

Apoyo con Cariño: Strategies to Promote Recruiting, Enrolling, and Retaining Latinos in a Cancer Clinical Trial

Stacy M. Fischer, MD^a; Danielle M. Kline, BS^a; Sung-Joon Min, PhD^a; Sonia Okuyama, MD^{a,b}; and Regina M. Fink, PhD, RN^a

Abstract

Background: We present and describe tailored strategies to address known barriers to minority participation in clinical trial research. The strategies used allowed our team to engage communities and successfully recruit, enroll, and retain a diverse underserved population of Latinos with advanced cancer for this clinical trial. **Methods:** Participants were recruited from 3 urban and 7 rural sites. We identified 4 critical barriers to recruitment for this underserved population: (1) mistrust; (2) language and communication barriers; (3) lack of access to academic cancer center; and (4) inability to participate due to transportation, childcare, or work responsibilities. We developed tailored strategies to engage referring sites and patients to participate in the clinical trial. **Results:** We identified 318 potentially eligible participants; 34 were found to be ineligible, and 223 consented to participate in the study, representing a 79.0% enrollment rate. All patients (100%) self-identified as Latino, and 47.5% spoke Spanish as their primary language. Patients were socioeconomically disadvantaged: 53.6% had an annual income <\$15,000 USD, and 50.2% had less than a high school education. A total of 177 participants completed the 3-month follow-up; 26 died before the 3-month follow interview, and 20 did not complete the follow-up evaluation (9% withdrawal rate). **Conclusions:** Our community-informed strategies were highly effective for recruiting, enrolling, and retaining an underserved diverse population of Latinos. The barriers we identified and the strategies we used have the potential to inform research to increase minority participation in cancer clinical trials. ClinicalTrials.gov identifier: NCT01695382

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There are innumerable compelling reasons why efforts should continue to increase minority enrollment in cancer clinical trials (CCTs). Minorities are a growing proportion of the general population, yet experience a disproportionate share of the cancer burden.^{1,2} Despite this disparity, minorities continue to be underrepresented in CCTs.^{3,4}

In 1993, the NIH passed the Revitalization Act requiring researchers to enroll a representative sample of patients.⁵ A review 20 years after the passage of the Revitalization Act found that minority patients remain

underrepresented and that <2% of the 10,000 clinical trials funded by NCI have adequate minority representation to meet the NIH's goals and priorities.³ Less than 1% (150 of 10,000) of the NCI-sponsored trials have a primary focus on an ethnic or minority group.³ Federal funds for clinical research come from tax revenues. The fact that minorities currently make up 45% of the population,⁶ yet comprise a very small fraction of current federally funded clinical research, represents a profound disparity. In essence, minorities are funding the NIH, yet remain underrepresented in the research they are

From ^aUniversity of Colorado School of Medicine, and ^bDenver Health and Hospital Authority, Denver, Colorado.

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Correspondence: Stacy M. Fischer, MD, University of Colorado School of Medicine, 12631 East 17th Avenue, General Internal Medicine, 8th Floor, Aurora, CO 80045. E-mail: stacy.fischer@ucdenver.edu

funding. Cancer therapies have become more targeted and tailored to unique genetic mutations and markers. We need to ensure that genetic mutations and markers with a high prevalence in minority populations are identified and targeted for molecular and immunotherapies, or we risk worsening disparities in cancer treatment outcomes. To that end, advocates have proposed including recruitment approaches in the scientific scoring criteria, rather than considering after scoring, as is the current directive.⁷

Our study, *Apoyo con Cariño* (roughly translated to *Support With Caring*), was funded through the American Cancer Society and focused on improving palliative care outcomes for Latinos with advanced cancer. The study aimed to enroll 240 adult Latinos with stage III or IV cancer in a randomized controlled trial (RCT) of a patient navigator (PN) intervention. In our previous pilot work,⁸ we identified barriers for patient participation in clinical trials based on a review of the literature. These challenges were used to inform our study design and clinical trial:

- **Mistrust:** although the Tuskegee study is the most well-known, numerous abuses of trust have occurred in research that have targeted or exploited minority populations.⁹ Persistent mistrust and wariness on behalf of minority populations are justified and understandable.
- **Language barriers and communication preferences:** language can be a significant barrier to recruiting Spanish-speaking Latinos into clinical research.^{10,11} Even when English is spoken fluently in daily life, the complexity of scientific and medical terms used in biomedical research requires translation into a potential participant's primary language to assure full comprehension.
- **Lack of access to an academic cancer center:** one recognized barrier to engaging minorities in CCTs is the lack of access to academic centers.¹² Because academic cancer centers are nearly always located in urban settings, this also excludes minorities living in rural areas.
- **Inability to participate due to transportation, work responsibilities, childcare:** minorities are more likely to experience poverty and have socioeconomic challenges that cause well-documented barriers to cancer screening and treatment, as well as research.¹³

This report describes these potential barriers to recruitment and evaluates the strategies we imple-

mented to achieve our enrollment goals and engage an underrepresented population in a CCT.

Methods

Formative Work

We developed our study methods and intervention content using community participatory action methods. We began this process by conducting 4 focus groups at a community health center examining care for Latinos at the end of life. Two groups each encompassed a convenience sample of approximately 10 to 12 English-speaking Latinos, and 2 other groups each had approximately 10 to 12 Spanish-speaking Latinos. Focus group transcripts were analyzed using open coding qualitative analysis and identified key areas of need for palliative intervention, as well as core Latino values that informed all aspects of the study (*familia* [family], *personalismo* [the value of personal relationships], *confianza* [trust], and *fatalismo* [fatalism]). This pilot work also called attention to the need for further research to improve palliative care outcomes for Latinos with advanced cancer.

Apoyo con Cariño Participants

Our RCT recruited participants from 3 urban and 7 rural/mountain cancer centers from July 2012 to January 2016. Urban centers included a safety-net hospital, an academic NCI-designated Comprehensive Cancer Center, and a community cancer center; rural/mountain sites were all community cancer centers or clinics. Working with on-site clinical staff, we screened patients for study eligibility at the time of clinic appointment, chemotherapy infusion, or radiation visit. Patients were eligible if they were aged ≥ 18 years, self-identified as Latino, spoke either English or Spanish as a primary language, and had stage III or IV cancer; all cancer types were included. We excluded patients lacking decisional capacity. As hospice use was a study outcome, we excluded patients currently enrolled or being referred to hospice before study enrollment. We also excluded patients if they had been incarcerated or were pregnant. This study was approved by the Colorado Institutional Review Board and registered on ClinicalTrials.gov (NCT01695382).

Recruitment

Cancer clinic staff members (including nurses, physicians, social workers, and PNs) identified all po-

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Table 1. Overview of Strategies and Procedures Used to Address Known Barriers

Barrier	Procedures to Overcome Barrier
Mistrust	Community input on study processes and/or content Ongoing oversight of study by a community advisory panel Use community liaison (lay navigator, community health worker)
Language barriers/communication preferences	Translate all materials into Spanish using rigorous forward and back translation process Bilingual research personnel Ensure all materials are written at 5th/6th grade reading level Use teach/teach-back methods for difficult concepts (eg, randomization) Patient-centered/preferred communication methods (eg, texting vs phone call)
Lack of access to academic cancer center	Engage community cancer clinics, making frequent visits to build relationships Offer educational and financial compensation to community sites for trial participation
Inability to participate due to transportation, work responsibilities, childcare	Flexible location when possible for consenting, intervention, and follow-up visits (eg, home visits) Flexible timing for research visits (eg, nights or weekends when needed)

tentially eligible patients and asked if they would be willing to be contacted to participate in the study. Patients who were willing and agreed to be contacted signed a HIPAA form, and their contact information was then released to our study team. Bilingual, bicultural PNs contacted the potentially eligible patients and arranged for a consenting visit.

Intervention Overview: Briefly, patients randomized to the control group received a culturally tailored packet of written materials in the appropriate language (English or Spanish) covering advance care planning, pain management, and hospice care. Patients randomized to the intervention group received the same packet of written materials and 5 visits from the bicultural, bilingual lay PN focusing on these 3 palliative care domains. Visits took place mainly in the home during a 3-month period. Patients were surveyed at baseline and at 3 months with various quality of life, pain, and satisfaction measures. All instruments were translated into Spanish.

Patient Navigators: All of the PNs we hired had health-related backgrounds (eg, certified nurse assistant training, patient navigation, and research experience with a longitudinal diabetes study). They were hired through the University of Colorado system and participated in structured educational and training sessions. We ensured that all of the PNs underwent a 3-day patient navigator training and a 2-day motivational interview training through the Colorado Patient Navigator Training program.¹⁴ In addition, the PNs enrolled in the 2-day End-of-Life Nursing Education program offered by the Universi-

ty of Colorado nursing department, which reviewed advanced palliative care strategies, including pain and symptom management, psycho-social-spiritual-ethical content, and care for patients at the end-of-life.¹⁵ PNs also shadowed inpatient, outpatient, and home-based palliative care and hospice interdisciplinary team providers to observe their diverse roles and functioning, and received ongoing education on palliative care-related topics throughout the study period.

Specific Strategies Used for Accrual and Retention

Based on the focus group results, we identified key themes to incorporate in a palliative care intervention that included advance care planning, pain management, and hospice care. These domains were areas where we identified significant barriers, knowledge deficits, and persistent unmet needs (Table 1).

We then convened a community advisory panel of key stakeholders. This panel consisted of individuals with academic expertise in the content area, community leaders, and frontline community-based PNs. The advisory panel reviewed the findings of the focus groups and confirmed the intervention domains. The panel then selected, refined, or adapted written materials for the intervention.

Barrier #1: Mistrust: We worked closely with study sites to identify and hire the local on-site PN. Our study benefited from the local expertise and knowledge of the cancer center personnel who were highly motivated to work with the local on-site PN they

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helped identify. This helped build trust with the research sites and with the participants who viewed the PN as someone from their own community and culture. Navigators worked on the final refinements of the intervention to ensure their buy-in and ownership of the intervention manual to increase fidelity to the intervention. This process helped to build trust not only with study participants and their caregivers, but also with staff from the community sites.

Barrier #2: Language/Literacy and Communication: We followed a rigorous process for translating all the written study materials. In brief, all materials were translated into Spanish, then back-translated to English by certified translators. Any discrepancies were adjudicated within a group of 4 bilingual study personnel. Each of the PNs were bilingual and all research processes (recruitment, consent, intervention delivery, and follow-up data collection) and materials were provided in patient's preferred language: English or Spanish. In addition, the consent form included additional language that allowed for a teach/teach-back method to ensure comprehension (Figure 1). All of the educational study materials were written at a 5th/6th grade reading level (Flesch-Kincaid); used bold, bulleted points; and included pictures to illustrate points whenever possible.

The PNs were all bilingual. They grew up within the communities that they worked in and shared a similar upbringing and culture as the study participants. Furthermore, the navigators drew on the Latino value of *personalismo*—that a personal connection fosters trust and facilitates communication. Following the initial meeting, we built in flexibility within the research protocol for how to contact research participants. We found that some patients preferred telephone calls but many preferred text messaging. Text messaging has been shown to be a highly effective form of communication within the Latino community and can impact health behaviors and engagement in interventions.¹⁶ We found that relatively few patients

had access to computers, and e-mail was rarely used for communication. Rather than restricting the form and timing of communications, the PNs tailored the contact to individual patient preference and carefully tracked all patient contacts.

Barrier #3: Access to Academic Cancer Centers: By including a broad representation of healthcare sites, we were able to address the barrier to access to clinical trials among underserved populations. This included a large, academic NCI-designated Comprehensive Cancer Center, a community-based cancer center in an urban setting, the cancer center affiliated with the city/county safety-net healthcare system, and 7 sites in rural or mountain communities. This strategy increased the external validity of the study's potential findings, met our own comprehensive cancer center goals of rural outreach, and met rural and urban community cancer center goals of engaging in CCTs.

We continued to use community-based participatory action methodology to build rapport and develop and maintain engagement with nonacademic urban and rural sites. The principal investigator (PI) and co-investigator (Co-I) traveled for at least 3 to 4 site visits per year to each of the rural sites throughout the state. Although these site visits were time-consuming (some were located >5 hours from Denver), they demonstrated commitment to the sites, support to the on-site research navigator, and allowed for repeated opportunities to remind local cancer center staff about the study.

The PI and Co-I also offered each of the participating rural sites a 4-lecture series focused on topics related to palliative care. These educational sessions included continuing education credits for participants and were open to cancer center staff, medical staff affiliated with the hospital system, and the broader community. Based on feedback, we tailored lectures to local communities' unique requests and needs. PNs made visits to the sites at least every oth-

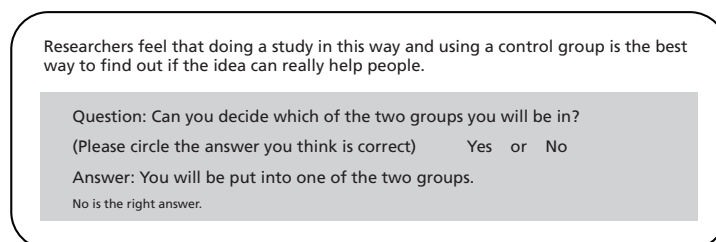


Figure 1. Sample from consent form.

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er week throughout the study period to continue to maintain rapport with cancer center staff.

Barrier #4: Inability to Participate due to Transportation, Work Responsibilities, Childcare: PNs recruited participants from cancer center clinical sites, but the informed consent process and intervention delivered occurred in the setting preferred by the study participant, with the vast majority in the patient's home. These meetings sometimes occurred in the evenings or on the weekend to accommodate a patient's work schedule or a caregiver's schedule. This eliminated common barriers to participating in research including transportation, childcare, and work responsibilities.¹²

Analysis

SAS version 9.4 (SAS Institute Inc., Cary, NC) was used for all quantitative analyses. For this manuscript, we used simple frequency statistics and means to describe the referral and enrollment rates and participant characteristics.

Results

Enrollment/Retention Results

We identified 318 adult Latinos who were potentially eligible for study participation. Of those, 8% (n=25) were found to be ineligible for the following reasons: incorrect staging, lived out of state, lacked capacity, or did not self-identify as Latino. We were unable to make initial contact with 3% (n=9) of those referred due to incorrect contact information or no returned calls to the PN. When approached by a clinic staff person who was known or familiar to the patient, all 284 (89%) agreed to be contacted by study staff.

We enrolled a total of 223 Latinos with stage III or IV cancer who were randomized to the control group (n=111) or the PN intervention visits (n=112) (Figure 2), representing a 79% enrollment rate. Enrollment was proportionately distributed across all study sites (Table 2) based on the number of eligible patients, with 36% enrolled from rural sites. Patients enrolled in the study all self-identified as Latino and 47.5% spoke Spanish as the primary language in the home. Most patients were underserved as evidenced by sociodemographic characteristics: 53.6% of participants had an annual income <\$15,000 USD and the majority (50.2%) had not completed a high school education. Most patients had stage IV dis-

ease (68.2%) and represented a wide variety of cancer types (Table 3). Of the 61 patients who declined to participate, the most common reasons cited were no interest in participating in research, did not feel like they needed additional help, did not have time, or caregivers preferred that they not participate in a study that focused on palliative care.

Participants completed follow-up surveys 3 months after enrollment, reporting on patient-centered outcomes of the trial. We projected that 186 patients would complete the 3-month follow-up, with 54 patients unable to follow-up due to drop-out, illness, or death. We found that 177 patients completed the 3-month follow-up, with 26 patients dying, 5 too ill to complete the follow-up surveys, and 8 drop-outs in the control arm and 7 in the intervention arm (Figure 2); this represents an 8% drop-out rate for the study.

Discussion

Our team was able to successfully identify and enroll eligible patients from geographically diverse areas across the state of Colorado from a wide variety of cancer care settings (academic center, safety-net clinic, community clinics) for this cancer-focused clinical trial. We considered and used strategies a priori to ensure successful enrollment, and we regularly reviewed and refined these strategies to continue to engage community sites and referring providers. Our team achieved a very high enrollment and

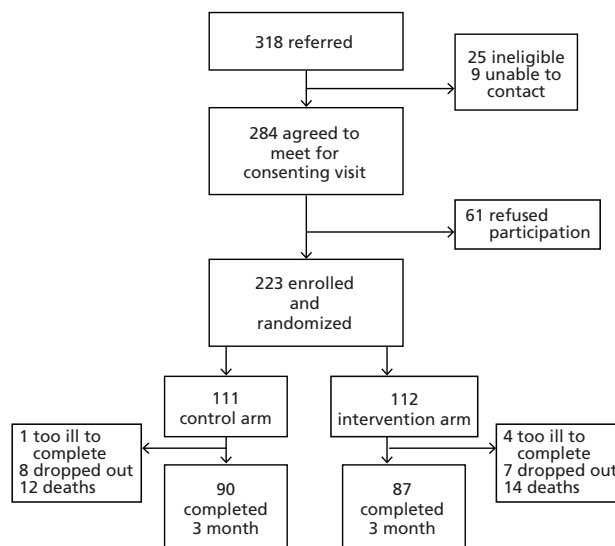


Figure 2. Accrual figure for Apoyo con Cariño.

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Table 2. Description of Study Site and Enrollment

Study Site	% Latino Ethnicity ^a	Referring Oncologists/Site (N)	Control (N)	Intervention (N)
Denver Health	48% ^b	3	25	26
University of Colorado Cancer Center	11% ^b	42	18	17
St. Joseph Hospital	30% ^b	5	8	8
San Luis Valley Regional Medical Center	46%	1	26	27
Rocky Mountain Cancer Centers - Pueblo	43%	1	4	4
VH Shaw Cancer Center	30%	1	4	4
VVH Calaway-Young Cancer Center	28%	2	9	10
St. Mary's Cancer Center	14%	3	16	16
Aspen Valley Hospital	10%	1	1	0

Abbreviations: VVH, Valley View Hospital; VH, Vail Health.

^aUnless otherwise specified, percentages reflect census data of the Latino population in the county in which the cancer center is located.

^bPercentages reported are reflective of the patient population at this cancer center.

retention rate representative of the most successful CCTs. The study enrollment rate was also considerably higher than most of the cancer-focused palliative care intervention trials, suggesting that the enrollment strategies, rather than the scope and nature of the intervention, impacted participation.^{17–19} The fact that our Latino patient population is historically underrepresented in CCTs is all the more remarkable. Further, the strategies and approaches we used allowed us to earn trust and engagement among a cohort of patients that had low education levels and were seriously ill with an advanced cancer, half of which did not speak English. In our study, we found that Latinos were willing to be involved in a clinical trial if simply asked by their providers.

The barriers we describe in this manuscript are well-recognized in the literature.^{12,20,21} In fact, review of existing literature helped our team anticipate common barriers and develop strategies to address them. For instance, the work of EMPaCT (Enhancing Minority Participation in Clinical Trials), a consortium of academic NCI-funded cancer centers that also have active National Institute on Minority Health and Health Disparities–funded programs, has helped define the scope of the problem.²² However, research suggests that few centers are equipped to recruit minority and/or non-English-speaking participants.^{23,24} EMPaCT offers a framework on how to increase minority participation in CCTs.²² However, at this time, the evidence base for the proven effectiveness of these strategies remains limited. Interestingly, the strategies with demonstrated results in recruiting and retaining minority participants have included the use of lay community people for outreach in the

form of PNs or community health advisors.^{25–27} Although the initial results of these methods are positive, in a position paper, EMPaCT leaders call for more research in this area.²² Our study makes a significant contribution to this limited evidence base on pragmatic and effective strategies to increase minority recruitment for CCTs.

The strategies we used for this clinical trial were time-consuming and added additional costs to the research implementation for frequent site visits to build rapport and trust with the community research sites. In addition, some of the recruitment sites had clinical staff turnover, including research site coordinators. Thus, we were in regular contact with clinical and research staff at the outlying rural sites, visiting, reorienting, and reminding them of our study and eligibility criteria. We also recognized and addressed the frequent barriers that may disproportionately affect minorities and underserved patients. For example, many of our subjects only spoke Spanish and wanted a family member to be with them during the consenting process. Patients often looked to the family caregiver for support during the consenting process to ensure they were in agreement with their participation in the study. Often, those family caregivers worked multiple jobs and long hours, and had children requiring care. We recruited and hired flexible bilingual PNs who were willing to work weekends and evenings to accommodate working family members and patients; we believe this increased our enrollment percentage.

The creative solutions we used can easily be translated to other therapeutic CCTs. First, it is crucial to have bilingual research coordinators or PNs to

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Table 3. Participant Characteristics

	Total, n (%) (N=223)	Intervention, n (%) (n=112)	Control, n (%) (n=111)	P Value
Age (mean ± SD), y	58.06±13.55	57.50±13.31	58.62±13.83	.54
Female sex	124 (55.6%)	59 (52.7%)	65 (58.6%)	.38
Married or domestic partner	129 (57.8%)	66 (58.9%)	63 (56.8%)	.74
Spanish primary language spoken in the home	106 (47.5%)	54 (48.2%)	52 (46.8%)	.84
Less than high school education	112 (50.2%)	56 (50.0%)	56 (50.5%)	.95
Annual income <\$15,000 USD	118 (53.6%)	64 (58.2%)	54 (49.1%)	.18
Not currently working	195 (88.2%)	96 (87.3%)	99 (89.2%)	.66
Payment				.23
Medicaid	84 (38.0%)	48 (43.2%)	36 (32.7%)	.11
Medicare (Parts A ± B)	56 (25.3%)	24 (21.6%)	32 (29.1%)	.20
Other	81 (36.7%)	39 (35.1%)	42 (38.2%)	.64
Stage IV disease	150 (68.2%)	79 (71.2%)	71 (65.1%)	.34
Cancer type				.75
Breast	43 (19.3%)	19 (17.0%)	24 (21.6%)	
Lung	20 (9.0%)	9 (8.0%)	11 (9.9%)	
Genitourinary	26 (11.7%)	13 (11.6%)	13 (11.7%)	
Gastrointestinal	75 (33.6%)	38 (33.9%)	37 (33.3%)	
Gynecologic	23 (10.3%)	11 (9.8%)	12 (10.8%)	
Hematologic	17 (7.6%)	9 (8.0%)	8 (7.2%)	
Other	19 (8.5%)	13 (11.6%)	6 (5.4%)	

Percentages may not total 100% due to rounding. There were <2% missing data. Intervention and control groups were compared using *t* tests for continuous variables, and chi-square tests for categorical variables.

interpret during the consent process, be available at subsequent infusion and follow-up visits, and call or text patients regularly to inquire about symptom and side-effect prevalence and management and ensure timely follow-up. Our PNs established trust and rapport; both are critical to continued participation in a clinical trial and may not be established with the use of phone interpreters. The consenting process often takes time ($\approx 2\text{--}3$ hours), especially if the patient speaks Spanish or has low literacy. We ensured that the bilingual PNs were fluent and comfortable with the consent form and measures, in English and Spanish, that were used in our research study. They practiced the consenting process in observed settings and were coached to address patient concerns. Patients often depend on family caregivers to be present and offer support at these visits with healthcare professional staff. If family caregivers are working, they often do not have adequate time to be with their loved one in the clinic; thus, offering weekend and evening consenting and infusion times may enable patients to participate in clinical trials.

Patient transportation and childcare are other significant barriers that need to be addressed. Patients often have difficulty finding transportation to the cancer center for treatment. They also care for children and grandchildren while their caregivers are working. Budgeting for patient transportation including Uber or Lyft vouchers and childcare assistance may support patient participation.

For researchers, building these needs into research budgets is critical to ensure successful recruitment of diverse and underserved minority populations into CCTs. The strategies we successfully used could also be standardized and incorporated into the Clinical Trials Office of cancer centers to promote diversity and minority representation across studies, allowing for additional cost- and resource-sharing. Finally, at a policy level, there have been recommendations for the NIH to include an evaluation of the recruitment plan as part of the scientific-merit scoring to ensure diverse representation in funded trials.⁷ Identifying likely barriers and describing planned evidence-based strategies to overcome the barriers would be an important step in addressing concerns

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regarding minority recruitment. Further pragmatic research is needed to identify and refine successful strategies for recruitment, enrollment, and retention of diverse populations.

Conclusions

This article details our specific approach and success in a tailored study designed to improve palliative care outcomes for Latinos with advanced cancer. Our intervention and our recruitment and enrollment strategies were all developed with direct input from the community. Although some aspects of our strategies are unique to our population, community, and intervention, many can be adapted and applied to other settings to improve the engagement and enrollment of underserved and minority patient participation in clinical trials. This was a time-consuming process, yet there are simply no shortcuts for the per-

sistence, rapport building, and commitment to build trusting relationships. Clinical research needs adequate funding to support these time-intensive strategies to ensure successful recruitment, enrollment, and retention of underserved persons and improve the ongoing disparities that persist in CCTs.

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