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Apoyo con Cariño: (Support with Caring): RCT Protocol to Improve Palliative Care Outcomes for Latinos with Advanced Medical Illness

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Abstract

Latinos are more likely to experience uncontrolled pain, and institutional death, and are less likely to engage in advance care planning. Efforts to increase access to palliative care must maximize primary palliative care and community based models to meet the ever-growing need in a culturally-sensitive and congruent manner. Patient navigator interventions are community-based, culturally-tailored models of care that have been successfully implemented to improve disease prevention, early diagnosis, and treatment. We have developed a patient navigation intervention to

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improve palliative care outcomes for seriously ill Latinos. We describe the protocol for a National Institute of Nursing Research-funded randomized controlled trial designed to determine the effectiveness of the manualized patient navigator intervention. We aim to enroll 240 Latino adults with non-cancer, advanced medical illness from both urban and rural clinical sites. Participants will be randomized to the intervention group (five palliative care patient navigator visits plus bilingual educational materials) or control group (usual care plus bilingual educational materials). Outcomes include quality of life (Functional Assessment of Chronic Illness Therapy), advance care planning (Advance Care Planning Engagement survey), pain (Brief Pain Inventory), symptom management (Edmonton Symptom Assessment Scale-revised), hospice utilization, and cost and utilization of healthcare resources. This culturally-tailored, evidence-based, theory-driven, innovative patient navigation intervention has significant potential to improve palliative care for Latinos, and facilitate health equity in palliative and end-of-life care.

Keywords

palliative care; patient navigation; underserved; advance care planning

Introduction

Minority patients suffer disproportionately at the end of life. While nationwide rates of completed advance directives (ADs) are low for all groups, Latinos are less likely to have a living will, medical durable power of attorney (MDPOA), or a Do Not Resuscitate (DNR) order (Carr, 2012; Hong, Yi, Johnson, & Adamek, 2017; Huang, Neuhaus, & Chiong, 2016; Rao, Anderson, Fin, & Laux, 2014; Smith et al., 2008). Latinos are also more likely to choose very aggressive care in the face of serious or incurable illness, and are less likely to acknowledge their terminally ill status (Barnato, Anthony, Skinner, Gallagher, & Fischer, 2009; Johnson, 2013; Kelley, Wenger, & Sarkisian, 2010; Smith et al., 2008). In the most recent study designed to examine these differences in a cohort of cancer patients, researchers found that only 40% of Latinos completed an AD compared with 80% of Caucasians (Smith et al., 2008).

Hospice services are rarely accessed by non-Caucasians (Carrion & Bullock, 2012; Evans & Ume, 2012; NHPCO, 2018; Payne, 2016). Minorities are more likely to die in the hospital, which has been shown to be associated with increased pain, decreased quality of life (QOL), and post-traumatic stress disorder, and with complicated grief for family members (Gaudio et al., 2013; Meghani, Polomano, Vallerand, Anderson, & Gallagher, 2012; Wright, 2010). Lower rates of hospice utilization by Latinos are associated with lack of knowledge about hospice, lack of health insurance, language barriers, low education levels, and lack of clarity about the hospice concept (O'Mara & Zborovskaya, 2016), as the word *hospicio* in Spanish means orphanage or asylum.

Ethnicity is also increasingly recognized as a predictor for poor pain assessment and management (American Geriatrics Society Panel 2009; Chiauzzi et al., 2011; Meghani et al., 2012; Tait & Chibnall, 2014) Barriers to adequate pain management have been identified at the patient level, institutional level, due to physician bias, and as a result of diverse cultural

beliefs (Brennan, Carr, & Cousins, 2007; Carrion & Bullock, 2012; Kwon, 2014; Ortiz, Carr, & Dikareva, 2014).

Palliative care focuses on symptom management and quality of life (QOL), and it helps patients with life-limiting illness match goals and preferences for care. In a randomized controlled trial (RCT) of a palliative care intervention, Temel et al. (2010) demonstrated that patients with advanced lung cancer who received palliative care had better QOL, less depression, and longer survival. Yet, this tertiary or specialty level palliative care cannot grow fast enough to meet the demand (Quill & Abernethy, 2013).

Models of care that promote primary palliative care are required to increase capacity for the ever-growing needs, especially in poor urban and rural settings, where tertiary palliative care is often non-existent (Bakitas et al., 2015; Ewald, Marr, & van de Mortel, 2018; Robinson et al., 2009). Furthermore, although the evidence base for the benefits of palliative care has grown, minority patients are consistently under-represented in these trials (Chochinov et al., 2011; Kutner et al., 2008; Temel et al., 2010; Wilkie & Ezenwa, 2012). This fact alone raises the concern that the quality gap in palliative care outcomes may grow (Johnson, 2013). Cultural and linguistic barriers may also increase disparities in palliative care for Latinos (Evans & Ume, 2012).

In this study protocol we describe ongoing research to test the effectiveness of a reproducible, scalable patient navigation (PN) intervention to improve palliative care outcomes. This research is significant because persons at the end of life continue to experience substantial unmet palliative care needs, particularly in non-cancer and underserved populations (Institute of Medicine, 2015). Furthermore, from the beginning, we have designed the intervention to be easily amenable to future dissemination and implementation by training and leveraging existing PN networks throughout the United States. This research is also noteworthy because it focuses on reducing health disparities in urban and rural underserved communities. Disparities researchers increasingly demonstrate the value of working outside clinic walls to improve care for minority patients (Clarke et al., 2013).

This study is an RCT of a culturally tailored PN intervention to improve palliative care outcomes for seriously ill Latinos and their family caregivers. We propose to determine the effectiveness of the PN intervention. We hypothesize that participants randomized to the intervention group (PN and bilingual educational materials consisting of information on advance care planning [ACP], pain and symptom management, and hospice care) will have a more palliative approach to their care that includes improved QOL (primary outcome) and higher ACP rates, better pain and symptom control, and higher rates of hospice utilization (secondary outcomes) compared to the control group (usual care plus bilingual educational materials). Family caregivers in the intervention arm will have decreased caregiver burden and greater satisfaction with care.

We also aim to conduct a cost analysis of the PN intervention by analyzing direct costs of the intervention and cost and utilization of health care resources for all participants. We hypothesize that participants randomized to the intervention will have lower costs in the 6

months following study enrollment compared to participants in the control arm and that participants randomized to the intervention who die during the study period will have lower costs in the last 3 months of life compared to participants in the control arm who die.

This study is registered with ClinicalTrials.gov () and is approved by the Colorado Multiple Institutional Review Board (COMIRB) and appropriate IRBs at study sites. A Data Safety and Monitoring committee oversees recruitment, enrollment, and data collection and management as well as any adverse events. Subject recruitment and data collection are currently underway.

Methods

Participants and Sites

We aim to recruit a total of 240 adult (18–98 years of age) Latino participants who meet eligibility criteria. Adults must self-identify as Latino and have a serious illness defined by meeting at least one of the CARING criteria (Fischer, Gozansky, Sauaia, Kutner, & Kramer, 2006) or having a provider answer “NO” to the surprise question. These are detailed in Table 1. Patients may also identify and invite a patient-defined family caregiver (we aim to enroll 120 family caregivers), although the presence and participation of the family caregiver is not required for study enrollment. Caregivers must be at least 18 years of age and have capacity to consent. Participants are actively being recruited from five sites affiliated with an academic medical center and five community sites. Sites encompass a wide geographic distribution across Colorado representing urban and rural populations.

Recruitment Strategies

At each clinical site we identified a healthcare provider (e.g. nurse, physician, clinical trials coordinator, or medical assistant) who is the study’s onsite coordinator. The research team works with this healthcare provider or directly screens electronic health records (EHR) to identify potentially eligible patients for this study. The COMIRB has granted a HIPAA waiver to allow for this screening of potentially eligible patients.

Two recruitment methods are employed. First, a recruitment letter, signed by the patient’s provider inviting the patient to participate, is mailed through the U.S. Postal Service (USPS). If the patient prefers not to be contacted by a study team member, she or he can opt out by calling the study team. Ten days later, if the patient has not opted out, a study team member contacts the patient either in person or by telephone, with an invitation to participate. Additionally, the study team member presents patients with the option of inviting their family caregiver to participate. The second recruitment method is more direct. Patients are approached at the clinic site by the healthcare provider who has a treating relationship with them. A simple script has been developed to assist the provider in presenting consistent information about the study to the potential subject. Patients who wish to learn more about the study, sign a HIPAA A form providing name and contact information (telephone number and address) to the onsite coordinator who passes this information to the study team member in a confidential manner.

Consent Process

If the patient meets eligibility criteria, is interested in learning more about the study, and agrees to be contacted by the study team member, an informational session and potential consenting visit is scheduled in the patient's preferred location. Patients and family caregivers must provide informed consent separately and in writing. The PNs have been extensively trained in the consenting process with specific training directed towards working with patients with both low health literacy and low literacy in general. The PNs read and summarize each section of the consent form, assessing comprehension as well as willingness to consent. In addition, the consent form includes additional language that enables teach-teach back methods to ensure comprehension (Figure 1). At the time of enrollment, all participants are provided a packet of written educational materials covering the three domains (ACP, pain and symptom management, and hospice) in the appropriate language (Spanish and English).

Baseline Assessment

Before randomization, study participants (patient and family caregivers) complete baseline measures that include sociodemographic items, the FACIT (Webster, Cella, & Yost, 2003) (QOL primary outcome measure), the Brief Pain Inventory Short Form (BPI-SF) (Cleeland, 1989), the Edmonton Symptom Assessment Scale-revised (ESAS-r) (Watanabe et al., 2011), and the ACP Engagement Survey (Sudore et al., 2013). Family caregivers complete the Caregiver Reaction Assessment (Given et al., 1992) at baseline and at three months follow up. Based on initial feedback from patients to navigators, the protocol was changed to provide a $25 grocery gift card to compensate for their time after completion of the baseline surveys. The study team also reviews EHRs for detailed data on diagnoses and co-morbidities, list of current medications and dosages, and presence (and type, if applicable) of an ACP document in the EHR.

Randomization

Patients are randomized using blocked randomization (random permuted blocks) for assignment to intervention or control group within each clinic site to avoid serious imbalance in the number of subjects between the two groups throughout the study period. The block size is randomly varied between 2, 4, and 6 to preserve the randomization scheme. The patient's primary PN is the only study team member that is unblinded to the study group allocation.

Intervention

After the initial contact for the enrollment and consent process, the PN schedules the first study visit. The intervention was developed based on qualitative research and the advice and guidance of a community advisory panel; the palliative care focused content is grounded in core Latino values. The function of the initial visit is to establish trust (core value: *confianza*) and ensure a more personal approach (core value: *personalismo*) with the participants. In addition, if the patient's family caregiver has also consented to participate in the study she or he is asked to be present at this initial visit to provide more of an

opportunity for the PN to establish a relationship with the caregiver (*familia*) as well. These core Latino values ground the intervention starting at the most preliminary stage.

Visit content overview.—The PN arranges to meet the participants (and family caregiver, if consented) at the home or another location if the participant prefers. At the first visit, the PN provides and reviews the educational materials that cover the target domains (selected by the community advisory panel based on the preliminary qualitative work) with the participant and family caregiver. Additionally, during that visit, the PN works with the participant and family caregiver to create a plan for subsequent visits based on the participant's and family's needs and acceptance of palliative care. A framework of the target domains and the planned intervention by visit is described in Table 2. Because participants are at various points in their illness trajectory and participants and family caregivers differ in their acceptance and readiness to address each of the domains, the PN visits vary in both the content and activities covered during each visit as well in number. Nevertheless, all intervention content is covered with each participant and family caregiver during the course of their study participation. The plan is customized to the needs of each participant. For example, a visit may include accompanying the patient to a specialty or primary care appointment. All educational materials and the visit scripts are available from the investigators upon request.

Based on data from previous studies, at least five navigator-initiated PN intervention visits are planned. We found in our feasibility study that further time investments were unlikely to yield improved outcomes (Fischer, Cervantes, Fink, & Kutner, 2015).

The PN continues to be available to the participants on a non-urgent basis as needed throughout the study period. In keeping with the patient-centered approach that grounds both patient navigation and palliative care, the PNs are always responsive to patient or caregiver needs. There will not be a specified limit to the number of additional patient or family caregiver-initiated visits.

PN training and qualifications.—This intervention uses lay PNs with a community health worker background (i.e. not social workers or nurse navigators). Training of the PNs was developed in our pilot RCT and manualized in the recently completed cancer-focused trial (Fischer et al., 2015; Fischer, Kline, Min, Okuyama, & Fink, 2017) The PNs are bicultural and bilingual lay members of the community. All PNs are embedded members of their own participating and remote community site.

The training plan balances the cost and burden of in-person training with the need to ensure fidelity and adherence to the prescribed intervention. Mandatory training for all PNs includes the Colorado Patient Navigator Training (www.patientnavigatortraining.org) motivational interviewing course and two one-hour webinars adapted from the curriculum (http://bioethics.northwestern.edu/programs/epec/docs/TrainerGuide2010.pdf) developed by Dr. Joshua Hauser (with Livestrong Foundation support) entitled "Navigating the System." The PNs also complete the two-day End-of-Life Nursing Education Consortium course (http://www.aacnnursing.org/ELNEC) providing them with foundational knowledge of core palliative care elements. In addition, the PNs complete the IRB-required CITI coursework.

The PI (SF) and Co-I (RF) provide formal training regarding each of the five scripted navigator visits and the role of the PN in addressing barriers to care utilizing core Latino values. PNs independently study and learn the visit guides and tool-box language to communicate about palliative care domains to participants. Using video technologies (e.g. Skype or FaceTime©), the PNs work with the Project Manager (DK) to practice the visit guides using a series of standardized "patient" role playing exercises. PNs must demonstrate proficiency with the enrollment process and each visit guide before entering the field to navigate. Final proficiency is determined by the PI (SF) and Co-I (RF).

Follow up data collection.—Study personnel, who are blinded to randomization allocation, conduct the three-month follow up interview with participants by phone. On completion of the FACIT, BPI-SF, ESAS-r, ACP Engagement survey, and an investigator developed Patient Navigation Process and Outcome Measure (PNPOM), the interviewer asks participants if they were in the intervention group (i.e. had PN visits). Detailed description of the outcomes assessment and timing is provided in Table 3. Only intervention participants complete additional questions about their satisfaction with the PN, the number and frequency of visits, and have the opportunity to suggest additional feedback about the PN intervention visits. Upon completion of the three-month follow up surveys, participants in both groups receive a $50 grocery gift card to compensate for their time.

EHR assessment.—Blinded study team members, review EHRs at baseline, 6 months, and at the time of the patient's death or study completion (month 46) for detailed data on medical diagnoses and treatment, a list of current medications and dosages, and presence (and type, if applicable) of an ACP document. Patient follow-up data (date of death, place of death, use of hospice, etc.) are also requested from the All Payer Claims Database managed and overseen by the Center for Improving Value in Health Care (CIVHC) (http://www.civhc.org/).

Fidelity to the intervention.—Using a standardized electronic form (REDCap) (https://www.project-redcap.org/), the PN records the duration of each visit and who was present. Each PN also records how each domain was addressed during the visit and documents detailed field notes of what occurred during the visit and how participants responded to the discussions and activities. The PN tracks phone calls made to the participant or caregiver and logs each visit in the tracking chart to provide an accurate count of the total number of visits per participant. Careful tracking of the "dose" of intervention each participant receives facilitates a dose-response analysis. If participants refuse visits, the PN attempts to contact the participant or family caregiver to understand the reason for no longer wishing to continue with the program. The reason for drop-out is recorded in the study tracking chart.

The PN aims to audio-record 10% of their home visits, and the study team reviews the tapes using a fidelity checklist to evaluate if each domain was addressed and if the core Latino values were utilized in the discussion. This detailed study tracking allows the team to demonstrate fidelity to the intervention for each participant. This level of documentation has been identified as necessary to provide rigor and increase reproducibility (Wells et al., 2008). Audio files are permanently destroyed.

Analysis

For continuous outcome measures derived from participant interviews (FACIT, PNPOM, BPI-SF, Caregiver Reaction Assessment, ACP Engagement Survey, and ESAS-r), differences between baseline and 3 month measurements will be examined *within* each group using paired t-tests. Then pre-to post-test differences will be compared *between* groups using t-tests. The arithmetic mean of the four severity items in the BPI-SF will be used as a measure of pain intensity. The arithmetic mean of the seven interference items will be used as a measure of pain interference with functional status. The arithmetic mean of the nine symptom ratings in the ESAS will be used as a measure of symptom severity. Hospice utilization in days of hospice enrollment will be compared using t-tests (or Wilcoxon tests, if skewed). For the dichotomous outcome measures (presence of an AD in the EHR and aggressiveness of end-of-life care), chi-square tests will be used to test the intervention's effect on the outcome.

Refusal rates, withdrawals, and missing data.—De-identified demographic data (gender, age, medical diagnosis category) are collected on potential participants who refuse to participate to assess the extent to which study participants differ from study decliners. Participants wishing to withdraw are asked for continued consent to review their EHRs and remain in the database for analysis (for outcomes of AD completion and hospice utilization) as randomized (intent-to-treat analysis). If participants withdraw from the study and do not provide consent to perform the EHR review, outcome variables are not available for those subjects and it will not be possible to do a traditional intent-to-treat analysis. Therefore, the statistician (SM) will conduct a sensitivity analysis, assuming all possible scenarios, if the participant withdrawal rate is >5% or there is differential withdrawal from the study groups.

Multiple steps are taken to minimize missing data. Appropriate imputations or likelihood inference (based on ignorable missing-data mechanism when data are missing at random) will be used to address any severe missing data concerns. Sample size has been calculated to ensure adequate power for outcome analysis accounting for the expected high mortality rates (~20% at three months) of the study population.

Statistical power.—This study is powered based on effectiveness within the patient population rather than the family caregiver population. A target sample size of 240 patient participants (120 patients in each group) provides ample power to detect statistically and clinically significant differences between the two groups. For improvement from baseline to three months in the primary outcome, QOL, 186 patients (conservative estimate based on preliminary data that 20% will be lost to death and drop-out) provides > 80% power to detect a medium effect size (f=0.21 from a mean difference of 0.42 SD between groups) for a two-sided test comparing two means at a Type I error rate of 0.05.

Cost analysis.—The difference in costs between intervention and control groups is the cost saving (direct medical expenditures) of intervention. Changes in direct medical expenditures are estimated as the sum of cost savings assessed every three months following enrollment and end-of-life cost savings for decedents. Adjusted analysis will be employed to examine medical utilization of patients in intervention and control groups including but not

limited to outpatient visits, length of inpatient stay, hospice utilization, number of Emergency Department visits, and medical procedures (e.g. dialysis, mechanical ventilation, surgery). All utilization measures are count variables, thus we will use negative binomial regression controlling for intervention group, age, gender, insurance coverage type, and co-morbidity burden. Overall medical costs will be compared between intervention and control groups. To deal with skewedness of cost variables we will use generalized linear model regression with log link and Gamma family distribution controlling for intervention group, age, gender, insurance coverage type and chronic condition index.

Reduced pain and improved QOL.—Given the short survival time of study cohorts, the usual cost-utility analysis is not feasible for this study. However, we still can estimate the monetary benefits of improved QOL. The traditionally accepted cost-effectiveness threshold of an intervention in the United States is $50,000/Quality Adjusted Life Year (QALY) (Neumann, Cohen, & Weinstein, 2014). With an expected 0.05 improvement of QOL and on average one year expected survival after the intervention, the QALYs of intervention will also equal to 0.05. Applying the $50,000/QALY threshold, 0.05 QALYs translates into $2,500 monetary benefit. Thus, the final cost-benefit analysis comparing the intervention and control groups will account for direct health care cost differences as well as monetary benefit due to QOL differences.

Discussion

As with any clinical trial, we face many challenges to implementing the protocol we describe above. First and foremost is the issue of recruitment. We demonstrated in our previous work that our team has successfully developed and utilized culturally acceptable strategies to recruit and retain a diverse and seriously ill underserved population (Fischer et al., 2017). In our previous study, we found that sites had overestimated, by 75%, the number of patients they projected they would have meeting eligibility criteria. We also learned that provider-only based referrals were very time consuming for our lay PNs who often travelled long distances to check in at referring sites. In our current trial, we have attempted to address these challenges through the use of querying EHRs to identify potentially eligible patients. This solved the “pipeline” problem, and we have identified sufficient numbers of potentially eligible patients to meet our referral estimates. However, to recruit patients, several other steps are in place and required by the IRB. First, we contact providers through email messaging to inform them that one of their patients is eligible for our study. Providers have to approve the study referral before we can proceed with the referral of the eligible patient. Initially we experienced a very low response rate from providers. However, after switching from an email request to a request within the EHR messaging, the response rate from providers has risen from 48% to 73%, with few providers refusing (<5).

Another difference in our current trial is that patients are first informed about the study through a brief letter (sent by USPS mail in both English and Spanish). The letter allows patients who do not want to participate or to be contacted the opportunity to “opt out” either proactively or when the navigator contacts them directly to invite them to participate. Although we have only had two patients directly call us to opt out, the PNs have found it extremely challenging to reach the patients by phone following the letter mailing. Patients

rarely answer the phone and do not return calls. This may be due to the importance of personal connection or the cultural value *personalismo.* We have learned that face-to-face connection is very important for patients. They prefer to meet navigators and hear about the study in person at an appointment rather than over the phone. Thus, our navigators meet patients at their next scheduled appointment.

A common concern with this study and other palliative care intervention research is the question of what is in the "palliative care syringe" (Smith, 2013). In fact, for any behavioral intervention, questions of reproducibility and fidelity to the intervention figure prominently in evaluating its impact. The gold standard for fidelity would be to record every navigator visit and randomly review a sample of the recordings for fidelity to the visit guides. We found in our previous research (Fischer et al., 2017) that patients were rarely comfortable with conversations being recorded and sometimes refused. Furthermore, PNs reported that asking patients to record these conversations undermined the rapport and trust they were building. Therefore, to address fidelity while honoring the patient-centered nature of the intervention, we have manualized the intervention delivery. While it is not mandatory to record visits, PNs do ask patients if they would volunteer to have their visit recorded for fidelity purposes. In addition to receiving the navigator training focused on palliative care content and communication strategies, PNs participate in extensive role playing for each visit before they start seeing patients, following the visit guides.

The PNs also document field notes after each visit. The field notes template includes a brief checklist that was developed based on our previous trial's detailed qualitative analysis of over 500 field notes. PNs use the checklist to confirm that critical items were addressed during the visit, and the narrative portion is designed to help PN capture the psycho-social-spiritual-ethics aspects of the interaction. This approach can be used later in implementation studies to ensure reproducibility of the results.

A final concern is the timing of patient referral. Currently, we are trying to capture patients who may be appropriate for a palliative approach further "upstream" in the illness experience trajectory. To ensure we are enrolling a sample that is appropriate for palliative care, we are using a validated screening method, the surprise question and the CARING criteria (Fischer et al., 2006; Moss et al., 2008; Moss et al., 2010; Murray & Boyd, 2011; Youngwerth, Fischer, Min, & Kutner, 2011). This will allow us to identify patients with a wide spectrum of advanced non-cancer medical illness who are appropriate for palliative care yet who still have an expected survival in months (Moss et al., 2008; Moss et al., 2010; Murray & Boyd, 2011; Weissman & Meier, 2011). We acknowledge, based on existing evidence, that disease management and survival vary widely across participants who are likely to have symptom needs appropriate for our intervention (Bekelman et al., 2007; Lynn et al., 1997; Murtagh, Addington-Hall, & Higginson, 2007). Loss to follow-up is minimized through the development of a trusting relationship with the PNs. If death is expected, immigrant patients may return home to their country of origin for their final days. However, based on our experiences to date, these plans are shared with the PNs and measures can be collected before travel. Additionally, there are outcome measures across the three domains that rely solely on secondary data sources rather than participant self-report.

Conclusions

Study implementation is underway. We anticipate recruitment will be completed in March 2020, allowing for completion of the intervention delivery and follow up period by September 2020. Patient navigation is an innovative model for addressing palliative care needs. Our aim for this protocol is to demonstrate that a culturally-tailored PN intervention is an effective way to improve palliative care outcomes for Latinos with non-cancer, advanced medical illness. By conducting this trial in the real-world setting of multiple diverse communities and healthcare systems, we can demonstrate effectiveness and generalizability. Once we establish the effectiveness of the PN model for palliative care for all types of advanced medical illness (cancer and non-cancer), we will disseminate and implement this intervention and training in established PN networks across the country for those who work with Latinos in both urban and rural settings. Then, for those patients whose disease does progress despite early diagnostic and intervention efforts, a navigator they know and trust can continue to follow them, provide support, and help to reduce barriers to quality palliative care.

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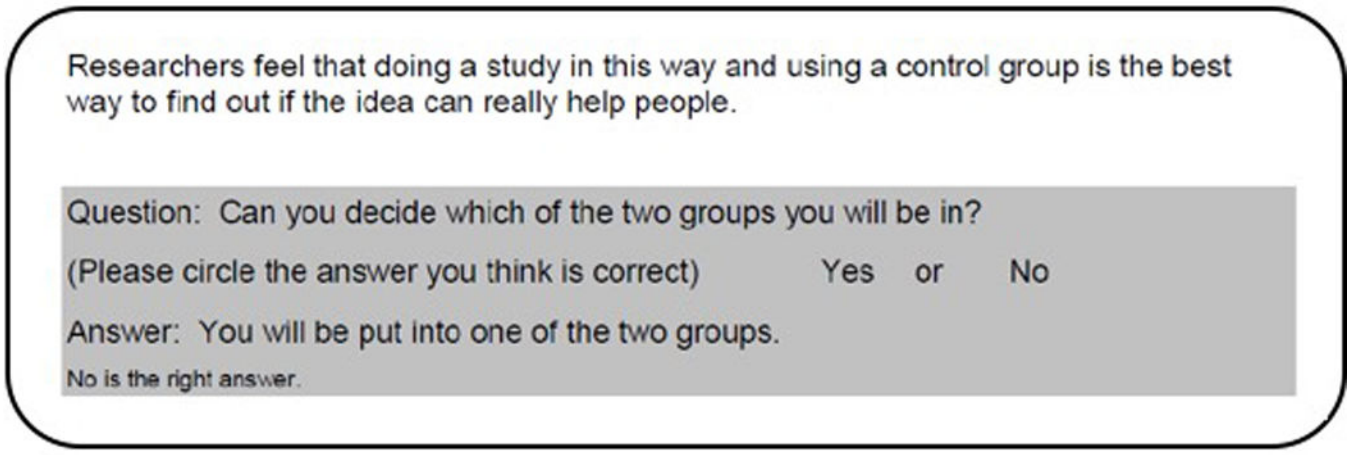

Figure 1.
Sample from consent from

Table 1.

Study inclusion criteria

Self-identify as Latino		
Age between 18 and 90 years		
Advanced medical illness as defined by meeting one of the following two criteria:		
Meeting at least one of the CARING (Fischer et al., 2006) criteria (excluding a primary diagnosis of cancer, a primary diagnosis of cancer excludes patients from this trial): • Admitted to the hospital ≥ 2 times in the past year for a chronic illness • Resident in a nursing home (long term care facility or admitted directly from a subacute nursing facility back to the hospital) • ICU admission with at least two organ systems involved in multi-organ failure • Meeting at least 2 items within any disease category of the National Hospice and Palliative Care Organization Non-Cancer Hospice Guidelines: renal disease, liver disease, cardiac disease, pulmonary disease, stroke, HIV/AIDS, neuromuscular disease	**OR**	Patient's primary or specialty care provider answers "no" to the following question: "Would you be surprised if this patient died within the next year?"
Participants must be able to provide informed consent		
Speak either English or Spanish as a primary language		

Table 2.

Intervention domains and related outcome measures

Domain	Intervention approach	Outcome measures
Overall palliative approach	• Utilize core values in all messaging (cultural tailoring) • Importance of family (*familia or familism*) • Personal Connections based on trust (*confianza*) • Value/build strong interpersonal connections (*personalismo*)	FACT-G PNPOM Aggressive care at the very end of life
Advance care planning (ACP)	• Review educational materials about advance directives (AD) • Leave a blank copy of AD with participant • Help patient complete a goals/values history • Help participant complete an AD • Reinforce benefits and limitations of ACP • Ensure AD reaches medical record • Review AD documents	ACP Engagement survey AD documentation in EHR
Pain and symptom management	• Review educational materials about pain and symptom assessment and management; discuss participant's current symptom level • Discuss strategy to talk about pain and symptom related issues with primary care provider • Facilitate achieving adequate pain and symptom control by empowering participant through role playing • Explore and help resolve barriers and problems with pain and symptom management • Review current pain and symptom management plan; explore and help resolve barriers	BPI ESAS-r
Hospice utilization	• Review educational materials about palliative care and general goals of hospice care • Discuss goals and values history with participant • Start working on a plan for palliative care that incorporates values and goals of participant • Review plan for palliative care • Referral if appropriate and requested by participant	Hospice utilization: • Enrollment • Length of Stay

Table 3.

Study outcome measures

Patient Outcome Measure	Measure description	Time of blinded data collection		
		Baseline	3 months	6 months
FACT-G	• A quality of life assessment • Demonstrated reliability, validity, and sensitivity to change (Cronbach's alpha consistently > 0.75) • Difference of 3–7 points on the overall score is considered to be clinically meaningful	X	X	
PNPOM	• Research team developed survey • Evaluates the extent to which the process of the essential elements of the navigator intervention relates to the outcomes • Used in our team's previous palliative care focused PN studies	X	X	
ACP Engagement Survey	• Process Measures and Action Measures related to advance care planning • Measure has good internal consistency (Process Measures Cronbach's alpha, 0.94) and test-retest reliability (Process Measures intraclass correlation, 0.70; Action Measures, 0.87) and good discriminate validity	X	X	
BPI	• 32-item self-report survey instrument • Reliable and validated in English and Spanish (Cronbach's alpha ranging from 0.77–0.91)	X	X	
ESAS-r	• 9 symptoms (e.g., fatigue) rated from 0 ("no fatigue") to 10 ("worse possible fatigue") on a numeric rating scale • Valid and reliable self-report measure of symptom severity (Cronbach's alpha = 0.75)	X	X	
AD documentation in EHR	• EHR review to determine the presence of any form of AD (MDPOA, the Apoyo AD form, other forms, living will)	X		X
Aggressive care at the very end of life	• Composite measure collected at time of participant death • No hospice referral, hospice less than 3 days, or death in hospital. • Used in the most rigorous RCT of palliative care published to date	At time of participant death		
Hospice utilization: • Enrollment • Length of Stay	• Research team has developed and validated processes to collect these data to ensure complete and accurate information • Data collection includes interviews, hospice provider data, and public death records	Every 3 months until participant death or study data collection completion (month 46)		
Caregiver Outcome Measure				
Caregiver Reaction Assessment	• 24-item survey that focuses on specific positive and negative aspects of caregiving • Cronbach's alpha ranges from 0.62–0.83 with good construct validity	X	X	