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# Latinas' Appraisal of Participation in Breast Cancer Prevention Clinical Trials

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## Introduction

Few data are available to substantiate the reasons for the underrepresentation of Latinos and other ethnic minority groups in clinical trials.<sup>1,2</sup> Despite the limited literature, Brown et al<sup>3</sup> have proposed a conceptual model to understand the factors that influence the lack of participation by ethnic minority women and to design outreach interventions to recruit these women more successfully. The model outlines the interplay of three factors found to be relevant to the recruitment of ethnic minorities into research studies: awareness, acceptability, and access. Basically, women must have an understanding of the importance of the research (awareness), an appraisal that society approves of their participation (acceptability), and the presence of adequate resources to overcome participation barriers (access).

Many ethnic minority women, including Latinas, have been observed to have limited or no awareness about the importance of clinical trials research or the procedures involved in such studies. Moreover, their acceptance of and participation in clinical trials might be dependent on a particular ethnic group's social, psychological, and cultural factors related to seeking health care services. Group-specific studies rather than studies that generalize across ethnic minority groups may be needed. Access barriers might be somewhat more similar across disadvantaged ethnic minority groups because these barriers are more likely to be linked to low socioeconomic status, health literacy levels, and institutional practices. Thus, a logical first step in an effort to increase Latinas' participation in clinical trials is to understand their level of clinical trials knowledge and their views about what factors would motivate or discourage them from enrolling and adhering to clinical trials in the context of social, psychological, and cultural variables. The aim of this pilot study is to contribute to such understanding.

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*Submitted February 28, 2005; accepted July 1, 2005.*

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*This project was funded with a 2001 grant from the Denver Metropolitan Affiliate of The Susan G. Komen Breast Cancer Foundation, Denver, Colorado. The writing of this article was supported with a 2003 grant to the author from the American Association of University Women Educational Foundation (an American Research Publication Grant).*

## Methods

### *Design and Instruments*

The pilot study used a qualitative one-on-one interview design. A semi-structure interview was created to ask specific in-depth questions about how participants appraised their potential enrollment in and adherence to a breast cancer prevention clinical trial, such as the Study of Tamoxifen and Raloxifene (STAR). The content of the questions tapped into the conceptual model by Brown et al<sup>3</sup> (ie, awareness, acceptability, and access) for the recruitment of ethnic minorities to clinical trials research, but from the women's perspective. In addition, a self-report measure was developed in order to gather demographic information and data about each participant's cancer history, cancer screening practices, and participation in clinical trials.

### *Procedures*

Two urban cities and two rural cities located along the Rocky Mountains Front Range in Colorado were chosen based on the high density of Latinos living in those cities at the time the study was conducted.<sup>4</sup> To help us recruit the participants in the semi-structure interview, we had built personal connections with community leaders who had access to the target population in each city. A convenient time and location to conduct the interview was arranged with each participant. All the interviews lasted approximately 1 hour, and women were compensated with a gift worth \$25.

### *Analysis*

Content analysis<sup>5,6</sup> was used to organize emerging themes from the data into six categories. All of these categories were exhaustive (every instance was assigned to a category) and exclusive (every instance was assigned to only one category). Two coders who conducted the analysis reached an adequate interrater reliability, Cohen's alpha of .91.

## Results

### *Participants*

Fourteen Latinas participated in the one-on-one interviews. Table 1 lists the sample sociodemographic characteristics, health insurance coverage, cancer history, and cancer screening practices. Our sample of Latinas is similar to other medically disadvantaged populations because of their low socioeconomic, literacy, and underinsured status. Consistent with this lower status, none of the 14 participants had ever met with a health care professional who educated them about breast cancer clinical trials or who referred them to one. Likewise, none of the women had ever participated in either a treatment or a preventive breast cancer clinical trial.

## Themes

Table 2 lists the percentage of the 14 participants who responded to each of the interview questions and their answers to the questions.

**Willingness to Participate:** The majority of the participants (58%) were not willing to voluntarily participate in a clinical trial. Among the reasons for their unwillingness were that women did not want to run the risk of taking something that might be harmful to their health or simply because they did not like taking medication. For example, one woman said, “I don’t know because I am taking several pills from the doctor and I don’t know if they would counteract.”

**Perceived Benefits and Costs of Chemoprevention Interventions:** The majority of participants (72%) believed that an intervention could prevent the development of breast cancer, primarily because they believe that with medical advances a preventive medicine could be created. With regard to the opposite effect, 50% of the women did not know whether the intervention could

cause breast cancer. Further probing revealed that several women (79%) also had concerns about potential health threats or harmful side effects. Those willing to accept any side effects (64%) were willing to tolerate only minor side effects.

**Commitment and Adherence to Clinical Procedures:** STAR is a randomized clinical trial in which a “pill” containing either tamoxifen or raloxifene is taken for 5 consecutive years. Less than half of the women (42%) said that they would not be committed to taking a pill for 5 years. Lack of commitment was expected for various reasons, including that some women do not like trying any new medicines or would rather take herbal remedies. The STAR trial also requires pre-entry and regular medical examinations for 7 years once participants are accepted. Unlike their responses to the medication compliance question, 11 (79%) of the women expressed that they would be likely to comply with the yearly medical examinations for 7 years, mostly because they are already participating in some form of medical examinations.

**Table 1. — Latinas’ Sociodemographic Characteristics, Health Insurance Coverage, Cancer History, and Breast Cancer Screening Practices (N = 14)**

Variables	Mean	SD	Range	%	(n)
<b>Sociodemographics</b>					
Age (in years)	66.36	8.99	51–80		
Education (in years)	7.79	3.89	2–14		
Acculturation score*	2.90	1.18	1–5		
Mexican descent but US born				64	(9)
Annual income:					
Less than \$5,000				21	(3)
\$5,001–\$10,000				50	(7)
\$10,001–\$20,000				29	(4)
\$20,001–\$40,000				0	(0)
More than \$40,000				0	(0)
Marital status:					
Never married				0	(0)
Married				29	(4)
Divorced				0	(0)
Separated				29	(4)
Cohabitate				0	(0)
Widowed				42	(6)
Employment status:					
Employed				50	(7)
Retired				50	(7)
<b>Health insurance</b>					
No insurance				36	(5)
Medicare or private insurance				64	(9)
<b>History of cancer</b>					
Personal (% ever diagnosed any cancer)				14	(2)
Relative (% ever diagnosed with breast cancer)				14	(2)
<b>Breast cancer screening</b>					
Mammogram in past year (% yes)				71	(10)
Breast self-exam in past month (% yes)				71	(10)
Clinical breast exam in past year (% yes)				36	(5)
Only the numbers and percentages for the specific response indicated in parentheses are included in the table. n = number of participants in each cell. * Mean score (1 = low acculturation to 5 = high acculturation).					

**Table 2. — Percentage of Participants (N = 14) Who Responded to Each of the Structure Interview Questions**

Question Content	Responses		
	Yes % (n)	No % (n)	Don't Know % (n)
Willingness to participate in a clinical trial	21 (3)	58 (8)	21 (3)
Belief that the intervention can prevent breast cancer	72 (10)	21 (3)	7 (1)
Belief that the intervention can cause breast cancer	14 (2)	36 (5)	50 (7)
Willingness to take any side effects	64 (9)	36 (5)	
Perceived medication compliance in a clinical trial	42 (6)	29 (4)	29 (4)
Perceived procedures compliance in a clinical trial	79 (11)	7 (1)	14 (2)
Ability to trust clinical trial's health care providers	72 (10)	14 (2)	14 (2)
Preference for a female physician	72 (10)	7 (1)	21 (3)
Preference for a Latino/a physician	7 (1)	93 (13)	
Ability to find transportation to a clinical trial	50 (7)	50 (7)	
Ability to navigate a health care setting	50 (7)	50 (7)	
Ability to read a clinical trial's medical information	64 (9)	36 (5)	
Ability to fill out forms that asked for information	58 (8)	42 (6)	
Motivation to participate to be there for family	58 (8)	42 (6)	
Motivation to participate to benefit others	58 (8)	42 (6)	
n = number of participants in each cell.			

**Ability to Trust Medical Professionals:** Most women (72%) said that they would trust the clinical trial specialty physicians because they are likely to be more knowledgeable and prepared than their primary care physicians are. Regarding the physician's gender, the same number of women (72%) said they would prefer a woman rather than a man. Primarily, they would feel more *confianza* (equivalent to *trust*) with another woman.<sup>7</sup> On the other hand, 13 (93%) of the participants had no preferences for the ethnicity of the health care providers in a clinical trial study. However, 5 (38%) of these 13 women noted that the ability of the health care provider to communicate with them in Spanish or the presence of a translator was important.

**Ability to Overcome Medical Access Barriers:** Participants' responses to questions about their ability to travel to a clinical trial were equally split, with 7 women indicating that they would be able to find transportation and 7 indicating that they would not. Those who anticipated that transportation would not be an issue were more likely to plan on using public transportation or have a family member take them to their destination. With regard to navigating a large medical setting, 50% of the women confirmed that this would be difficult for them, particularly because they could not read or speak English. However, they indicated that having a Spanish-speaking person (a family member or a system navigator) with them throughout their hospital visit to guide them on where to go and what to do would be extremely helpful.

Another medical access barrier is introduced when consent form explanations are above participants' literacy levels and rely heavily on medical terms. When asked if they would be able to read the medical information regarding a clinical trial, assuming that it was similar to other information that they have received at a medical setting, the majority of women (64%) anticipated that they would be able to read such information without major problems if there was someone who would explain it to them in understandable terms. When asked how difficult it would be to fill out forms that asked for personal information (eg, medical history), most women (58%) did not anticipate that completing the forms would be difficult or believed that they could ask for help if needed.

### **Perceived Contributions to Family and Society**

We asked our study participants to what extent the value of *familismo* (holding family as central in life) would be influential in their decision to participate or abstain from a clinical trial. Most women (57%) confirmed that they would be motivated to participate in a breast cancer prevention clinical trial if the medication could prevent them from developing and dying of breast cancer and allow them to be there for their children in years to come. Surprisingly, 42% of the participants appraised the benefits as ambiguous and had difficulty believing in the intergenerational benefits from their individual participation in clinical

trials and, thus, they were not motivated to participate for this reason.

## **Discussion**

Enrollment in cancer clinical trials by ethnic minorities and women remains low.<sup>8,9</sup> In breast cancer preventive clinical trials, Latina women have accounted for less than 2% of participants.<sup>10</sup> The factors that are specifically influential in the underrepresentation of Latinas have not been identified. However, we found that they are likely to be similar to the factors that influence the participation of other medically underserved populations. For example, the evidence in the literature is convincing regarding the role of low socioeconomic status, health literacy, and access barriers in impeding the fair participation of ethnic minority populations in clinical studies. Less is known, however, about the social, psychological, and cultural factors that also affect participation by ethnic minority women in clinical trials. To our knowledge, no studies have explored Latinas' appraisal of the factors that would be influential in their enrollment and adherence to breast cancer prevention clinical trials. This pilot study is an initial attempt to explore, from the target women's perspective, some of the influential factors that need to be considered and incorporated into programs for the successful recruitment and retention of Latinas in cancer clinical trials.

We found in this small pilot study that the most influential group-specific social factor that contributes to Latinas low participation rates was their lack of English proficiency. Spanish-speaking Latinas eloquently explained how they would be more encouraged to participate in a clinical trial if information was available in their language and if bilingual health care providers were available. This factor was more important than their desire to have physicians of their same ethnicity. Such was not the case regarding the provider's gender, where most women prefer and have more trust (*confianza*) in a woman physician. Incorporating such enabling sociocultural variables is likely to increase recruitment and retention of Latinas in breast cancer clinical trials and warrants future study.

*Appreciation is expressed to the anonymous reviewers and Dr Peter Raich for their suggestions on preliminary versions of the article.*

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