (e.g., language, music) and is widely used in research with diverse NLW groups. SASH correlates with participants' generation, length of U.S. residency, age at arrival and ethnic identity, and has demonstrated good reliability (Cronbach's $\alpha = 0.92$).
Life Experience Survey (LES-10)	We administered a 10-item version of the LES [63], which assesses stressful events that occurred within the past 6 months (e.g., death of spouse, job loss, financial difficulties). Participants were asked to rate how the event impacted their life, the extent to which they expected the event to happen, how much control they had over it and how long it affected his/her life.
The Perceived Efficacy in Patient-Physician Interactions (PEPPI)	This questionnaire [64] assesses the cancer survivor's ability to effectively obtain medical information and attention to their medical concerns from physicians. The PEPPI is a valid, reliable brief instrument that assesses perceived self-efficacy in interacting with physicians. It consists of 10 items scored in a 5-item Likert scale with 5 being "very confident" and 1 being "not at all confident." English and Spanish versions are available, and both have shown adequate validity and reliability (Cronbach's α 's > 0.83).
Charlson score	This instrument aggregates a set of illnesses severe enough to influence mortality into one score [65]. A person's score is a weighted sum of the number of existing conditions.
Supportive Care Needs Survey (SCNS)	The SCNS [66] is used to assess unmet needs of survivors. Although originally developed for active-treatment cancer patients, the SCNS is a valid, reliable 34-item instrument that measures unmet needs of survivors in five domains: psychological, health system and information, physical/daily activity, patient care/support, and sexuality. Participants endorse a perceived need for help in a 5-item Likert scale (1 = not applicable, 2 = satisfied, 3 = low need, 4 = moderate need and 5 = severe need). Reliabilities for all 5 factors have been adequate, ranging from 0.87 to 0.97 [66].
Health Behavior Change from Study of Cancer Survivors-II (SCS-II)	Health behavior change is assessed using a measure developed as part of the American Cancer Society's SCS-II [67]. This 15-item measure asks respondents to indicate the extent to which they have engaged in 15 specific behaviors ("more," "less," or "the same amount") since their cancer diagnosis. Respondents also can endorse "N/A or never" if they have never engaged in the behavior or if it is not applicable. The list of behaviors assessed reflects survivor-encouraged actions, such as getting regular checkups, exercising, eating healthy, avoiding alcohol, etc.
Functional Assessment of Cancer Therapy – General (FACT-G)	The FACT-G [68] evaluates general domains of QOL and is one of the most widely used instruments to assess overall adjustment to cancer treatment and survivorship. It is a 27-item self-report questionnaire that takes < 15 min to administer [68]. The FACT-G assesses QOL in four domains of well-being: physical, social/family, emotional and functional well-being. Patients are asked to indicate the extent to which they agree with statements such as "I have pain," "I feel ill," "I get emotional support from my family," "I get support from my friends," "I feel sad," "I feel nervous," "I am sleeping well," and "I am content with the quality of my life right now."
Functional Assessment of Cancer Therapy – (FACT- B) Breast Cancer Only	The FACT-B (breast cancer survivors) inquiries about hair loss, shortness of breath and swelling in the arms [69]. Reliability of all cancer site-specific FACT measures are acceptable (Cronbach's $\alpha > 0.70$) [70].
Functional Assessment of Cancer Therapy – (FACT- C) Colorectal Cancer Only	FACT-C (colorectal cancer survivors) asks questions about bowel movement control, weight loss and cramping in the abdominal area [71].
Functional Assessment of Cancer Therapy – (FACT- P) Prostate Cancer Only	FACT-P (prostate cancer survivors) evaluates concerns on sexuality, pain, and bowel and bladder function [72].
Level of distress	This somatic anxiety scale is an adapted version of the Cognitive Somatic Anxiety Questionnaire (CSAQ) [73,74]. This instrument consists of a 10-item version of the 14 item CSAQ. Items are scored on a 5-point likert scale ranging from "not at all" (1) to "very much so" (5).
Worry interference	This is 5-point likert scale that demonstrates the extent to which the patient experienced fears or concerns specific to cancer, such as, if concerns about cancer have impacted ability to have fun, whether worries have affected one's ability to meet the needs of the family, etc. [75].
Self-efficacy	Self-Efficacy is assessed with a 19-item scale that taps into general and health specific coping and self-efficacy strategies. Items are scored on a 5-point likert scale ranging from "not at all confident" (1) to "totally confident" (5) [76].
Distress thermometer	This scale [77] is scored from 0 ("no distress") to 10 ("extreme distress") with the midpoint (5) as "moderate distress."
Patient satisfaction with cancer care	This instrument [78,79] assessed modifiable patient-centered cancer care practices, such as patient inclusion in care decisions, sufficient time with provider, ready access to medical advice, timely appointments, and courteous/respectful staff.

standard follow-up treatment available for Latino cancer survivors in combination with traditional PN services but without the PN-LCNS component. Participants in the PN only condition had limited access to PN services for a maximum of six phone calls to the PN in each study site. Information was also available on cancer survivorship, available community services, and print material relevant to either breast, colorectal or prostate cancer survivorship. These materials were also available to PN-LCNS participants.

5. Recruitment strategies

To be eligible for our study, participants had to: 1) report a primary

diagnosis of breast, colorectal or prostate cancer; 2) have completed primary treatment within the past 15 months, a timeframe selected based on feedback from discussions between the research team and community partners during Phase I; 3) have no evidence of distant metastatic disease; 4) have no current severe mental illness (e.g., psychosis); 5) report no substance dependence within the past year; 6) report no active suicidality; 7) have no ongoing neoadjuvant therapy (chemotherapy or radiation); 8) show evidence of verbal fluency in English or Spanish; 9) be available for follow-up over the course of the study period; and 10) self-identify as Latino.

Participant recruitment was accomplished throughout the Chicago and San Antonio metro areas. Recruitment in Chicago occurred

Table 2
Sociodemographic characteristics.

	Intervention (N = 144)		Control (N = 144)		Total (N = 288)		P value ^a
Age, mean (SD)	56.3	(10.0)	55.8	(10.4)	56.1	(10.2)	0.631
Years living in US, mean (SD)	29.0	(15.6)	28.3	(13.1)	28.7	(14.5)	0.745
Gender, % (n)							0.723
Female	52.8%	(76)	54.9%	(79)	53.8%	(155)	
Male	47.2%	(68)	45.1%	(65)	46.2%	(133)	
Race, % (n)							0.433
White	86.1%	(124)	90.3%	(130)	88.2%	(254)	
Black	0.0%	(0)	0.7%	(1)	0.3%	(1)	
American Indian, Aleutian or Eskimo	0.7%	(1)	0.0%	(0)	0.3%	(1)	
Other	10.4%	(15)	6.9%	(10)	8.7%	(25)	
Unknown	2.8%	(4)	1.4%	(2)	2.1%	(6)	
Missing	0.0%	(0)	0.7%	(1)	0.3%	(1)	
Hispanic Heritage, Country/Territory of Origin, % (n)							0.206
Mexico	78.5%	(113)	82.6%	(119)	80.6%	(232)	
Puerto Rico	4.9%	(7)	5.6%	(8)	5.2%	(15)	
Central America	0.7%	(1)	2.8%	(4)	1.7%	(5)	
South America	9.0%	(13)	3.5%	(5)	6.3%	(18)	
Caribbean	0.7%	(1)	1.4%	(2)	1.0%	(3)	
Other	0.7%	(1)	1.4%	(2)	1.0%	(3)	
Unknown	2.1%	(3)	0.7%	(1)	1.4%	(4)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Language, % (n)							0.246
English monolingual	13.2%	(19)	20.8%	(30)	17.0%	(49)	
Spanish monolingual	56.3%	(81)	52.1%	(75)	54.2%	(156)	
English-Spanish bilingual	27.1%	(39)	25.0%	(36)	26.0%	(75)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Nativity, % (n)							0.134
US Born	33.3%	(48)	42.4%	(61)	37.8%	(109)	
Foreign Born	63.2%	(91)	55.6%	(80)	59.4%	(171)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Immigrant Generation, % (n)							0.612
1st generation	61.1%	(88)	52.1%	(75)	56.6%	(163)	
2nd generation	13.9%	(20)	11.8%	(17)	12.8%	(37)	
3rd generation	7.6%	(11)	13.9%	(20)	10.8%	(31)	
4th generation	4.9%	(7)	8.3%	(12)	6.6%	(19)	
5th generation	5.6%	(8)	8.3%	(12)	6.9%	(20)	
Not Applicable	1.4%	(2)	2.8%	(4)	2.1%	(6)	
Unknown	1.4%	(2)	0.7%	(1)	1.0%	(3)	
Missing	4.2%	(6)	2.1%	(3)	3.1%	(9)	
Household income, % (n)							0.863
Less than \$12,000	22.2%	(32)	22.2%	(32)	22.2%	(64)	
Between \$12,000 and \$24,999	24.3%	(35)	29.2%	(42)	26.7%	(77)	
Between \$25,000 and \$49,999	20.1%	(29)	18.8%	(27)	19.4%	(56)	
Between \$50,000 and \$99,999	9.0%	(13)	10.4%	(15)	9.7%	(28)	
Unknown	20.8%	(30)	17.4%	(25)	19.1%	(55)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Educational history, % (n)							0.634
Less than high school	41.7%	(60)	36.8%	(53)	39.2%	(113)	
High school or equivalency (GED)	26.4%	(38)	26.4%	(38)	26.4%	(76)	
Associate's degree	2.8%	(4)	9.7%	(14)	6.3%	(18)	
Bachelor's degree	11.1%	(16)	4.9%	(7)	8.0%	(23)	
Master's degree	1.4%	(2)	2.8%	(4)	2.1%	(6)	
Doctoral degree (PhD, DPhil)	0.7%	(1)	1.4%	(2)	1.0%	(3)	
Professional degree (MD, JD, DDS)	1.4%	(2)	0.0%	(0)	0.7%	(2)	
Other	1.4%	(2)	4.9%	(7)	3.1%	(9)	
Unknown	9.7%	(14)	11.1%	(16)	10.4%	(30)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Relationship status, % (n)							0.555
Single	9.7%	(14)	13.2%	(19)	11.5%	(33)	
Married or Living with Partner	60.4%	(87)	62.5%	(90)	61.5%	(177)	
Dating	0.0%	(0)	0.7%	(1)	0.3%	(1)	
Separated	6.9%	(10)	4.2%	(6)	5.6%	(16)	
Divorced	13.2%	(19)	13.9%	(20)	13.5%	(39)	
Widowed	6.3%	(9)	3.5%	(5)	4.9%	(14)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Parental status, % (n)							0.870
No	9.0%	(13)	9.7%	(14)	9.4%	(27)	
Yes	87.5%	(126)	88.2%	(127)	87.8%	(253)	
Missing	3.5%	(5)	2.1%	(3)	2.8%	(8)	
Cancer type, % (n)							0.963
Breast	43.8%	(63)	45.1%	(65)	44.4%	(128)	
Colorectal	24.3%	(35)	24.3%	(35)	24.3%	(70)	
Prostate	31.9%	(46)	30.6%	(44)	31.3%	(90)	

^a based on t-test or Pearson's or Fishers' exact chi-square.

primarily through Mt. Sinai Hospital Cancer Center (Mt. Sinai) and John H. Stroger Jr. Hospital of Cook County (Stroger). In San Antonio, recruitment was conducted mainly from the Mays Cancer Center, South Texas's only academic cancer research and treatment facility.

6. Eligibility assessments

Participants underwent face-to-face, interview-based psychosocial assessments. Each participant received \$25 per assessment visit. Participants had the option to be assessed at their homes to reduce travel burden to the facilities, or at the community-based clinics that provided a private assessment room for our interviewers.

Once potential participants were identified via our recruitment sources, a preliminary phone screen survey was administered to determine whether the participant met the general inclusion criteria for the study. Once it was deemed that a potential participant met the criteria, a formal screening interview and the baseline (T1) assessment visit to administer the psychosocial battery was scheduled. First, participants provided informed consent approved by the Institutional Review Boards (IRBs) at Northwestern University (NU) and University of Texas Health San Antonio (UTHSA). The Short Portable Mental Status Questionnaire (SPMSQ) was then administered to assess for cognitive impairment. Participants who did not meet the requisite cutoff of ≥ 3 for the SPMSQ were excluded, as such impairment could have interfered with participation in the intervention, understanding of assessment materials, etc. Then, the screening items from the Structured Clinical Interview for DSM-IV (SCID) for psychotic disorder from the psychosis module, as well as screener items for substance dependence (from the SCID-II) were administered. The SCID offers a time-efficient way to move through prospective diagnostic categories by using decision trees for further probing only when initial responses indicate. All excluded participants were handed English or Spanish materials on breast, colorectal or prostate cancer survivorship from the National Cancer Institute, American Cancer Society, and other groups, as well as referred to appropriate and relevant services. Table 1 contains full descriptions for all scales/measures utilized during assessment periods T1-T4.

At the baseline visit (T1), all PN-LCNS participants completed the LIVESTRONG navigation services intake form with the Chicago and Texas patient navigators. This intake data was transferred via a secure and HIPAA compliant interface to the LIVESTRONG PNs. In addition to standard sociodemographic information, the intake form collected data specific to cancer type, stage of treatment and areas that the individual identified as potential or actual unmet needs (coping emotionally, learning more about their cancer and treatment options, community resources, etc.).

7. Randomization

Upon completing the T1 baseline assessment, participants were randomized 1:1 into the PN-LCNS or the PN only condition to reduce potential bias. Once a cohort of 2 participants in the same disease type were identified (e.g., 2 completed breast cancer T1 assessments) at each site (Chicago and San Antonio), randomization by disease site was done to assure equivalence of cancer type across the experimental and control condition (e.g., 5 breast cancer survivors in the PN-LCNS condition & 5 breast cancer survivors in PN only condition).

8. Results

We consented a total of 288 Latino men and women who received primary treatment within the past 15 months for breast ($n = 128$), colorectal ($n = 70$) or prostate cancer ($n = 90$) and who did not have any evidence of distant metastatic disease. Average age for participants was 56 years old and most were married or living with their partner (61.5%). About 65% of the participants had an education level of high

school/GED or less and almost half (48.9%) had a household income of less than \$24,999. Participants were mostly foreign born (59.4%), with 54.2% speaking only Spanish and 26% being bilingual (Table 2).

9. Discussion

Patient navigators (PNs) have proven effective in helping patients get screened for cancer [54–58]. Engaging community organizations using CBPR concepts is well-documented in the literature [80–82] and is key to engaging minority populations such as Latinos to increase representation in clinical research trials and ultimately reduce health disparities.

Here we detailed the study design of a mixed-methods intervention combining culturally relevant PNs and the LIVESTRONG Foundation's LCNS program to improve quality of life (QOL) and treatment follow-up compliance in breast, colorectal, and prostate Latino cancer survivors. Notable aspects of our study design include a mixed-method and two-phase approach. In Phase I, we partnered with organizations serving cancer survivors and we present our recruitment for the study along with the sociodemographic characteristics of the participants.

This study's unique contribution was in its application of a randomized controlled trial (Phase II) to test the effect of the PN-LCNS approach on Latino survivor QOL and follow-up after treatment, by linking Latinos to appropriate psychosocial services. This has not been reported in the literature. The high proportion of participants with high school/GED or less education, and household income of less than \$24,999 reflect socioeconomic barriers to care that Latinos face nationwide [83–85]. The predominantly foreign country of origin and Spanish-dominant language preference are characteristic of San Antonio and Chicago Latinos [86–88] (Table 2).

We have previously conducted analyses to explore the influence of self-efficacy on the relationship between satisfaction with cancer care and health-related QOL in this sample at baseline. These results are detailed elsewhere [89]. Primary and secondary outcome results analyses for this study are ongoing and will be published separately. Future analyses will focus on relationships between positive and negative patient experiences, self-efficacy, and health related QOL across the intervention period. Future studies from our results will target specific contributors to Latino survivors' QOL in breast, colorectal, and prostate cancers. This model will also be applied to cancers with disproportionately increasing morbidity and mortality in Latinos, including liver and stomach cancers.

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References

- [1] American Cancer Society, *Cancer facts & figures for Hispanics/Latinos 2015–2017*, American Cancer Society, Atlanta, 2015.
- [2] S.L. Colby, J.M. Ortman, *Projections of the Size and Composition of the US Population: 2014 to 2060*, 9 US Census Bureau, 2015.
- [3] American Cancer Society, *Cancer facts & figures 2018*, American Cancer Society, Atlanta, 2018.
- [4] J.Z. Ayanian, et al., Patients' perceptions of quality of care for colorectal cancer by race, ethnicity, and language, *J. Clin. Oncol.* 23 (27) (2005) 6576–6586.
- [5] F.J. Penedo, et al., Ethnicity and determinants of quality of life after prostate cancer treatment, *Urology* 67 (5) (2006) 1022–1027.
- [6] B. Yanez, E.H. Thompson, A.L. Stanton, Quality of life among Latina breast cancer patients: a systematic review of the literature, *J. Cancer Surviv.* 5 (2) (2011) 191–207.
- [7] T. Luckett, et al., Psychological morbidity and quality of life of ethnic minority

- patients with cancer: a systematic review and meta-analysis, *Lancet Oncol.* 12 (13) (2011) 1240–1248.
- [8] American Cancer Society, *Cancer Treatment & Survivorship Facts & Figures 2016–2017*, American Cancer Society, Atlanta, 2016.
- [9] National Cancer Institute, *Office of Cancer Survivorship: Survivorship Definitions, Available from, 2014*. <https://cancercontrol.cancer.gov/ocs/statistics/definitions.html>.
- [10] E.J. Clark, et al., *Imperatives for Quality Cancer Care: Access, Advocacy, Action, and Accountability*, National Coalition of Cancer Survivorship, 1996, pp. 7–8.
- [11] S.D. Ramsey, et al., Financial insolvency as a risk factor for early mortality among patients with cancer, *J. Clin. Oncol.* 34 (9) (2016) 980–986.
- [12] Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, B.D. Smedley, A.Y. Stith, A.R. Nelson (Eds.), *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, National Academies Press (US) Copyright 2002 by the National Academy of Sciences. All rights reserved, Washington (DC), 2003.
- [13] Agency for Healthcare Research and Quality, *National Healthcare Quality and Disparities Report*, Agency for Healthcare Research and Quality, Rockville, MD, 2016.
- [14] M.T. Halpern, et al., Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: a retrospective analysis, *Lancet Oncol.* 9 (3) (2008) 222–231.
- [15] Agency for Healthcare Research and Quality, *National Healthcare Quality Report*, Agency for Healthcare Research and Quality, Rockville, MD, 2014.
- [16] L. Vélez, P. Chalela, A. Ramirez, *Hispanic/Latino health and disease: An overview. Health Promotion in Multicultural Populations: A Handbook for Practitioners and Students*, 2nd edn, SAG E Publications, Thousand Oaks, CA, 2008.
- [17] Agency for Healthcare Research and Quality, *Healthcare disparities report*, Agency for Healthcare Research and Quality, Rockville, MD, 2014.
- [18] A.L. Stanton, et al., Outcomes from the moving beyond cancer psychoeducational, randomized, controlled trial with breast cancer patients, *J. Clin. Oncol.* 23 (25) (2005) 6009–6018.
- [19] A.L. Stanton, et al., Promoting adjustment after treatment for cancer, *Cancer* 104 (S11) (2005) 2608–2613.
- [20] T. Smith, et al., The rationale, design, and implementation of the American Cancer Society's studies of cancer survivors, *Cancer* 109 (1) (2007) 1–12.
- [21] L.P. Buki, et al., Latina breast cancer survivors' lived experiences: diagnosis, treatment, and beyond, *Cult. Divers. Ethn. Minor. Psychol.* 14 (2) (2008) 163–167.
- [22] N. Galván, L.P. Buki, D.M. Garcés, Suddenly, a carriage appears: social support needs of Latina breast cancer survivors, *J. Psychosoc. Oncol.* 27 (3) (2009) 361–382.
- [23] P.N. Schultz, et al., Health profiles in 5836 long-term cancer survivors, *Int. J. Cancer* 104 (4) (2003) 488–495.
- [24] K.R. Yabroff, et al., Burden of illness in cancer survivors: findings from a population-based national sample, *J. Natl Cancer Inst.* 96 (17) (2004) 1322–1330.
- [25] Institute of Medicine, N.E. Adler, A.E.K. Page (Eds.), *Cancer care for the whole patient: meeting psychosocial health needs*, The National Academies Press, Washington, DC, 2008, p. 454.
- [26] P.B. Jacobsen, Promoting evidence-based psychosocial care for cancer patients, *Psycho-Oncology* 18 (1) (2009) 6–13.
- [27] L. Traeger, et al., Illness perceptions and emotional well-being in men treated for localized prostate cancer, *J. Psychosom. Res.* 67 (5) (2009) 389–397.
- [28] D.P. Lawrence, et al., Evidence report on the occurrence, assessment, and treatment of fatigue in cancer patients, *JNCI Monogr.* 2004 (32) (2004) 40–50.
- [29] C.H. Kroenke, et al., Functional impact of breast cancer by age at diagnosis, *J. Clin. Oncol.* 22 (10) (2004) 1849–1856.
- [30] V.S. Helgeson, P.L. Tomich, Surviving cancer: a comparison of 5-year disease-free breast cancer survivors with healthy women, *Psycho-Oncology* 14 (4) (2005) 307–317.
- [31] K.A. Robb, et al., A pain management program for chronic cancer-treatment-related pain: a preliminary study, *J. Pain* 7 (2) (2006) 82–90.
- [32] J.E. Bower, et al., Fatigue in long-term breast carcinoma survivors, *Cancer* 106 (4) (2006) 751–758.
- [33] National Institutes of Health State-of-the-Science Panel, National Institutes of Health State-of-the-Science Conference Statement: symptom management in cancer: pain, depression, and fatigue, July 15–17, 2002, *J. Natl. Cancer Inst.* 95 (15) (2003) 1110–1117.
- [34] J. Savard, C.M. Morin, Insomnia in the context of cancer: a review of a neglected problem, *J. Clin. Oncol.* 19 (3) (2001) 895–908.
- [35] J.J. Mao, et al., Symptom burden among cancer survivors: impact of age and comorbidity, *J. Am. Board Fam. Med.* 20 (5) (2007) 434–443.
- [36] K. Bosompra, et al., Swelling, numbness, pain, and their relationship to arm function among breast cancer survivors: a disablement process model perspective, *Breast J.* 8 (6) (2002) 338–348.
- [37] V.S. Erickson, et al., Arm edema in breast cancer patients, *J. Natl Cancer Inst.* 93 (2) (2001) 96–111.
- [38] J.A. Petrek, et al., Lymphedema in a cohort of breast carcinoma survivors 20 years after diagnosis, *Cancer* 92 (6) (2001) 1368–1377.
- [39] L.H. Heflin, et al., Cancer as a risk factor for long-term cognitive deficits and dementia, *J. Natl Cancer Inst.* 97 (11) (2005) 854–856.
- [40] C.E. Jansen, et al., Chemotherapy-induced cognitive impairment in women with breast cancer: a critique of the literature, *Oncol. Nurs. Forum* 32 (2) (2005) 329–342.
- [41] D.C. Miller, et al., Long-term outcomes among localized prostate cancer survivors: health-related quality-of-life changes after radical prostatectomy, external radiation, and brachytherapy, *J. Clin. Oncol.* 23 (12) (2005) 2772–2780.
- [42] D.F. Penson, et al., 5-Year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study, *J. Urol.* 173 (5) (2005) 1701–1705.
- [43] M.T. Knopf, The influence of endocrine effects of adjuvant therapy on quality of life outcomes in younger breast cancer survivors, *Oncologist* 11 (2) (2006) 96–110.
- [44] J.R. Molina, D.L. Barton, C.L. Loprinzi, Chemotherapy-induced ovarian failure, *Drug Saf.* 28 (5) (2005) 401–416.
- [45] M. Frumovitz, et al., Quality of life and sexual functioning in cervical cancer survivors, *J. Clin. Oncol.* 23 (30) (2005) 7428–7436.
- [46] L.R. Schover, et al., Seeking help for erectile dysfunction after treatment for prostate cancer, *Arch. Sex. Behav.* 33 (5) (2004) 443–454.
- [47] L.R. Schover, *Sexuality and fertility after cancer*, ASH Education Program Book, 2005(1) 2005, pp. 523–527.
- [48] A. Agarwal, S.S.R. Allamaneni, Disruption of spermatogenesis by the cancer disease process, *JNCI Monogr.* 2005 (34) (2005) 9–12.
- [49] J. Carter, et al., Gynecologic cancer treatment and the impact of cancer-related infertility, *Gynecol. Oncol.* 97 (1) (2005) 90–95.
- [50] J.H. Rowland, F. Baker, Introduction: resilience of cancer survivors across the lifespan, *Cancer* 104 (S11) (2005) 2543–2548.
- [51] F. Baker, et al., Adult cancer survivors: how are they faring? *Cancer* 104 (S11) (2005) 2565–2576.
- [52] G.T. Deimling, et al., Cancer survivorship and psychological distress in later life, *Psycho-Oncology* 11 (6) (2002) 479–494.
- [53] G.T. Deimling, et al., Cancer-related health worries and psychological distress among older adult, long-term cancer survivors, *Psycho-Oncology* 15 (4) (2006) 306–320.
- [54] T. Fowler, et al., Reducing disparities in the burden of cancer: the role of patient navigators, *PLoS Med.* 3 (7) (2006) e193.
- [55] S.F. Oluwole, et al., Impact of a cancer screening program on breast cancer stage at diagnosis in a medically underserved urban community, *J. Am. Coll. Surg.* 196 (2) (2003) 180–188.
- [56] D. Dohan, D. Schrag, Using navigators to improve care of underserved patients, *Cancer* 104 (4) (2005) 848–855.
- [57] K. Ell, et al., Patient navigation and case management following an abnormal mammogram: a randomized clinical trial, *Prev. Med.* 44 (1) (2007) 26–33.
- [58] J.M. Ferrante, P.H. Chen, S. Kim, The effect of patient navigation on time to diagnosis, anxiety, and satisfaction in urban minority women with abnormal mammograms: a randomized controlled trial, *J. Urban Health* 85 (1) (2008) 114–124.
- [59] E.A. Parker, et al., *Methods in Community-Based Participatory Research for Health*, Jossey-Bass, San Francisco, CA, 2005.
- [60] Lance Armstrong Foundation, *Promotores cancer survivorship training materials, Available from, 2009*. https://www.livestrong.org/site/c.khlXK1PxHmF/b.2662615/k.3526/Promotores_Training_Materials.htm.
- [61] MacArthur Foundation's Research Network on SES and Health, *Sociodemographic Questionnaire, Available from http://www.macses.ucsf.edu/research/sociolenviron/sociodemographic.php*.
- [62] G. Marin, et al., Development of a short acculturation scale for Hispanics, *Hisp. J. Behav. Sci.* 9 (2) (1987) 183–205.
- [63] I.G. Sarason, J.H. Johnson, J.M. Siegel, Assessing the impact of life changes: development of the life experiences survey, *J. Consult. Clin. Psychol.* 46 (5) (1978) 932.
- [64] R.C. Maly, et al., Perceived efficacy in patient-physician interactions (PEPPI): validation of an instrument in older persons, *J. Am. Geriatr. Soc.* 46 (7) (1998) 889–894.
- [65] M.E. Charlson, et al., A new method of classifying prognostic comorbidity in longitudinal studies: development and validation, *J. Chronic Dis.* 40 (5) (1987) 373–383.
- [66] B. Bonevski, et al., Evaluation of an instrument to assess the needs of patients with cancer. Supportive Care Review Group, *Cancer* 88 (1) (2000) 217–225.
- [67] K. Stein, et al., The American cancer society's studies of cancer survivors: the largest, most diverse investigation of long-term cancer survivors so far, *Am. J. Nurs.* 106 (3 Suppl) (2006) 83–85.
- [68] D.F. Cella, et al., The functional assessment of cancer therapy scale: development and validation of the general measure, *J. Clin. Oncol.* 11 (3) (1993) 570–579.
- [69] M.J. Brady, et al., Reliability and validity of the functional assessment of cancer therapy-breast quality-of-life instrument, *J. Clin. Oncol.* 15 (3) (1997) 974–986.
- [70] D. Cella, *The Functional Assessment of Cancer Therapy-Anemia (FACT-An) Scale: a new tool for the assessment of outcomes in cancer anemia and fatigue*, *Semin. Hematol.* 34 (3) (1997) 13–19 Suppl 2.
- [71] W.L. Ward, et al., Reliability and validity of the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) quality of life instrument, *Qual. Life Res.* 8 (3) (1999) 181–195.
- [72] P. Esper, et al., Measuring quality of life in men with prostate cancer using the functional assessment of cancer therapy-prostate instrument, *Urology* 50 (6) (1997) 920–928.
- [73] P. Critis-Christoph, The factor structure of the cognitive-somatic anxiety questionnaire, *J. Psychosom. Res.* 30 (6) (1986) 685–690.
- [74] D.E. Degood, R.C. Tait, The cognitive-somatic anxiety questionnaire: psychometric and validity data, *J. Psychopathol. Behav. Assess.* 9 (1) (1987) 75–87.
- [75] P.C. Trask, et al., Cancer-specific worry interference in women attending a breast and ovarian cancer risk evaluation program: impact on emotional distress and health functioning, *Psycho-Oncology* 10 (5) (2001) 349–360.
- [76] K. Lorig, *Outcome Measures for Health Education and Other Health Care Interventions*, Sage, 1996.
- [77] Roth AJ, et al., Rapid screening for psychologic distress in men with prostate carcinoma, *Cancer* 82 (10) (1998) 1904–1908.

- [78] P. Jean-Pierre, et al., Structural and reliability analysis of a patient satisfaction with cancer-related care measure: a multisite patient navigation research program study, *Cancer* 117 (4) (2011) 854–861.
- [79] P. Jean-Pierre, et al., Psychometric validation and reliability analysis of a Spanish version of the patient satisfaction with cancer-related care measure: a patient navigation research program study, *Support Care Cancer* 20 (9) (2012) 1949–1956.
- [80] C.D. Meade, et al., Creating community-academic partnerships for cancer disparities research and health promotion, *Health Promot. Pract.* 12 (3) (2011) 456–462.
- [81] D. Las Nueces, et al., A systematic review of community-based participatory research to enhance clinical trials in racial and ethnic minority groups, *Health Serv. Res.* 47 (3pt2) (2012) 1363–1386.
- [82] A. O'Mara-Eves, et al., The effectiveness of community engagement in public health interventions for disadvantaged groups: a meta-analysis, *BMC Public Health* 15 (1) (2015) 129.
- [83] G. Flores, Language barriers to health care in the United States, *N. Engl. J. Med.* 355 (3) (2006) 229–231.
- [84] G. Freeman, M. Lethbridge-Cejku, Access to health care among Hispanic or Latino women: United States, *Adv. Data* 2006 (368) (2000-2002) 1–25.
- [85] J.B. Kirby, G. Taliaferro, S.H. Zuvekas, Explaining racial and ethnic disparities in health care, *Med. Care* 44 (5 Suppl) (2006) I64–I72.
- [86] U.S. Census Bureau, 2012–2016 American Community Survey 5-Year Estimates, Table DP05, <https://factfinder.census.gov/>, (2018).
- [87] U.S. Census Bureau, 2012–2016 American Community Survey 5-Year Estimates, Table S0501, <https://factfinder.census.gov/>, (2018).
- [88] U.S. Census Bureau, 2012–2016 American Community Survey 5-Year Estimates, Table S1601, <https://factfinder.census.gov/>, (2018).
- [89] P.I. Moreno, et al., Satisfaction with cancer care, self-efficacy, and health-related quality of life in Latino cancer survivors, *Cancer* 124 (8) (2018) 1770–1779.