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Feasibility of a Spanish-language multimedia clinical trial educational intervention

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Abstract

Background—Hispanic cancer patients are underrepresented in clinical trials (CTs). Research suggests lack of knowledge and language barriers contribute to low accrual. Audiovisual materials offer advantages to Hispanic populations because they have high acceptability; are easy to disseminate; and can be viewed with family.

Purpose—Hispanic cancer patients and caregivers participated in focus groups to aid in developing a Spanish language audiovisual intervention. This project explored the feasibility of delivering the intervention in medical oncology clinics.

Methods—35 patients were randomized to either the intervention condition where they were given the audiovisual intervention (n=18); or a control condition where they were asked to read the National Cancer Institute's Spanish language brochure (n=17). Self-report data on knowledge, attitudes, and self efficacy for participating in a CT, intention to participate in a CT, and receptivity to CT information, were collected at two time points

Results—Knowledge in the intervention condition improved (p=0.06). Intention to participate in a CT remained positive in the intervention condition (p=0.484), but declined over time in the control condition (p=0.031). There were no statistical differences in attitudes or self-efficacy for making a decision to participate in a CT.

Limitations—Preliminary pilot data should be confirmed in a larger randomized control trial as the sample size was small. Although the patients randomized to the intervention group believed themselves to be willing to participate in a CT, this decision was hypothetical. Not all patients

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were being considered for enrollment in a CT which may have removed any fear or uncertainty from the situation. In addition, the study was conducted with a small sample of Spanish-speaking Hispanic cancer patients at a comprehensive cancer center in Florida. Thus, the results may not generalize to other populations.

Conclusion—The pilot showed feasibility to deliver an audiovisual intervention in medical oncology clinics. The audiovisual intervention increased Hispanic patients' knowledge of CTs and positive intention to participate in a CT. An audiovisual may improve quality of care for Hispanic cancer patients who are eligible for CTs.

Keywords

cancer clinical trials; Hispanic cancer patients; audiovisual intervention

Introduction

Participation of minorities in cancer research, including behavioral research and clinical trials (CTs), is vital to reducing cancer health disparities. It is estimated that only 1.3% of eligible Hispanic cancer patients participate in clinical trials.¹ With approximately 16% of the nation's total population being Hispanic², enrollment in CTs is far below their representation in the US population. Barriers cited for Hispanic patients choosing not to enroll in a CT include cost, time, and disruption of family and work responsibilities.³ In addition, knowledge and language barriers are particularly prevalent among Hispanics, especially for those individuals with limited or no English proficiency.^{4, 5} Ellington *et al.* explored factors influencing Hispanic patients' decision to enroll in a CT and found an imperative need for culturally sensitive education.³

Recent studies indicate that health education efforts, particularly those with a focus on promoting behavior change, are more successful when “transcreated” and available to the target population in their native language.^{6–8} Transcreation is the process of adapting not only the text of written materials, but infusing culturally relevant context, photos and themes. In transcreated materials, the text is not merely translated into another language, but reconstructed to meet the health literacy and informational needs of the target audience.⁷ Multistage qualitative approaches are needed to ensure health education materials are linguistically and culturally relevant for the heterogeneous populations of Hispanics.^{7, 8}

Using audiovisual materials as a way to increase knowledge of the research process and promote positive attitudes towards CTs offers several advantages⁹. Audiovisual materials demonstrate high acceptability to patients¹⁰, show good potential for dissemination, and may be favored for individuals with low literacy.¹¹ In addition, patients are able to review them with family.^{10–12} This is particularly important given that several studies have reported that Spanish-speaking patients prefer group decision-making involving opinions of family members.³

In response to the information barriers experienced by Hispanic patients, the research team developed an 8-minute DVD and accompanying 12-page booklet titled: *Estudios clínicos: considere todas sus opciones* (Clinical Trials: consider all your options). The methods of

development are described elsewhere.¹³ In brief, Hispanic cancer patients/survivors and caregivers participated in focus groups to guide the development of the DVD and booklet intervention. Based on the focus group results, a creative brief for a DVD and accompanying booklet was developed. A final DVD and booklet was created, in Spanish, which contained the information deemed important from the focus groups. The ultimate goal of this work was to design an intervention that would meet the specific needs of Spanish language preferring cancer patients to enable them to make informed decisions about any CTs. This study was built on the institution's prior work with English-speaking cancer patients, which was aimed at developing an educational intervention that addressed specific informational needs about CTs identified by this audience. The English-language audiovisual intervention is entitled: *Clinical Trials: Are they Right for You?*

¹⁴ This pilot project explored the feasibility of delivering the transcoded audiovisual intervention (*Estudios clínicos: considere todas sus opciones*) in medical oncology clinics at a comprehensive cancer center. In addition, the project collected preliminary data on the intervention's impact. The primary objective of this project was to examine the impact of providing Hispanic cancer patients with a transcoded audiovisual intervention in their preferred language (Spanish) on attitudes towards CT participation, knowledge about CTs, self-efficacy for making the decision to participate in CTs, receptivity to learning more about CTs, and intention to participate in a CT. Specifically, we examined whether patients provided the audiovisual intervention would have more favorable attitudes toward CT participation, have increased knowledge about CTs, would believe themselves to be more capable of participating in a CT, would have increased receptivity to learning more about a CT, and would report greater likelihood of participating in a CT if asked, compared to patients provided standard Spanish language materials.

Methods

Design

Patients were randomized to receive either *Estudios Clínicos: considere todas sus opciones* (Clinical Trials: consider all your options) or a Spanish-language brochure developed by the National Cancer Institute entitled "*Si tiene cáncer... Lo que debería saber sobre estudios clínicos*" (*If You Have Cancer... What You Should Know About Clinical Trials*).¹⁵ All outcomes were measured by self-report surveys at two times: 1) following consent but prior to randomization to treatment groups; and 2) approximately 10 days after enrollment. The study was approved by the University of South Florida Institutional Review Board (IRB).

Participants

Eligible patients: were > 18 years old; were diagnosed with any cancer; were scheduled for a consultation visit with a medical oncologist at Moffitt Cancer Center; had not been previously asked to participate in a clinical trial for the treatment of cancer; had identified Spanish as their preferred language in the new patient registration form.

Procedures

Prior to initiation of the study, the research team presented the project to physicians in different clinics throughout Moffitt Cancer Center. Those physicians who agreed to participate in the study allowed recruitment during their clinic hours and provided a patient room for study procedures. A bilingual research assistant (RA) reviewed medical and scheduling records to identify potentially eligible patients from participating clinics including Hematology, Thoracic, Breast/Gynecology, and Bone Marrow Transplant. Moffitt Cancer Center is a National Cancer Institute-designated comprehensive cancer center located in Tampa, Florida. The RA met with these patients just before or after the medical oncologist saw the patient for a consultation. The RA had a designated patient room in each participating clinic to complete all study procedures. During these meetings, the RA confirmed eligibility, described the study, and obtained written informed consent using an IRB approved Spanish language consent form. Immediately after providing written consent, patients completed a baseline assessment via a paper questionnaire. Participants who consented and completed baseline surveys were randomly assigned to the intervention or control condition using a centralized computerized program. The randomization table was generated by the study statistician using permuted block randomization method before uploading it to the computerized programs. The randomization sequence was concealed from all other study personnel, including the RA, until the time that the RA accessed the computer system to randomize each individual patient to intervention or control conditions. Only the specific patient's group assignment was provided by the computer system at the time of a patient randomization, keeping the remaining group assignments concealed.

The RA asked participants randomized to the intervention condition to view a short 9-minute video and read an accompanying 12-page brochure about clinical trials developed by the investigative team through formative research (*Estudios Clínicos: considere todas sus opciones*). The RA showed the video to each patient randomized to the intervention condition using a portable DVD player. After watching the video, intervention participants were provided a copy of the video for home viewing, along with the educational booklet to be reviewed at home.

The RA asked participants randomized to the control condition, to read the National Cancer Institute's Spanish-language brochure entitled "*Si tiene cáncer... Lo que debería saber sobre estudios clínicos*" (*If You Have Cancer... What You Should Know About Clinical Trials*) and a copy of this brochure was also provided to be reviewed at home. Due to the nature of the intervention, neither participants nor the RA was blinded to study group assignment.

Approximately 10 days after enrollment, patients were contacted by telephone at a prescheduled time to complete a follow-up assessment, during which the RA administered the same outcome measures contained in the baseline questionnaire.

Study Measures

All study measures were translated validated surveys used in previous studies of media interventions to inform cancer patients about cancer CTs.^{16, 17} To ensure cultural relevance and appropriate language, all study instruments were forward and back translated by

members of the study team. The forward and back translations of study materials were reviewed by an ATA-certified Spanish translator employed by Moffitt Cancer Center. All of the recommended changes were mutually agreed upon by the study team and certified translator.

Positive attitudes toward CTs (e.g., “being in a clinical trial benefits other patients”) and negative attitudes (e.g., “being in a clinical trial is likely to cause a patient harm”) were measured using 20 items with response options ranging from “strongly agree” (1) to “strongly disagree” (5). After reverse coding negatively worded items, an average score was calculated (possible range = 1–5). The measure demonstrated high internal consistency (Cronbach’s alpha = .87 for baseline measurement and .80 for follow-up).

Knowledge about CTs was measured using 13 items. Response options were “true,” “false,” or “don’t know.” A total score represents the number of items answered correctly (possible range = 0–13).

Perceived ability (i.e., self-efficacy) to carry out actions involved in making an informed decision about CT participation (e.g., “I think I could get the information I need to decide whether or not to be in a clinical trial”) was assessed using 9 items with response options ranging from “strongly agree” (1) to “strongly disagree” (5). After reverse coding negatively worded items, an average item score was calculated (possible range = 1–5). The measure demonstrated high internal consistency (Cronbach’s alpha = .89 for baseline and .83 for follow-up).

Receptivity to learning more about clinical trials was measured using 1 item (“If you were offered a cancer clinical trial, would you be willing to hear more information about it?”) with response options ranging from “definitely yes” (1) to “definitely no” (5). Scores were reverse coded so higher scores indicate greater receptivity (possible range = 1–5).

Intention to participate in CTs was measured using 1 item (“If a cancer clinical trial was offered to you, would you agree to take part in it?”) with response options ranging from “definitely yes” (1) to “definitely no” (5). Scores were reverse coded so higher scores indicate greater receptivity (possible range = 1–5).

Statistical Analysis Considerations

Analysis plan—Demographic characteristics were compared by assigned condition. To determine any differences in these characteristics between the intervention and control condition, Wilcoxon sum rank tests for continuous variables and MC simulation chi-square tests for categorical variables were used. Separate analyses were conducted to examine effects of assigned condition on each of the five outcomes (attitudes toward CTs, knowledge about CTs, self efficacy for CT decision making, receptivity to CT information, and intention to participate in CT). Stratifying by condition, the Wilcoxon signed rank test was used to determine if the improvement in each outcome after receiving the intervention was equal to zero. The Wilcoxon rank sum test was then used to determine if there was a difference in the outcome between conditions. The overall response rate and retention rate were calculated based on the total randomized participants. Data were analyzed using R

version 2.13.1 and SAS® v. 9.3 software. All tests were two-sided with a statistical significance level set at $p < 0.05$. As the goal of this pilot study was to evaluate the feasibility of delivering the intervention in medical oncology clinics and to collect preliminary data on the impact of the intervention, the sample size was not determined based on the statistical inferences.

Results

Seventy patients were approached for the study, however, 43 met inclusion criteria, and only 35 agreed to participate (overall response rate of 81%). Reasons for not participating included not feeling well ($n=4$) and not having enough time ($n=4$). Patient participation and flow are depicted in a CONSORT diagram (Figure 1).

Seventeen out of the 18 consented participants who were randomized to the intervention condition received the intervention. One person was unable to watch the video due to lack of time during the clinic appointment. Thus, this pilot project showed that it is feasible to deliver an audiovisual intervention in medical oncology clinics. Overall, the audiovisual intervention was well accepted by patients waiting to be seen by a medical oncologist, and the RA was able to deliver the intervention prior to the scheduled clinic visit without much disturbance of clinic flow.

Thirty-one of the 35 consented participants completed both baseline and follow-up surveys with a retention rate of 89%. In total, four participants (11.4%) did not complete the telephone follow-up survey (this includes the patient who was unable to receive the intervention) and, therefore, were not included in the analyses.

Demographic and clinical characteristics of randomized participants are described in Table 1. Participants represented various countries of origin, with the most common being Mexico, Puerto Rico, and Cuba. Overall, the intervention group was younger and more likely to have had chemotherapy in the last year (marginally significant, $p < 0.1$).

There were no significant differences between the intervention and control groups for attitudes toward CTs and for self-efficacy for clinical trial decision making. However, there was a trend towards improvement in knowledge from baseline to follow up in the intervention condition ($p = .06$, Table 2), the results were marginally statistically significant. No statistically significant differences in knowledge were found between the intervention and control conditions.

While not statistically significant, receptivity to learning more about CTs tended to become more positive over time in both conditions with a slight improvement in the intervention condition (intervention, $p = 0.469$; control, $p = 0.453$, Table 2). A statistically significant difference was observed for intention to participate in a CT between the control and the intervention conditions ($p = .032$, Table 2). Intention to participate declined over time in the control condition ($p = 0.031$, Table 2); however, in the intervention condition, intention to participate in a CT remained positive ($p = 0.484$, Table 2).

Discussion

This pilot work enabled us to explore the feasibility of delivering a transcoded audiovisual intervention in medical oncology clinics and to consider the implications of the findings for the design and procedure of a randomized controlled trial. We assessed the logistics of delivering the intervention without much disturbance of clinic flow. Before recruitment began, the project was presented to nurses and all staff in participating clinics. This allowed the RA to work closely with clinic staff to prioritize clinic flow and minimize disturbance. The response, retention and feasibility rates were promising. Most of the patients approached were ready to consider the project. In addition, participants who were assigned to the intervention condition were able to view the video using a portable DVD player while they were waiting to be seen by a medical oncologist. Overall, patients seemed interested in the video and the delivery method was found to be acceptable since the procedures did not interfere with their scheduled appointment. Only 1 participant was unable to view the video because they were called for their scheduled appointment earlier than anticipated.

The results of the preliminary pilot data on the intervention's impact showed that although the audiovisual intervention had no effect on attitudes toward CTs, self efficacy for clinical trial decision making or receptivity to CT information, it did have a positive effect on levels of knowledge about clinical trials over time, although it was statistically marginally significant. Also, those who were given the intervention were more likely to retain positive intention to participate in a CT when compared to those who received the control brochure. In addition, the intervention group was slightly more receptive to learning about a specific CT that may be presented to them in the future, compared to the control group.

An important finding for the CT setting was the effectiveness of the audiovisual intervention in improving knowledge among Hispanic cancer patients. This is consistent with previous research that has shown improvement in knowledge when a video is used as an educational tool.^{18–21} Furthermore, the video used in our study was transcoded rather than translated with voiceover. Transcoding has been shown to be more effective than translation in educating Hispanics because it considers both the language and culture of the target population^{8, 22}. Our study differs from other audiovisual interventions reporting increased knowledge in that the post-intervention questionnaire was administered two weeks after the intervention, rather than immediately after exposure to the intervention.¹⁸ This decreases the likelihood of any short-term impact which may diminish with time.

After watching the video, intention to participate in a CT remained positive for those individuals who received the intervention. Similar results were found in the study to evaluate the effectiveness of the English-language audiovisual intervention. In the English version, intention to participate in a CT declined over time in the control condition, but it did not change in the intervention condition.¹⁶ Also consistent with our study, Makoul et al. found significant increases in participants' willingness to undergo colorectal cancer screening after watching a transcoded audiovisual intervention.¹⁹ Furthermore, Du and colleagues found that an educational video was effective in increasing CT enrollment among lung cancer patients.²³

Although there have been other studies that have used audiovisual interventions to educate Spanish-speaking patients about cancer screening^{18, 19}, we could not find in the literature a study evaluating a transcreated audiovisual intervention about cancer CTs for Hispanic patients. The results from this study indicate that the audiovisual intervention created by our team was promising in increasing Hispanic patients' knowledge and intention to participate in a CT. In addition, an audiovisual intervention has the potential for broad dissemination. Dissemination of such an intervention may improve the quality of care for Hispanic cancer patients who are eligible for CTs. Future steps for this project include testing the intervention in a larger multisite randomized controlled trial.

Limitations

The purpose of this study was to evaluate the feasibility of delivering the intervention in medical oncology clinics and to collect preliminary data on the impact of the evaluation. The sample size of the study was small as it was not powered for formal hypothesis testing, and so the direction and the effect of the findings may be unstable. Preliminary pilot data should be confirmed in a larger randomized control trial. Another limitation is that although the patients randomized to the intervention group believed themselves to be willing to participate in a CT, this decision was hypothetical. Not all patients were being considered for enrollment in a CT which may have removed any fear or uncertainty from the situation. In addition, the study was conducted with a small sample of Spanish-speaking Hispanic cancer patients at a comprehensive cancer center in Florida. Thus, the results may not generalize to other populations.

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All authors confirm that all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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Figure 1.
Flow chart.

Table 1

Participant Demographic and Clinical Characteristics by Intervention Condition.

	Control N= 17	Intervention N= 18	p-value ^a
Age, years			
Mean (SD)	55.8 (12.9)	47.6(13.8)	0.076
Time since diagnosis, months			
Mean (SD)	40.7 (44.9)	27.8 (40)	
Median (min.–max.)	17 (0–123)	11.5 (1–143)	0.36
Gender			
Female	11(64.7%)	10(55.6%)	
Male	6(35.3%)	8(44.4%)	0.723
Place of birth			
U.S	2(11.8%)	4(22.2%)	
Cuba	5(29.4%)	2(11.1%)	
Mexico	4(23.5%)	4(22.2%)	
Puerto Rico	2(11.8%)	5(27.8%)	
Other	4(23.5%)	3(16.7%)	0.533
Race			
White	9(52.9%)	6(33.3%)	
Other	8(47.1%)	9(50%)	
Unknown	0(0%)	3(16.7%)	0.197
Marital status			
Married	13(76.5%)	13(72.2%)	
Single/Separated/Divorced/Widowed	4(23.5%)	5(27.8%)	1.0
Education			
Partial high school or lower	4(23.5%)	5(27.8%)	
High School graduate	3(17.6%)	4(22.2%)	
Partial college or higher	10(58.8%)	9(50%)	1.0
Household income			
Less than \$ 10,000	4(23.5%)	5(27.8%)	
\$10,000 –\$19,999	4(23.5%)	1(5.6%)	
\$20,000 –\$39,999	4(23.5%)	3(16.7%)	
Greater than \$40,000	2(11.8%)	6(33.3%)	
prefer not to answer	3(17.6%)	3(16.7%)	0.43
Disease stage			
0–II	7(41.2%)	5(27.8%)	
III–IV	5(29.4%)	8(44.4%)	
Unstaged/Not applicable	5(29.4%)	5(27.8%)	0.653
Cancer type			
Breast	2(11.8%)	3(16.7%)	
Lung	3(17.6%)	0(0%)	
Multiple myeloma	7(41.2%)	6(33.3%)	

	Control N= 17	Intervention N= 18	p-value ^a
Other	5(29.4%)	9(50%)	0.233
Chemotherapy in last year			
No	10(58.8%)	5(27.8%)	
Yes	7(41.2%)	13(72.2%)	0.096

^aP-values are for Wilcoxon sum rank tests for continuous variables and the Pearson chi-square exact test for categorical variables.

Table 2

Observed Baseline and Follow up Scores for Study Outcomes and Tests for Significance in Improvement.

	Control(N=15)		Intervention(N=16)		p value [*]	overall p- value ^{**}
	Mean(SD)	p value [*]	Mean(SD)	p value [*]		
Attitudes toward clinical trials						
Baseline	3.41(0.48)		3.37(0.5)			
Follow-up	3.35(0.46)		3.42(0.3)			
Improvement	0.05(0.43)	0.992	0.05(0.36)	0.611		0.632
Knowledge about clinical trials						
Baseline	5(2.17)		6.19(1.52)			
Follow-up	5.27(2.46)		7.31(1.4)			
Improvement	0.27(2.94)	0.551	1.12(2.09)	0.06		0.561
Self efficacy for clinical trial decision making						
Baseline	4.03(0.51)		3.86(0.57)			
Follow-up	3.99(0.43)		3.92(0.54)			
Improvement	0.04(0.23)	0.688	0.06(0.43)	0.446		0.321
Receptivity to clinical trial information						
Baseline	4.67(0.62)		4.19(1.05)			
Follow-up	4.47(0.64)		4.44(0.89)			
Improvement	-0.2(0.68)	0.453	0.25(1.13)	0.469		0.221
Intention to participate in clinical trial						
Baseline	4.53(0.64)		3.75(1.18)			
Follow-up	4.13(0.64)		4.00(1.21)			
Improvement	-0.4(0.51)	0.031	0.25(1.06)	0.484		0.032

* testing if improvement over time is equal to zero using exact Wilcoxon signed rank test

** testing difference in improvement between intervention and control using Wilcoxon rank sum test

Note: The 4 people lost to follow up (2 in the control and 2 in the intervention) were not included in the calculations.