Empowering Latina breast cancer patients to make informed decisions about clinical trials: a pilot study

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Abstract

Minority representation in clinical trials is vital for researchers to assess differential effects in outcomes of therapies on biological and genetic characteristics among groups. This study assessed the effect of Choices, a bilingual multi-component intervention, on perceived understanding of clinical trials, agreement with stages of decision readiness and consideration of clinical trials as a treatment option, among Latina breast cancer patients. This randomized controlled pilot study compared Choices with a control condition providing general clinical trial information to eligible patients. Seventy-seven Latina breast cancer patients were randomly assigned to either Choices ($n = 38$) or the control ($n = 39$). Choices included three components: an educational interactive video, a low-literacy booklet, and care coordination by patient navigation (i.e., educational and psychosocial support, coordinating appointments, translating, interacting with the medical team). Choices was more effective than the control in improving perceived understanding of clinical trials ($p = .033$) and increasing consideration of clinical trials as a treatment option ($p = .008$). Additionally, intervention participants showed significant changes between baseline and post-intervention on agreement with stages of decision readiness statements ($p < .002$) than control participants ($p > .05$); the percentage of intervention women in agreement with preparation to action statements increased from 52.8% at baseline to 86.1% at post-intervention, and those in agreement with ready to action stages rose from 50.0% to 88.9%. Computer-based videos and care coordination provided by patient navigation—specifically tailored to Latinos—are effective strategies to successfully address awareness, and improved decision-making skills to make informed decisions about clinical trial participation.

Keywords

Latinas, Clinical trials, Decision aids, Tailoring, Video, Coordinated care

INTRODUCTION

Knowledge gained through cancer clinical trials has proven critical to preventing, diagnosing, and treating the disease and provide the evidence base for clinical practice [1]. Major advances in cancer treatment, which are essential for improving patients' outcomes, come from investigations of new therapeutic agents in clinical trials. Despite the large number of available studies and improvements in public awareness about clinical trials [2], less than one in 20 adult patients enroll in cancer clinical trials [1–7]. In particular, recruitment of

Implications

Practice: Healthcare providers should implement strategies to provide decisional support on clinical trial participation using online videos and care coordination by patient navigation to improve patients' decision-making skills and attitudes toward trials, reduce common participation barriers, and increase trial accrual and retention while facilitating the provision of coordinated patient-centered care.

Policy: Policymakers should ensure that all population groups benefit from scientific advances in therapeutic agents for cancer by promoting the implementation of strategies proven effective in reducing barriers to enrollment and retention in clinical trials among underrepresented groups.

Research: Large-scale trials focused on multiple cancer types should assess whether culturally tailored online videos and care coordination by a patient navigator can effectively address the multiple factors and barriers influencing patient decision making regarding clinical trials and improve positive attitudes toward clinical trials participation among specific groups with low participation in clinical research.

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certain patients—minorities, socioeconomically disadvantaged and older patients—has not increased as expected over several decades, with only 2.2% of Latinos participating in cancer treatment trials [8, 9]. In contrast, research demonstrates that minority patients, including Latinos, are as willing to participate in clinical research as non-Hispanic whites [10], indicating that a lack of awareness and other key barriers are keeping these patients from participating. This highlights the need for tailored interventions to improve their participation in clinical research [Barriers to participation of minorities in clinical trials are complex and multifactorial, including study design (i.e., protocol length and complexity and patient exclusion criteria), healthcare system barriers (i.e., lack of cultural competence among staff and lack of minority staff), medical team-related

factors (i.e., lack of referrals and misconceptions about patients' compliance), and patient-related factors [13–21].

Some of the most frequently cited patient-related barriers to clinical trial participation include lack of awareness of available clinical trials, lack of knowledge about disease and treatment options, lack of understanding about the trial process (i.e., randomization), and treatment preference (i.e., preference for standard vs. experimental trial treatment and dislike of treatment assignment by random allocation) [13, 14, 16, 19, 20, 22–24]. Attitudinal barriers (i.e., fear of unknown reactions and side effects, the possibility of sacrificing quality of life, fear of being a guinea pig, and feelings of lost control) [13–16, 19, 20, 23, 25, 26] also may deter patients from considering a clinical trial as a treatment option for cancer. In addition, practical barriers, such as lack of transportation, lack of health insurance, financial constraints, lack of family support, cultural and language barriers as well as study design barriers (i.e., trial duration and high frequency of office visits), and others, have been found to deter patients from considering participation in clinical research [13, 14, 16, 17, 20, 22, 23, 25].

Most cancer patients experience higher levels of anxiety, depression, and feelings of loss of personal control when facing a life-threatening disease such as cancer [27–30]. Patients are given a lot of information regarding treatment options that can be quite complex, but is necessary to understand and process before making an informed decision regarding a course of treatment. In addition, the nature of the cancer care system involving multiple specialties, providers, and locations produces fragmentation and represents a challenge for the coordination of care for patients who frequently get lost in the system [31].

To address low participation rates in clinical trials among minorities, the National Cancer Institute and the American Society of Clinical Oncology Clinical Trial Symposium recommended a combination of approaches and tailored interventions involving culturally sensitive decision aids, educational tools, and strategies to address the multiple barriers to participation that cancer patients face and the factors that influence patient decision making (i.e., patient navigators, videos, and websites) [32].

Interventions providing decisional support, such as educational videos, and patient navigation for patients addressing common barriers and facilitating the provision of coordinated patient-centered care, have been effective in improving positive attitudes toward clinical trials, accrual, and retention [1, 32–38] and may be the feasible strategies to address low participation rates among Latinos. These strategies should be considered good practice, and be aimed at all patients, regardless of race or ethnicity, to improve minority and general participation rates in clinical research.

Patient navigation, a recognized care coordination strategy, for example, has proven effective in supporting timely access to cancer care to minority patients including Latinas, addressing specific barriers, and facilitating quality of care; care coordination by patient navigation has shown to have multiple benefits to the medical team, patients, and their families [39–44]. A systematic review on the subject found low rates of refusal to participate in clinical trials among minority patients receiving patient navigation services, with several studies reporting increased clinical trial enrollment due to patient navigation [33–35, 45–47].

In addition, several studies have effectively used educational videos and patient navigation as decision aids to increase patients' intent to enroll and enrollment into cancer clinical trials. A large randomized trial conducted by Meropol and colleagues found that, compared with the control group, patients assigned to an educational intervention with a video library addressing common barriers showed significantly greater increase in knowledge ($p < .001$), greater decrease in attitudinal barriers ($p < .001$), and a trend toward greater preparedness to consider clinical trial participation ($p < .09$) [1]. A study by Du et al. found that, among 126 patients with lung cancer who had not previously participated in a clinical trial, an educational video intervention was significantly associated with patients' self-assessed likelihood to enroll measured at 2-week follow-up ($p = .019$) [21]. In a similar study using a culturally sensitive video intervention aimed at African-American cancer patients, the intervention was effective in increasing patients' likelihood of enrolling in a therapeutic cancer clinical trial ($p < .001$) [38]. A recent prospective cohort study conducted by Cartmell and colleagues assessed the effect of an intervention involving patient navigation and an educational video on clinical trial participation among patients with lung and esophageal cancer. Results showed that navigated patients' clinical trial understanding significantly improved between pre-intervention and post-intervention ($p = .004$) and 95% of navigated patients consented to participate in a clinical trial (95% CI: 82%–98%) [48].

Providing patients with clear, easy-to-understand information and enhancing their decision-making process, while facilitating care coordination and addressing common barriers to timely cancer care, fosters a sense of control and provides patients with the information and skills they need to make informed decisions regarding their treatment options and the resources to implement those decisions. This results in more involvement in their physician–patient interaction, asking more questions about their treatment options and assuming an active role in decision making [29, 49–52].

At the time of the present pilot study, Latina breast cancer patients attending the Breast Clinic at the Cancer Therapy and Research Center (CTRC) had low participation rates in clinical research due to many of the common barriers described above. These patients also did not have navigation services available. Even if they met eligibility criteria for a clinical trial, the information provided to these patients contained language that was complex, technical, and difficult to understand and follow.

To address these issues, this pilot study aimed to assess the effect of Choices, a bilingual, multi-component intervention on perceived understanding of clinical trials, agreement with stage of decision readiness (stages of change) statements, and consideration of clinical trials as a treatment option among Latina breast cancer patients. The intervention, based on Social Cognitive Theory [53] and the Stages of Change Model [54], offered decisional support aids designed to address common barriers, assess risks and benefits of treatment options, and promote an informed decision-making process. It included a culturally tailored educational and interactive video (computer-based), a low-literacy booklet, and care coordination by a patient navigator. The navigator facilitated timely care, provided educational and psychosocial support, coordinated appointments, and interacted with the medical team. The control group received the National Cancer Institute (NCI) fact sheet on clinical trials.

The Choices intervention aimed to provide clear, easy-to-understand information that addressed common barriers to participation (i.e., lack of awareness and information, attitudinal and language barriers, lack of social support, and difficulty navigating the system), alongside decisional support. We hypothesized that participants in the Choices intervention group would show significant progress in their stage of decision readiness, have higher awareness of

clinical trials, and be more likely to consider clinical trials as a treatment option for breast cancer compared with the control group (Fig. 1).

METHODS

Study design

This was a single-blinded, two-group randomized controlled trial with two assessment points before and after the intervention (Fig. 2). Patients attending the Breast Clinic at the CTCRC were identified through review of medical records and schedule logs or directly referred by physicians. The study nurse navigator contacted the patient prior to their treatment consultation visit, assessed eligibility, and offered the study. Patients who agreed to participate were consented and responded to a baseline computer-based survey. At the end of the survey, patients were automatically randomly allocated to the intervention or the control group, using a 1:1 (allocation) ratio in blocks of two. Participants completed a follow-up survey at their treatment decision visit. Treating physicians were blinded to what study arm the patient was assigned to. The study was approved by the UT Health San Antonio Institutional Review Board.

Eligibility criteria

Eligible participants were English- and Spanish-speaking Latinas diagnosed with breast cancer. They were also at the age of 18 and older, had not had their initial doctor consultation to discuss treatment options, had not participated or were not participating in a clinical trial, were eligible to participate in one of the clinical trials available at the CTCRC, and were mentally and physically able to understand the information in the consent form, respond to the computer-based pre-intervention and post-intervention surveys, and interact with the educational video.

Fig 1 | CHOICES conceptual model.

Fig 2 | CONSORT diagram for Choices educational trial.

Measures

Relevant demographic and background variables were extracted from medical records (i.e., age, marital status, language preference, educational level, health insurance, and metastatic disease). The same measures were used for the pre-survey and post-survey. Both surveys were self-administered using a touch-screen computer or iPad and took about 10 min to complete. The short instrument was developed based on review of the literature [17, 18, 20, 54–57] and the authors' own experience. The first part of the survey assessed participants' stage of decision readiness to participating in a clinical trial with eight questions (i.e., participating in a clinical trial may have some benefits, I am already considering pros and cons of participating). The second part assessed participants' perceived understanding of clinical trials with five questions (i.e., I understand what randomization means) and consideration of clinical trials as treatment options with one question (i.e., a clinical trial is an appropriate treatment option for cancer). Response options used a Likert scale format ranging from 1 = strongly disagree to 5 = strongly agree.

Intervention

Development

Framed by the Social Cognitive Theory [53] and the Stages of Change Model [54] and their key constructs (i.e., observational learning by peer modeling, social support/reinforcement, self-efficacy, and decision readiness stage), the study's multicomponent intervention focused on providing the following: (a) information on what clinical trials are, types of trials, randomization process, informed consent, and reasons for participating in breast cancer clinical trials; (b) pros and cons of breast cancer clinical trials; (c) self-efficacy enhancement to make a decision;

(d) direct references to taking action and reinforcing self-efficacy; and (e) care coordination by a nurse navigator (female, bicultural, and bilingual) who provided support scheduling appointments with the multidisciplinary team, offering educational, psychosocial support and reinforcement, facilitating interactions with the medical team, and translating and addressing common barriers.

In particular, the Stages of Change Model was selected because it provides a useful framework to develop educational interventions to target patients at various stages of decision readiness. Our stage-targeted interactive video, for example, provided patients in early stages of pre-contemplation (unaware of clinical trials), contemplation (starting to consider), and preparation to action (aware and assessing risks and benefits) with clear information to reinforce pros and counter-perceived cons of considering clinical trials as a treatment option. Patients in the ready to action stage (ready to take action) received information and messages centered on cues to action, promoting self-efficacy and support to facilitate informed decision making.

Formative research

Formative research guided the development of the intervention components. Initial designs were based on the following: a comprehensive review of the literature to summarize the existing evidence; the research team's own experience; and personal interviews with Latina breast cancer patients to assess their understanding of clinical trials, attitudes toward clinical research, and common barriers that keep them from participating in research studies.

Then, the script and storyboards for the interactive video and the educational booklet were pre-tested in focus groups with patients. The oncology

team worked to make sure the content was culturally relevant, clear, easily understood, and scientifically sound.

Beta-Testing

Based on feedback received during formative research, the educational booklet design was modified to include colors and cover elements selected by focus group participants, and a beta-version of the video was created. Both components were assessed once more by a group of patients with breast cancer, and minor refinements (i.e., video interactive features, timing, testimonial video fading after viewing, and space to add own questions at the end of the booklet) were made prior to final production.

Educational video

The stage-targeted educational video included three different paths, which patients were able to choose based on their stage of decision readiness (pre-contemplation: I have never heard about clinical trials; contemplation: I'm considering participating in a clinical trial; and preparation to action: I'm aware of risk and benefits but need more information), with tailored information and interactive content (Fig. 3). These three paths were selected based on results from the initial formative research phase of the study. As part of the eligibility criteria, patients in the action stage (those who were participating in a clinical trial) were not included. The bilingual interactive video lasted a maximum of 30 min depending on the path selected, and featured a female narrator, doctors, and nurses providing health information related to breast cancer clinical trials and addressing common barriers identified in the literature and during patients' interviews. It also featured Latina breast cancer patients as role models with the same sociodemographic characteristics as the study participants, but who have already gone through the process of making a decision to participate in a breast cancer clinical trial; modeling skills to discuss clinical trial information with their doctors, family members, and friends; and addressing how they overcame common attitudinal and practical barriers, provided decisional support to make an informed decision, and encouraged getting informed and asking questions.

Intervention process

Patients were approached by the patient navigator prior to their consultation at the breast clinic and taken to a private room assigned to the study to provide consent. Once consented, they responded to the online pre-intervention survey. At the end of the survey, the computer program automatically randomized patients to either the intervention or the control group (Fig. 3). If a patient was assigned to the intervention, the educational video started automatically. The patient navigator was available to respond

to any questions and assist patients if needed. At the end of the video, the patient received the educational booklet. They also received care coordination and navigation services as described above.

If at the end of the survey the patient was assigned to the control group, a message appeared on the screen thanking her for completing the baseline survey and informing her that the patient navigator will escort her back to the waiting room for her medical consultation. Patients in this group received the NCI clinical trials educational fact sheet the breast cancer clinic offered to patients eligible to participate in clinical trials. The fact sheet included 16 topics presented as questions and answers and provided resources with web links and contact information. Once the survey ended, the patient navigator provided the fact sheet and escorted patients back to the waiting room. She did not provide any additional information about clinical trials. Patients who refused participation were asked to respond to a short refusal survey to assess differences between participants and nonparticipants. The post-intervention survey was administered to both groups between 2 weeks and a month post-intervention, right after the medical consultation when patients made their decision about the course of treatment they wanted to follow.

Analysis

Descriptive statistics were used to summarize socio-demographic information. Two-sample *t*-test, Wilcoxon's Rank Sum for continuous variables, and chi-square and Fisher's exact tests for categorical variables were used to assess differences in patient characteristics between intervention and control groups. Agreement with decision readiness statements and clinical trial consideration variables were recoded for analysis as needed; for example, patients who responded 4 (agree) or 5 (strongly agree) with statements corresponding to each stage of decision readiness were assigned to that specific stage. Agreement statements were then analyzed separately. McNemar chi-square tests were used to compare differences in agreement with decision readiness stages and clinical trial consideration before and after the intervention for each group. Perceived understanding of clinical trials was created by computing a summary index of five related questions. Treatment effects and their 95% CIs were estimated using the regression coefficient of the interaction term between time and group indicators from linear (for continuous outcomes) and logistic models (dichotomous outcomes) fitted with time, group, and time by group terms, and allowing intra-individual correlation in the estimation of their standard errors. The multiple linear regression model (for continuous outcomes) is equivalent to an analysis of covariance (ANCOVA) with the posttest as outcome and pretest as covariate; these analytic approaches are interchangeable and produce identical results, especially in the RCT

Fig 3 | Interventions process diagram.

framework [58]. The α level for significance was set at 0.05, and p -values were based on two-sided tests. Statistical analyses were performed using STATA version 14 and figures were created using the Stata *coefplot* command [59, 60].

RESULTS

A total of 93 eligible Latina patients were approached by the patient navigator. Of those, 17 did not agree to participate and four dropped out of the study and had incomplete data. No significant demographic differences were found between participants and nonparticipants. A total of 73 patients with complete data were included in the analysis (Table 1). Participants were a mean age of 53.1 (SD 10.9), mostly married (51.4%), and mostly English speakers (52.1%). Sizable portions of participants lacked a high school education (45.6%) and health insurance (28.8%). More than half (54.9%) had metastatic disease and 18.1% enrolled in a clinical trial after the intervention.

The McNemar test showed a significant change between pre-intervention and post-intervention on agreement with stages of readiness statements for

the intervention group ($p < .002$), but not for the control group ($p > .05$). In the intervention group, women agreeing to contemplation statements decreased from 91.7% at baseline to 88.9% at post-intervention (Fig. 4). As expected, intervention participants agreeing to statements corresponding to preparation to action and ready to action stages significantly increased from 52.8% and 50.0% to 86.1% and 88.9%, respectively, at post-intervention assessment. In contrast, in the control group, the proportion of women agreeing to contemplation statements increased from 91.9% at baseline to 97.3% at post-intervention and the proportion agreeing to preparation to action and action statements increased only slightly from 72.9% and 86.5%, respectively, to 75.7% and 89.2% at post-assessment.

Logistic regression analyses showed that, compared with the NCI fact sheet in the control group, the Choices intervention was more effective in progressing patients' agreement with "preparation" stage statements from pre-intervention to post-intervention ($p = .030$), with a positive trend in progression of patients' agreement with a "ready to action" stage statement ($p = .058$; Fig. 5).

Table 1 | Demographics and clinical characteristics of study participants

	Choices <i>n</i> = 36 (%)	Control <i>n</i> = 37 (%)	Total <i>N</i> = 73 (%)	<i>p</i> -Value
Age (mean)	36 (54.8)	37 (51.4)	73 (53.1)	.177
Married	15 (41.7)	24 (64.9)	39 (53.4)	.058
Spanish preference	18 (50.0)	17 (45.9)	35 (47.9)	.816
Less than high school	19 (54.3)	12 (36.4)	31 (45.6)	.143
No health insurance	13 (36.1)	8 (21.6)	21 (28.8)	.203
Medicaid	14 (40.0)	14 (38.9)	28 (39.4)	1.000
Metastatic disease	18 (51.4)	21 (58.3)	39 (54.9)	.637
Stage of disease				.406
Stage 0	2 (5.6)	0 (0.0)	2 (2.9)	
Stage I	9 (25.0)	7 (20.6)	16 (22.9)	
Stage II	14 (38.9)	20 (58.8)	34 (48.6)	
Stage III	10 (27.8)	6 (17.6)	16 (22.9)	
Stage IV	1 (2.8)	1 (2.9)	2 (2.9)	
Enrollment in clinical trial	6 (17.1)	7 (18.9)	13 (18.1)	1.000

Fig 4 | Percentage of participants at pre- and post-assessment by stages of decision readiness to consider clinical trials as a treatment option.

Demographic variables were assessed to determine whether they were associated with any arm of the study. There were significant differences on agreement with “preparation” stage statements on the basis of metastasis status ($p = .033$), in particular for the intervention group, whereas age ($p = .05$) was significantly associated with agreement with “preparation” stage in the control group. No other statistically significant differences were detected.

Linear regression also showed that Choices were more effective than the control in increasing agreement related to perceived understanding of clinical trials (i.e., their requirements, benefits, and risks [$p = .033$] and consideration of clinical trials as an appropriate treatment option for cancer [$p = .008$]). However, there were no significant differences detected of Choices versus control on the basis of any of the covariates (Fig. 6).

Fig 5 | Treatment effect on stages of decision readiness statements and covariate influences on treatment effect. Odd ratios and 95% CIs.

Fig 6 | Covariate influences on treatment effects on consideration of clinical trials as treatment option and perceived understanding of clinical trials. Means and 95% CIs.

DISCUSSION

Previous studies have shown that providing patients with clear information through decision aids, and educational tools and strategies (i.e., videos, websites, and patient navigators) to address the multiple factors that influence patient decision making regarding clinical trials, have successfully improved positive attitudes toward clinical trials, accrual, and retention [1, 39–45]. However, none of these studies were conducted specifically targeting Latina patients.

When comparing the study's two groups, the Choices pilot trial showed that our theory-based multicomponent intervention was more effective than the control (receiving the NCI fact sheet) in increasing agreement with perceived understanding of clinical trials and consideration of a clinical trial as a treatment option. Initial within-group analysis also showed that women who received the tailored interactive intervention were more likely than the control group to make significant positive progress in stages of decision readiness from contemplation to preparation and ready to action regarding participation in a clinical trial. They were also more likely to consider a clinical trial as an appropriate treatment option for breast cancer. The Choices intervention was also more effective than control in increasing Latina patients' agreement with stages of decision readiness statements—particularly from preparation to action statements with a positive (but not significant) trend in agreement with ready to action statements. The fact that a higher proportion of Latinas in the control group were already in agreement with ready to action and action statements at pre-test compared with the intervention group may have limited the ability to detect a statistically significant difference between the two groups. In addition, women in the control group were more educated than the intervention group (36.4% vs. 54.3%, respectively, with less than high school education), which may reflect a higher awareness of clinical trials among this group. Our pilot trial results also support prior research [1, 43–45] for the development of tailored interventions to improve decision making among specific groups with low participation in clinical research.

In our study, 13 patients (18%) enrolled in a clinical trial after the intervention, with no significant differences between the intervention and control groups. The small numbers did not allow analyses of potential predictors or assessment of intervention effects on enrollment while controlling for key variables. Enrollment numbers were affected by several factors including limited number of trials available at the Breast Clinic at CTRC at the time of the study; strict eligibility criteria of existing trials; patients' comorbidities, tumor characteristics and surgical treatment preference (i.e., mastectomy) affecting eligibility to participate in a clinical trial;

the quality of the interaction between the patient and the medical team when discussing suitable clinical trials; and factors and barriers not addressed by navigation (i.e., family influences, travel distance from trial center).

There are several limitations to consider when interpreting results from this pilot study. The study included Latina breast cancer patients attending the Breast Clinic at CTRC and results cannot be generalized to all patients with Latina cancer or other types of cancer. Participants were at different stages of the disease, which may have influenced their attitudes toward clinical trial participation and enrollment. The small sample size may have limited the power of the study to detect statistically significant differences between the groups. In particular, the small sample size and low enrollment numbers in both groups precluded further analysis for this variable and did not allow assessment of the association between stages of decision readiness statements and actual enrollment. There is also the possibility of selection bias since women who agreed to participate in the study may have more positive attitudes toward clinical research than those who refused to participate. Patients' intentions to participate in a clinical trial were not assessed in this pilot study, which could have helped determine whether intentions changed as a result of the intervention, and allowed use of intentions as a proxy of actual participation. In addition, participants may have spent more time in the intervention than the control condition, so the experimental condition may have been confounded by differential navigator contact. Lastly, there is also the possibility that patients responded to assessments in a socially desirable manner.

Despite the limitations, our study advances scientific knowledge regarding the potential of tailored interactive multicomponent interventions in addressing specific factors to clinical trial participation among Latina breast cancer patients. Almost half of participants had less than high school education, and our results suggest that the interactive-tailored video and care coordination by a patient navigator were effective in increasing perceived understanding of clinical trials as a treatment option, representing a practical delivery channel regardless of educational level. Using an online-based video may be a cost-effective way to reach minority populations who do not participate in clinical research due to lack of awareness and understanding of clinical trials.

CONCLUSION

Empowering interventions that enhance patients' understanding and their decision-making processes foster a sense of control and provide patients with the knowledge and skills they need to make informed decisions regarding their treatment options.

Computer-based videos and care coordination provided by a patient navigator—specifically tailored to Latinos—are effective strategies to successfully address awareness, cultural and attitudinal barriers to participation, and skills needed to make informed decisions about clinical trial participation. Care coordination by a patient navigator to address barriers provides educational and psychosocial support throughout the cancer continuum and allows patients to focus their efforts in their treatment, facilitating a seamless and timely provision of care with benefits for patients, their families, and the medical team. Further research is warranted to replicate this educational trial with a larger sample size and involving different types of cancer, and an independent assessment of the impact of care coordination by patient navigation on clinical trial accrual. Such research could lead to the implementation of effective culturally tailored interventions with the potential to reduce racial/ethnic disparities in clinical trial participation, allowing researchers to assess differential effects in outcomes of therapies on biological and genetic characteristics and ultimately improve cancer outcomes among Latinos and other ethnic and racial minority groups.

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Compliance with Ethical Standards

Conflict of Interest: None declared.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Primary Data: The authors have full control of all primary data and agree to allow the journal to review their data if requested. The findings presented in the manuscript have not previously been published in any journal and the manuscript is not being simultaneously submitted elsewhere. Basic preliminary results were presented at the 2014 Annual Meeting of the American Association for Cancer Research entitled: The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved our data if requested.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study did not involve animals.

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