DISSERTATION

LATINAS' PARTICIPATION IN BREAST CANCER CLINICAL TRIALS

Submitted by

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WE HEREBY RECOMMEND THAT THE DISSERTATION PREPARED UNDER OUR SUPERVISION BY CATALINA LAWSIN ENTITLED LATINAS' PARTICIPATION IN BREAST CANCER CLINICAL TRIALS BE ACCEPTED AS FULFILLING IN PART REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSPHY.

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ABSTRACT OF DISSERTATION

LATINAS' PARTICIPATION IN BREAST CANCER CLINICAL TRIALS

The main goal of this study was to understand the socio-cultural factors influencing Latinas' participation in breast cancer control and prevention activities, in particular prevention clinical trials. Guided by the Community Readiness Model data were collected in three phases. First, 19 key informants were interviewed in four communities, two rural and two urban to assess the level of community readiness to encourage participation in breast cancer prevention and control activities. Next, 48 Latinas over the age of 50 participated in focus groups to further examine the perceptions and barriers of breast cancer prevention in each community. Lastly, 14 semi-structured interviews were conducted in each community to obtain information not collected from the key informants and the focus group participants. Results demonstrated that Latinas had minimal awareness of breast cancer prevention activities and that communities were in low levels of readiness to address this issue. Feelings of distrust and fear influenced Latinas' decision to not participate in breast cancer prevention activities and in particular, chemoprevention clinical trials. Several systemic factors were identified that contribute to low recruitment and retention in clinical trials. Implications of the findings of this study are discussed and recommendations for how to heighten awareness of breast cancer prevention in these communities and increase participation in clinical trials are offered.

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INTRODUCTION

At the turn of the 20th century, the world experienced a change in the patterns of illness. In the United States, acute disorders, or short-term illnesses, such as tuberculosis or pneumonia, were the major causes of illness and death. However, as industrialization progressed and vaccinations and medicines impeded the progression of these acute illnesses, chronic illnesses became the major contributors to disability and death. Chronic illnesses are slowly developing diseases that individuals live with for long periods of time, such as heart disease, cancer or diabetes. With the increase of chronic illness there has been a trend towards prevention in public health. This trend has led to an increased awareness and open dialogue concerning the negative physical and emotional effects of chronic illness. Over the past decades, breast cancer (BC) has gained attention by the media, research, and health care industry. As women continue to gain a voice in society, attention to this illness has increased. More women are being educated about BC and its symptoms. While there has been an overall increase in BC awareness, minority populations continue to receive less medical attention in the preventative and curative arenas. As costs of medical care rise in the United States, and managed health care systems control where and when patients receive services, ethnic minorities often bear the brunt of additional stressors and limited access to health care in comparison to White non-Hispanic populations. The area of BC control dramatically exemplifies this phenomenon. This study will examine the socio-cultural factors that influence Latinas participation in BC prevention and control activities.

Prevalence of Breast Cancer Among Latinas

In 2005 an anticipated 1,372,910 new cancer cases (American Cancer Society, ACS, 2005) will be diagnosed in the United States (excluding carcinoma in situ, noninvasive cancers of any site except urinary bladder, and basal and squamous cell skin cancers). It is estimated that 211,300 women in the U.S. will be diagnosed with invasive breast cancer (BC) in 2003 and that 39,800 women will die due to this illness this year. BC is the most frequently diagnosed non-skin cancer in women. BC rates have continued to increase since the 1980's, although there was a slight decline in incidence in the 1990's. More recently, BC incidence rates have increased only in women aged 50 and over (ACS, 2003). Most recent data has shown a decline in mortality rates from BC by 1.4% per year during 1989-1995 and by 3.2% after this period. Non-Hispanic Whites and African Americans have demonstrated the largest decreases in mortality rates in the United States. These decreases are most likely the result of an increase in earlier detection of BC and improved treatment of the disease.

Mortality rates of BC in Colorado also appear promising. The mortality rate for BC among females from all ethnic groups between 1993-1997 was 13% lower than the U.S. rate. However, non-Hispanic White and Black women have seen stronger improvements in mortality rates, decreasing 13% and 7% respectively compared to only the 3% decrease in mortality among Hispanics. It appears that Hispanic women continue to be more likely to die of BC than non-Hispanic White and Black women.

While these statistics reported above appear to be moving in the positive direction, one must be cautious when considering the reported decrease in mortality rates among Hispanics and Blacks. Skepticism arises because of possible racial or ethnic biases that contribute to the misclassification and under reporting of Latinas with BC (Susan G. Komen Foundation, 1998). Incidence and mortality rates may be excluding the number of Latinas living in rural communities who do not have access to health care and who do not receive biopsies upon death and may have died of BC as opposed to other natural causes. Therefore, one must not interpret these statistics as improvement nor respond with complacency.

According to the Colorado Central Cancer Registry (CCCR), Colorado experienced a similar trend to the national increase in the incidence of BC in women over the age of 50 years old. In Colorado, between 1993-1997, the BC incidence rate among females increased by 6% (CCCR, 2001). This report indicated a lower BC incidence rate among Hispanic women (Latinas) when compared to non-Hispanic women (non-Latinas). However, they found that while early detection of BC, based on in-situ stage, improved among non-Latinas, Latinas and Black women continue to detect BC at later stages. This suggests that although incidence of BC may not be as high among Latinas, when it is present it may be detected at later, more harmful stages.

Staging refers to the process physicians use to assess the size and location of a particular cancer. Identifying the cancer stage is one of the most important factors in making treatment decisions and determining the prognosis of the illness. BC is classified on a continuum of stages between IV and I. The first stages reflect smaller tumor sizes and no metastasis, or spreading of the cancer, while the later stages indicate that the cancer has metastasized to other parts of the body. Health care providers are able to predict a patient's survival rate based on what stage the tumor is found. Tumors classified in stage I have a 98% 5-year relative survival rate (ACS, 2005). As the tumor grows survival rates gradually decrease to 88% at stage II, 56% at stage III, and 16% 5-year relative survival rate at stage

IV. These statistics do not account for individual differences in recovery. However, the statistics do provide strong evidence for the importance of detection and control cancer growth at earlier stages of development. According to the Surveillance, Epidemiology, and End Results (SEER) program population-based study (Clegg et. al., 2002), Latinas were diagnosed with BC at later stages compared to their White non-Latina counterparts. Compared to 62.9% of White non-Latina women, only 56.2% of Latinas were diagnosed with localized (stages I and II) BC between 1988 and 1997. Furthermore, 34.1% of Latinas were diagnosed with regional BC compared to 28.4% of White non-Latinas and 27% of Asian Americans. These percentages of stage distribution suggest that Latinas are being diagnosed at later stages than their White non-Latina peers are. As suggested earlier, detection at later stages of cancer growth may account for higher mortality rates for Latinas compared to non-Latina women.

Several factors contribute to ethnic differences in mortality rates due to BC across ethnicity. Participation in BC prevention and control activities leads to reduced mortality due to early detection of the BC. When cancer is detected during earlier stages of growth, several treatment options are available to control the spread of the cancer and in turn, improve the patient's prognosis. The American Cancer Society (ACS, 2002) stated that the 5-year relative survival rate for people with cancers for which the ACS has specific early detection recommendations (breast, colon, rectum, cervix, prostrate, testis, oral cavity, and skin) is about 82%. This five-year survival rate is defined as the percentage of people alive at least five years after diagnosis of cancer. BC prevention and control activities differ in their purpose and when they are implemented in the disease process. Prevention activities are activities that reduce the likelihood of a woman ever acquiring BC. Examples of prevention activities include a healthy diet, exercise, and the prophylactic use of medications such as Tamoxifen. The intention of BC control activities is to detect BC at an early stage and control its growth throughout the body. BC control activities include breast self-exams and mammograms. Therefore, BC prevention activities are geared towards preventing the onset or recurrence of BC while control activities work towards managing the illness after it has been acquired. In addition to regular physical checkups, the ACS (2002) recommends the following BC control activities:

1. Yearly mammograms starting at age 40 and continuing for as long as a woman is in good health.
2. Clinical breast exams (CBE) should be part of a periodic health exam, about every three years for women in their 20s and 30s and every year for women 40 and over.
3. Women should report any breast change promptly to their health care providers. Breast self-exam (BSE) is an option for women starting in their 20s.
4. Women at increased risk (e.g., family history, genetic tendency, past breast cancer) should talk with their doctors about the benefits and limitations of starting mammography screening earlier, having additional tests (e.g., breast ultrasound or MRI), or having more frequent exams.

Analysis of the 1998 National Health Interview Survey conducted during the SEER study (Clegg et. al., 2002), revealed that the 2-year mammography screening rate for women 50 years of age and older has increased to 69% across 6 racial groups in the U.S. When analyzed separately by ethnicity, mammography screening rates were 70% for non-Latina Whites, 67% for African Americans, 63% for Asian American and Pacific Islanders, 61% for Latinas, and 51% for Native Americans and Alaskan natives. Although this rise in screening rates is encouraging, Latinas appear to be participating in BC screening activities significantly less than their White non-Latina, African and Asian American counterparts. It has been suggested that these differences in BC screening rates contribute to BC diagnosis occurring at later stages of tumor growth and relatively low survival rates among Hispanics, American Indians, and Alaskan natives.

Latinas' Participation in Breast Cancer Control Activities

The decline in BC mortality rates has been attributed to two major causes: 1) the increased use of screening mammograms, which results in BC being diagnosed at early stages; and 2) improved therapies, including adjuvant chemotherapy and hormonal therapy (Colorado Cancer Research Program, 1999). However, ethnic minorities, particularly Hispanic women are often underrepresented in control activities. For example, the National Health Interview Survey (Breen, Wagener, brown, Davis, & Ballard-Barbash, 2001) indicated that Latinas consistently reported lower participation in screening and detection than non-Latina women did. Compared to 39% of White non-Latina women ages 40 and above, only 26% of Hispanics reported "ever" having a mammogram. In addition, more than 31% of the Hispanic sample in this survey reported that they had never heard what a mammogram is compared to 12.2% of the White non-Latina counterparts.

Sociodemographic Barriers

In general, while BC incidence is equal across ethnicities in the U.S., ethnic minorities are more likely to die from BC due to later detection (Saint-Germain & Longman, 1993; Ramiez, MacKellar, & Gallion, 1988). Numerous studies have examined factors that contribute to the lack of participation in BC control activities such as mammography and breast self-exams. Sociodemographic characteristics such as lack of health insurance, being married and being Latino have been shown to be independent predictors of not participating in BC prevention behaviors (Hubbell et al., 1997).

Psychosocial Barriers

Friedman and colleagues (1996) used self-administered questionnaires to assess barriers to BC screening in a number of low-income ethnic minorities, a third of which were Latinas. Participants reported not knowing how to do breast self-exams (BSE) and feeling fearful of finding a malignancy as barriers to BSE. Furthermore, cost and fear of finding a malignancy were barriers to clinical breast exams (CBE) and mammography screening. The role of fear in this decision process was not elaborated upon in this study. Due to the forced-choice format of the questionnaire, it is hard to determine exactly what participant's perception of fear might have been.

A belief in fate, a shame in discussing one's body, and a primary responsibility to care for the family before themselves, are common themes throughout the literature that serve as barriers to Latinas participation in BC control activities. Moreover, the literature has revealed issues associated with trust and fear in Latinas decisions to not participate in BC control activities (Suarez et. al., 1997). Distrust in healthcare providers, settings, and the medical system inhibit Latinas from using medical services such as routine check-ups, including mammograms and clinical breast exams (Borrayo & Jenkins, 2001b). In addition, a sense of fear of the consequences of a positive diagnosis of BC such as changes in women's role in the family, relationship with spouse, and ability to be a caretaker discourage many Latinas from acknowledging their risk of BC (Borrayo, Jenkins, & Lawsin, under review).

Socio-Cultural Barriers

Additional qualitative research has revealed cultural themes that are engrained in the health constructs of Latinas and discourage BC control activities. Borrayo and colleagues

(Borrayo & Jenkins, 2001ab; Borrayo, Jenkins, & Lawsin, under review) used focus groups with Mexican-descent Latinas to examine possible barriers to BC prevention activities. These authors conducted focus groups including 34 women of Mexican-descent living in the Dallas-Fort Worth Metroplex in Texas. The average age of the female participants was 62 years. Education and income levels varied between 2-17+ years of education and between less than $5,000 and $40,000 or more in yearly income respectively. Using the Acculturation Rating Scale for Mexican Americans (ARSMA; Cuellar, Harris, & Jasso, 1980) acculturation scale, a positive correlation was found such that more acculturated women were likely to have higher levels of education and income. This body of research revealed several constructs such as "feeling healthy," "feeling indecent," and "feeling threatened" as barriers to Mexican-descent women's participation in BC control activities. The construct of "feeling healthy" revealed how women perceived their risk of BC as low; therefore, they did not feel the need to participate in BC screening activities. Since some women were asymptomatic of BC, they felt "healthy" and therefore did not receive regular BC check-ups. "Feeling indecent" refers to women's beliefs towards not revealing their bodies in an effort to remain modest. This female modesty influenced some Latinas beliefs that showing their breasts during mammograms or clinical breast exams is "indecent." In turn, feelings of indecency inhibited some women from participating in BC screening procedures. The construct of "feeling threatened" describes how some Latinas perceived the BC screening procedures as increasing their threat of having a positive diagnosis of BC. These women associated being screened for BC as being very likely to be diagnosed with BC. Therefore, to deter the possibility of receiving a positive diagnosis of BC, these women chose to refrain from the screening procedures.

Borrayo and Jenkins (2001a) described in detail how a subjective sense of physically "feeling healthy" discouraged some Latinas from participating in BC screening behaviors. Their health beliefs regarding the cause and nature of BC underlie this subjective sense of health. There were four major causes of BC as perceived by Mexican-descent women. These causes include: physical predestination, detrimental external sources, and breast-feeding, and divine predestination.

Physical predestination basically refers to a family history of BC and it was seen as one of the major indicators of the disease. Women who had a family history of BC were more likely to indicate they would participate in BC screening than those who did not. Another determinant of screening behaviors is whether or not a woman believes she has been exposed to any detrimental external sources such as poor nutrition or trauma to one's breast (*golpe*). Breastfeeding has been seen to be both a deterrent and risk factor for BC. The idea that breast milk can stagnate and cause BC if a woman does not breastfeed is a recurring theme typical of this belief. On the other hand, breastfeeding is also seen as a method of draining breast milk, preventing it from stagnating in the breast and causing cancer. Lastly, divine predestination is seen as a cause of BC. This idea suggests that a higher being or supernatural force predetermines whether or not a woman will have BC. This belief assumes that if it is "God's will" to have BC, than a woman will have BC. A strong faith in a higher being is seen to lower one's personal risk of BC prior to being diagnosed and improves the course of the disease after diagnosis.

The belief that BC is by nature a symptomatic illness encourages women to disregard the need for screening for BC assuming that they will know when they have it due to experiencing physical symptoms. More traditional women of Mexican-descent also expressed the belief that BC is by nature a shameful illness, which further inhibits screening. The perception that BC will bring shame to oneself and one's family discourages women from being screened to postpone or avoid diagnosis of a shameful illness.

Olsen and Frank-Stromborg (1993) suggest that dignity and modesty are specific cultural norms that are most important to ethnic minority individuals who are very traditional in their views and behavior. Borrayo and Jenkins (2001b) found that this modesty applies towards Latinas BC screening behaviors. They found that behind Mexican-descent women's lack of participation in BC screening is also the perception that screening is an insensitive procedure that violates their cultural beliefs, values, and norms by requiring culturally inappropriate behavior (e.g. revealing one's breasts in front of a physician). This perception leaves Mexican-descent women "feeling indecent" during procedures such as mammograms or clinical breast exams, as the procedures are seen as inappropriate and induces feelings of embarrassment. Two subcategories were provided as extensions to the "feeling indecent" construct. The propriety of women's screening behaviors and those of their health care providers were seen as particular aspects that influence whether Mexican-descent women feel indecent during BC screening activities. The latter subcategory refers to norms held that male doctors should not be viewing women's breasts, even if it is for a medical procedure. Distrust in male doctors exacerbates feelings of indecency.

The construct of "feeling threatened" (Borrayo, Jenkins, & Lawsin, under review) suggests that some women of Mexican-descent assume that by participating in a CBE or mammograms they *will* be diagnosed with cancer. Upon receiving a BC diagnosis they are afraid that they will be treated with surgical removal of the breast. In other words, they think that there is a linear relationship between a diagnosis of BC and a mastectomy. The fear of this threat is so strong that it inhibits women from screening for BC to avoid feeling threatened by the illness. Two subcategories emerged to support the overall construct of "feeling threatened" among these women, including the threat of being diagnosed, as well as the repercussions of a positive diagnosis.

The anticipation of being diagnosed with BC theoretically induces a strong sense of fear that inhibits screening behaviors. Women reported experiencing cognitive dissonance and resolving it by assuming "just world" beliefs. Such a belief posits that in a just world an individual who lives a moral and valued-laden life will benefit and those who do not will be punished. Therefore, women who believed this typically assumed they had lived a life led by traditional values and consequently were unlikely to have BC and saw no need to participate in screening behaviors.

Women also expressed concerns over repercussions, the social and physical consequences, of being diagnosed with BC. Many women shared the concern that a diagnosis of BC is directly associated with treatments such as mastectomies. This fear of losing one's breast has implications on one's feminine identity as a woman, a mother, and a wife. This threat of losing one's feminine identity induced women to feel threatened and inhibited them from considering screening behaviors that may begin this process.

Borrayo & Jenkins (2003) found that health beliefs about BC might sometimes inhibit screening behaviors more so than low income and education barriers. In that study education level and income were not significantly correlated to BC screening as expected. Although SES accounts for many of the logistical or tangible barriers to participating in BC control and prevention activities, cultural barriers seem to impede the participation of some women, even if resources are available to them. Latinas who hold more traditional beliefs regarding BC screening often tend to be born in Mexico, to be less acculturated to U.S. traditions, and to have lower levels of education and SES (Borrayo & Jenkins, 2001a, 2001b). Perceptions about how BC is acquired and about its symptoms seem to be strongly influenced by traditional beliefs (Borrayo & Jenkins 2001a, 2001b). Together both economic and cultural factors influence Latinas participation in BC prevention and control activities. In order to increase early detection and decrease mortality in Latinas, it will be necessary to counteract economic barriers and to work with cultural factors more effectively.

Latinas' Participation in Breast Cancer Prevention Activities

While the literature examining ethnic minorities' participation in BC control is fairly large and continues to grow, the research on barriers to participation in BC prevention activities is limited at best (Giuliano et al., 2000). Previous research has identified barriers such as lack of trust and fear of the procedures that inhibit participation. In addition, socioeconomic factors such as lack of insurance and lower levels of education do not permit many ethnic minorities to take advantage of prevention activities available in the community. Socio-cultural barriers may influence ethnic minorities' perception of health care providers, which further reduces the likelihood of minorities utilizing services. Furthermore, when minorities do present in health care settings, the cultural paradigm they are accustomed to may account for differences in communication between patients and providers. Although there have been numerous hypothesis as to what barriers exist to Latinas' participation in prevention activities, there has been a neglect of how underlying processes influence Latinas' decision to participate in BC prevention, more specifically, BC prevention clinical trials.

Ethnic Minority Participation in Clinical Trials

Definition of Clinical Trials

Clinical trials have played a predominant role in furthering medical research. In general, clinical trials are designed to test the efficacy of particular protocols, medications, or prevention activities to increase survival and reduce illness. An example of the various types of clinical trials include those testing medications or protocols with medically ill patients in order to discover whether using this medication alters or improves health. Another type of clinical trial is one in which it tests whether a particular behavior or medication can reduce the likelihood of contracting a particular illness. When describing prevention clinical trials to potential participants and individuals at high-risk of developing cancer, scientist from the National Cancer Institute (1998) write:

> "Clinical trials, also known as clinical studies, are research studies in which people help doctors find ways to improve health and health care. Many of today's treatments for cancer are based on the results of past clinical trials. Examples include clinical studies to treat or prevent breast and childhood cancers. Because of progress made through clinical trials, many people treated for cancer are now living longer. In cancer prevention trials, people take medicines, vitamins, minerals or other supplements that doctors believe may lower the risk of a certain type of cancer."

Following this description these scientists proceed to delineate between prevention clinical trials and other types of clinical trials. This is a basic definition of studies testing the efficacy of preventative drugs from inhibiting the onset of particular diseases. Primarily clinical trials are useful in that they enable the government, for example the Federal Drug

Administration (FDA), to permit and regulate the distribution of various medications for the public. Prior to distributing a particular medication to the general public it must be examined in the controlled setting of a clinical trial for possible side effects and efficacy. Furthermore, ideally medications should be examined across different ethnicity's to test the generalizability of its distribution.

History of Ethnic Minority Participation in Clinical Trials

Since the 1940's ethnic minorities' inclusion in clinical trials has been minute and limited (Bull, 1959). Upon the inception of clinical trials, ethnic minorities, particularly African-Americans, and the underprivileged were over represented and mistreated in demonstrations, medical experimentation, and surgeries. A prime example of ethnic minorities' mistreatment in clinical trials is the Tuskegee syphilis study in the 1930's. During this study, 399 men signed up with the U.S. Public Health Service for free medical care. The service was conducting a study on the effects of syphilis on the human body and, at the time, the sexually transmitted disease was rampant in Macon County, Alabama. The men were never told they had syphilis. They were told they had "bad blood" and were denied access to treatment, even years after penicillin came into use in 1947. By the time the study was exposed in 1972, 28 men had died of syphilis, 100 others were dead of related complications, at least 40 wives had been infected and 19 children had contracted the disease at birth.

Women have been the recipients of unethical treatment throughout history with regards to medical decision-making subjected to mistreatment during clinical research. An example of women's mistreatment dates back to the 1800's when Dr. J. Marion Sims, "the father of modern gynecology," purchased black African slaves to practice gynecological surgical procedures prior to testing them on white women, (Gamble, 1993). During 1929, the U.S. Supreme Court ruled that impoverished, white, and unwed women could be sterilized without their explicit consent in effort to lower the production of "socially inadequate offspring" (Killien et. al., 2000). During the 1970's several reports were made of African American and Puerto Rican women who underwent unnecessary hysterectomies in the rural south, Boston, and New York, as a means of sterilization without their informed consent (Roberts, 1997). Women have been the participants of contraceptive studies around the world, particularly in impoverished countries with high illiteracy rates, such as Bangladesh, Pakistan, and Mexico (Hartman, 1995; Potts & Paxman, 1984). These and other scientific experiments that exploited ethnic minorities, specifically women, foster a sense of distrust in research and encourage ethnic minorities to heed caution when recruited to participate in a clinical study (Killian et. al., 2000).

After the 70's and early 80's public perception of clinical trials changed. These experiments began to be considered "state of the art" treatments, a change in attitude that led to a heightened prestige in participation. This shift resulted in the increased participation of higher-privileged individuals and limited participation of ethnic minorities (Byrd & Clayton, 1992). DeVita and colleagues (1989) raised the fact that currently clinical trials are the primary experimental approach used to examine the efficacy and safety of protocols and medications for cancer drug treatment. Participation in clinical trials is crucial to further understanding of medical interventions to enhance health and improve survival. However, it was not until 1990 that NCI addressed the problem of under representation of ethnic minorities in clinical trials. The Minority Community Clinical Oncology Program at NCI tried to improve the under representation of minorities in clinical trials. Participation rates in clinical trials in the general population are low, ranging from 3% to 20% (Swanson & Ward, 1995). Moreover, socially disadvantaged and ethnic minorities have been underrepresented in general in clinical research (Roberson, 1994).

Under representation of ethnic minorities was addressed as a critical issue during the congressional hearing on NCI's Breast Cancer Prevention Trial (BCPT). Among the main concerns was the failure to recruit adequate numbers of ethnic women for participation. Of the 13,388 women who participated nationwide in the randomized trial to evaluate the worth of the drug Tamoxifen for the prevention of BC, approximately 220 (1.67%) women were Black and 249 (1.89%) women were of "other" ethnic background, for a total of approximately 3.5% of ethnic minority women (Fisher et al., 1998). Of importance is that no strategic plan was developed to include ethnic minority women or improve accrual rates. Little discussion occurred on the reasons for why so few minorities participated in this study or on what are the implications of this under representation of ethnic minorities. However, these demographics raise questions regarding the generalizability of these results to ethnic minority populations.

A current example of the under representation of Latinas in clinical trials is seen in the Study of Tamoxifen and Raloxifene (STAR). STAR is a clinical trial that is currently being conducted throughout the United States (NCI, 1999). STAR began on May 25, 1999, to compare two drugs, Tamoxifen and Raloxifene, for their effectiveness in reducing the occurrence of BC. STAR expects to include 22,000 participants nationwide in its clinical trial including a representative number of ethnic minorities across states. In Colorado, enrollment of ethnic minority women to clinical trials such as STAR has been recognized as a priority (Raich, 1999). Strategies (e.g., ensuring community involvement in program development and implementation) have been suggested to significantly improve the recruitment and retention of ethnic minority women to cancer clinical trials in order to decrease mortality from cancer and improve survival for these women (Krebs, 1999). However, it is recognized that in spite of these efforts ethnic minority women continue to be underrepresented in cancer prevention clinical trials. Many significant barriers to joining clinical trials for Colorado ethnic minority women still exist, including socioeconomic, logistics, and a misunderstanding of the scientific community (Bunn, 1999).

Throughout this study, the STAR clinical trial was used as a reference point for participants. Implications of referring to a clinical trial that is being conducted within Colorado include: increased recruitment of Latinas into the STAR clinical trial in Colorado and increased awareness of a community effort toward BC control activities. Findings produced from this study may facilitate the increase in recruitment of Latinas into the studies like the STAR clinical trial in Colorado and other studies throughout the United States.

In conclusion, the implications of the under representation of minorities in clinical trials are endless. The acceptance of pharmaceuticals in drug market without adequate testing across ethnicities is hazardous. It seems unwise, however accepted, to prescribe medication to the general public when it has only been tested on a select segment of the public population.

Socio-demographic Barriers to Minority Participation in Clinical Trials

The majority of participants in clinical research is White, middle class, highly educated, and married men. Giuliano and colleagues (2000) summarized three factors that have been hypothesized to contribute to the under representation of ethnic minorities in clinical trials research. Structural, cultural, and linguistic factors are discussed. Structural factors are those primarily related to logistical requirements of participation (e.g. time, cost, transportation) and socioeconomic factors. Socioeconomic factors play a significant role in this phenomenon particularly because lack of economic means limits access to health care, lack of insurance coverage impedes participation in trials and economic survival takes precedence over health care prevention in these populations. It has been demonstrated how socioeconomic status constructs a hierarchy such that individuals from lower socioeconomic status prioritize basic needs such as food and shelter over health care prevention activities.

Lastly, considering that English is the predominant language in the United States and some minorities do not speak, read, or understand English proficiently, linguistic factors contribute to the lack of participation of minorities in clinical trials. Linguistic factors are considered major barriers to participation in health care activities because communication and relaying of information between patients and medical staff is often faulty. Furthermore, the level of health literacy necessary to fully understand the purpose and procedures involved in clinical trials excludes many individuals from participating due to health literacy and socio-economic inequalities.

Socio-cultural Barriers

Barnouw (1979) defines culture as "the way of life for a group of people, the configuration of the patterns of learned behavior that is passed down to generations through language and imitation" (as cited in Giuliano, 2000). Cultural influences on health care practices may include behaviors such as seeking alternative medical, like from healers as opposed to traditional western medical care due to distrust in medical practitioners. Culturally insensitive provision of health care often does not acknowledge cultural factors and inhibits access to health care services.

As the number of ethnic minorities in the United States continues to rise, the urgency for public health agencies to provide culturally sensitive care increases. By the year 2010, it is estimated that Hispanics will represent 13% of the U.S. population reaching 39 million, a considerable increase from the percentage of the Hispanic population in the last census. Considering this dramatic increase, health care providers should be proactive in their assessment and handling of health issues when working with this population. Minorities in general are less likely to participate in clinical trials than Caucasians. A pervasive pattern of minority under representation appears to exist in what are considered positive health behaviors. For example, Latinas are less likely to utilize health care services than their White counterparts (Millon-Underwood, Sanders, & Davis, 1993). Earlier it was suggested that Latinas participate less in BC screening and detection that non-Latina women. Consequently, Latinas are more likely to die from BC due to the detection of BC at later stages. As the United States expands in its diversity, it is becoming more difficult to overlook the necessity for cultural sensitivity in health care services.

Patient-Provider Communication Barriers

Often medical staff use terminology that patients, particularly ethnic minorities or individuals with less education, do not understand. This faulty communication leads to feelings of depersonalization by the patient (Kaufman, 1970). Additional factors that may contribute to faulty communication between patients and medical providers include not listening and baby talk. Beckman and Frankel (1984) studied 74 office visits. In only 23% of the cases did the patient have the opportunity to finish his or her explanation of concerns before the provider began the process of diagnosis. In 69% of the visits, the physician interrupted the patient and asked questions leading to a particular disorder. Rather than using technical terms and jargon, medical practitioners may also underestimate the knowledge patients have regarding a particular disorder or procedure, resulting in the use of baby talk (Waitzkin, 1985). This miscommunication between patients and clients impedes the building of rapport and in turn may affect treatment compliance or utilization of medical services in the future (Ross & Duff, 1982).

Implications

The fact that few minorities participate in clinical trials (Byrd & Clayton, 1992) necessitates the identification of avenues of intervention to improve recruitment and retention strategies. To understand what changes must be made to increase the numbers of Latinas participating in prevention clinical trials, investigations must be conducted to explore the decision making process of Latinas. This area is a relatively new area of exploration, therefore qualitative methodology is an optimal approach to build an understanding of Latinas decision-making process to participate in BC prevention clinical trials. In this study, the use of open-ended questions during interviews provided access to participant's decision-making process, which counteracts restrictions and biases often inherent in quantitative studies that utilize questionnaires.

Research Questions

The primary goal of this study was to answer the question: How do psychosocial and cultural factors influence Latinas' participation in BC prevention and control activities, and in particular clinical trials? More specifically this question was answered by exploring the following clusters of questions:

Question 1: At what stages of community readiness are the participating communities with regards to BC prevention and control activities?

Question 2: What is the relationship between community leaders and members in efforts to increase Latinas' participation in BC clinical trials?

Question 3: How do Latinas perceive BC clinical trials and how do these perceptions influence their willingness to participate in these studies?

Question 4: What are the specific cultural factors (beliefs, values, and norms) that play a role in deciding to participate in BC clinical trails among Latinas?

Question 5: When provided information regarding BC prevention clinical trials, what specific factors influence Latinas' decision to participate in these studies?

Question 6: Assuming a Latina woman has decided to participate in a BC prevention clinical trial, what factors (logistical or cultural) would encourage retention in the study?

To address these questions a qualitative study was conducted. Key informant interviews, focus groups, and semi-structured interviews were conducted in four communities throughout Colorado. These interviews were analyzed using grounded theory methods and content analysis in an effort to gain a theoretical understanding of the barriers to Latinas participation in BC clinical trials.

METHOD

Overview

In order to examine the socio-cultural variables that influence Latinas' participation in BC clinical trials, this study involved three stages. First, 19 key informant interviews were conducted in four communities throughout Colorado, two urban (Denver and Fort Collins) and two rural communities (Greeley and San Luis). These interviews assessed the level of community awareness of BC prevention and control activities in general and in particular clinical trials. Interview questions and methodology used during this stage derived from the Community Readiness Model developed at the Tri-Ethnic Center for Prevention Research at Colorado State University. Next, focus groups were conducted in each of the four communities, recruiting 48 Latinas 50+ years of age. These focus groups were designed to assess Latinas overall perceptions of BC clinical trials and their potential participation in them. To explore Latinas' perceptions of BC prevention clinical trials in particular, 14 semi-structured interviews were conducted. Interviewees were selected using theoretical sampling techniques. Semi-structured interviews targeted Latinas who were underrepresented in the focus groups by age or other sociodemographic criteria.

The data gathered from the focus groups and semi-structured interviews were analyzed using grounded theory procedures (Strauss & Corbin 1999). Considering that minimal research that has been conducted in this area, a grounded theory approach to analysis was deemed appropriate because it is a focused and in-depth analysis. The strength of grounded theory lies in developing theory grounded in the data, or directly from the target population, in this case, Latinas throughout Colorado.

Guiding Theoretical Framework

Community Readiness Model

The Community Readiness Model (CRM) developed at the Tri-Ethnic Center for Prevention Research at Colorado State University guided the methodology and foundation of this project. In 1991, Mary Ann Pentz, director of the Midwest Prevention Project, presented a paper at the Kentucky Conference for Prevention Research. This paper suggested that if a community was not ready, initiation of programs were likely to fail (as cited in Edwards et al. 2000). This paper ignited the researchers at the Tri-Ethnic Center to reflect on past work in communities and begin examining this concept. In 1995, Oetting et al. extrapolated from Prochaska and DiClement's Transtheoretcial Model (DiClemente & Prochaska, 1982; Prochaska & DiClemente, 1983) to assess a community's level of readiness to address a problematic concern. The Transtheoretical model demonstrated that an individual's readiness to participate in psychotherapy was an essential component to initiating an effective treatment plan. The model includes five stages of readiness for personal change from precontemplation to the final maintenance stage.

The CRM was initially developed to be an assessment tool for research and applied practices in the alcohol and drug abuse arena. The CRM has many similarities to the Transtheoretical Model; however, the CRM is tailored to address group dynamics involved in creating change. For example, the influence of community leaders is an essential component to a community's readiness to change. It is not a component of an individual's readiness. Prochaska and DiClemente's (1983) model did not differentiate between stages of readiness at the group or community level and therefore the CRM incorporated this aspect. Also, unlike the Transthereortetical Model that assesses individual problems in a uni-dimensional fashion, the

CRM addresses problems in a multidimensional scope that includes all facets of a community, such as the role of community leadership and the willingness of community members to participate in program installation. Although the CRM model differs from the Transtheoretical Model, the core component of readiness for change is applicable to the need for readiness for change at the community level.

The construct of "community readiness" also stemmed from the early work in community development from Rogers' (1983) set of stages for the decision-making process in making behavioral changes such as weight management. These stages included knowledge (initial awareness of an innovation), persuasion (changing attitudes), decision (adopting the idea), implementation (trying the idea), and confirmation (when the idea is implemented or discontinued after initial trial). This theory was compared to Warren's (1978) model of social action, which is a community approach that focuses on group processes. Warren's stages include: stimulation (recognition of a problem or need), initiation (definition of the problem and problem solving among community members for possible resolutions), legitimization (when community leaders acknowledge the need for action), decision to act (development of specific plans to involve select community members), and action (implementation of the plan). In contrast to Prochaska and DiClemente's model (1983), Warren's plan considers group processes. However, Warren's model neither adequately defined all the stages of community readiness for change nor did he address the multidimensional aspects involved in the process of change. In development of the CRM, Wandersman (Hallman & Wandersman, 1992) composed terms such as "coalition readiness" that focused on community and environmental stress and how these factors inhibit "community motivation."

Community motivation is a similar construct to community readiness in that it ascertains community climate. Included in community climate are distinct aspects of individual climate, participant climate, and organizational climate. These authors suggested that these climates were "catalysts for action" and added that a sense of community has a catalytic effect on community action (Chavis & Wandersman, 1990, Florin, Giamartino, Kenny, & Wanderman, 1990). The works of Rogers (1983), Warren (1978), and Wanderman (1992) described the change process among groups; however, they did not fully compose a theoretical model of community readiness for change. The Tri-Ethnic Center ultimately composed the community readiness theory that captures dimensions of "community readiness" and developed specific interventions that are tailored to a community's specific level of readiness for change. The CRM can be considered a theoretical model that primarily provides insight into the process of change in communities.

Similar to the Transtheoretical Model, the CRM assesses community readiness on a continuum of stages. These stages include no awareness, denial or resistance, vague awareness, preplanning, preparation, initiation, stabilization, confirmation/expansion, and professionalization stages. At the *no awareness* stage community members do not recognize that there is a problem. The goal at this stage is to raise awareness of the problem and its impact on the community. The *denial* or *resistance* stage describes when a community has little recognition of a problem or is actively resistant to addressing it. If there is recognition that a problem exists then there might be a general feeling that "it's not our problem" or "we can't do anything about it." At this stage the goal is to raise the awareness that the problem exists and affects the community. The *vague awareness* stage of readiness suggests that a few community members are aware of the problem and that something should be done to address the problem; however, there is no immediate motivation to act towards solving the problem. Leaders in the community are not influenced by the community climate or concerns expressed by community members. Interventions at this stage include forming groups and raising the motivation in the community climate by encouraging community members that they can do something to address the problem. The next stage in CRM is the *preplanning* stage of readiness for change. At this stage there is clear recognition of a local problem and that something should be done about it. Leaders can be identified and a committee to address the problem may have already been developed. However, at this stage there is no definite plan of how to address the problem. As community members begin to address the problem, the goal is to fully assess the problem and begin planning the means of addressing the problem.

During the *preparation* stage of community readiness, planning is in process and practical details are being addressed. The pros and cons of the plan are being explored and leadership is active. Resources are being sought to provide financial and skilled support is being utilized. At this stage interventions include gathering data based on research methodology, planning a resolution, and prioritizing the needs of the project. Once adequate information has been gathered to justify the efforts for change, action takes place during the *initiation* stage of readiness. Leaders may be initially enthusiastic because no problems have arisen and the community climate is fairly supportive of the endeavor to take action. At this stage communities should focus on the details and purpose of the plan and conduct outreach programs in the community to integrate community members in the change process. As programs are running and have the administrative support necessary to maintain a stable status a community is described as being in the *stabilization* stage of readiness. At this point there is no perceived need for expansion of existing programs and the community climate is generally supportive. The primary goal at this stage is to stabilize efforts of the program.

After the program has been evaluated, efforts may be made to expand services to underserved areas during the *confirmation/expansion* stage of readiness. Resources may be sought to provide financial and other tangible support to expand the program and to serve more community members. Although community climate may challenge specific limitations of expansion plans, the climate is fundamentally supportive. The goal at this stage is to sustain and enhance current programs. During the final stage in the CRM, the *professionalization* stage, sophisticated data regarding the risk or the problem and how the intervention has addressed the problem has been gathered. Action targets specific local community members and perhaps the population at large. Although community involvement is high and community climate is generally supportive, community members should act diligently to hold programs accountable to working according to their mission statement. At this stage, communities should work towards maintaining and expanding existing programs.

The CRM provides a theoretical framework with which to design scientific investigations, assess a community's level of awareness of particular problem, and provide tangible solutions to address the problem at hand based on community members' input. This model has been utilized in an array of areas. Early examples of the utility of the CRM include examining alcohol and drug abuse programs (Plested, Smitham, Thurman, Oetting, and Edwards, 1999) and most recently the model assessed community readiness surrounding HIV/AIDS (Plested, Edwards, Jumper-Thurman, in press). The CRM has proven to be a flexible model with wide applicability.

In addition to being used to assess a variety of community problems, the CRM has also demonstrated to be a culturally sensitive model to work with ethnically diverse communities. Although Western values and beliefs root many of the research assumptions of the CRM regarding effective community action, such as project mobility and progression, the model is applicable to non-Western cultures as well. As stated by Thurman, Edwards, and Plested (in press), "...while community readiness theory is not culture-free, it is more importantly, culture-embracing. It encourages the development of creative cultural strategies." Examples of this can be seen in past work in Native American tribes. Considering that a means of evaluating a program's implementation within the Native American community may be more culturally appropriate in a storytelling manner, rather than via focus groups, culturally appropriate means were utilized. That is, "talking circles" were used to gather information in a circular fashion in line with Native America culture, rather than a more linear fashion typically endorsed by Western culture.

Participants

Key Informant Interviewees

The community readiness model assesses a community's level of readiness by talking to key informants in each community. Eight key informants were interviewed in the rural communities (four in San Luis; four in Weld County) and eleven interviews were conducted in the urban communities (six in Denver; five in Ft. Collins). Key informants are leaders in a community who work closely with community members and can provide informed opinions regarding the problem in question. The first four key informants on each community were chosen from among representatives of 1) the medical profession (often a public health nurse); 2) the spiritual community (often a spiritual leader); 3) alternative medicine community (often a healer); 4) social services; and 5) elders. In small rural communities, community leaders do not always hold formal roles, so in this study we attempted to ascertain who held the informal parallel roles and then contacted them. Key informants included: community organizers, curanderas (Hispanic medical practitioners), public health nurses, nuns, representatives from the health department, teachers, and community leaders working with Colorado State University's Agricultural Extension Program.

Focus Group Participants

During the next phase of the study four focus groups were conducted with 48 Latinas over the age of 50+ (mean=64.2) that are demographically representative of each community regarding language spoken in the area and SES (see Table 1). Of the participants 40% were bilingual, 33% spoke only Spanish, and 27% were primarily English speakers. Latinas were selected based on what language they spoke, self-identification as Latina, and suspected socio-economic status based on community profiles.

Table 1.

Descriptive Data for Sociodemographic and Acculturation Variables of Focus Groups

Variable/Group	M	SD	F(3,47)
Age (years)			
Denver	61.6	8.30	1.34
Ft. Collins	66.4	10.24	
Weld County	67.1	6.98	
San Luis	70.1	5.98	
Education (years)			
Denver	3.1	2.07	.649
Ft. Collins	9.9	3.57	
Weld County	9.1	6.98	
San Luis	11.6	3.87	

Income (annual) [a]			
Denver	1.83	.83	.933
Ft. Collins	1.78	.97	
Weld County	1.78	.97	
San Luis	2.14	1.07	
Acculturation [b]			
Denver	1.22	.44	.562
Ft. Collins	2.56	.91	
Weld County	2.66	.86	
San Luis	3.22	.86	

Note: Denver (n = 15), Ft. Collins (n = 13), Weld (n = 10), San Luis (n = 10). [a] Income: 1 = <$5000, 2 = $5000 to10000, 3 = $10001 to 20000, 4 = $20001 to 40000, 5 = >$40000. [b] Acculturation: 1 = low acculturation level, 5 = high acculturation level.

Semi-Structured Interviewees

A total of 14 semi-structured interviews were conducted throughout the four communities where the key informant interviews and focus groups were conducted (see Table 2.). The purpose of the semi-structured interviews was to provide information regarding their perceptions of specifically BC prevention clinical trials. The interviews were composed after initial analysis of the focus group revealed specific areas of concern regarding BC clinical trials. The interviewees were asked primarily close-ended questions that were geared towards gaining an understanding of their specific perceptions of participating in BC prevention clinical trials.

After preliminary analysis of the focus group data, it was found that those women who were of lower SES, spoke primarily Spanish, and over the age of 65 years old were under represented. Thus, the individual interviewees were selected according to the demographics that were underrepresented in the focus groups. Because of the criteria under which interviewees were selected created transportation and childcare barriers, participants were typically interviewed in their residence.

Table 2.

Descriptive Data for Sociodemographic and Acculturation Variables of Semi-Structured Interviews

Variable/Group	M	SD	F(3,13)
Age (years)			
Denver	66.2	10.26	.715
Ft. Collins	62.25	8.02	
Weld County	67.0	10.82	
San Luis	74.0	4.24	
Education (years)			
Denver	14	8.2	1.299
Ft. Collins	6	3.37	
Weld County	11	1.0	
San Luis	5.5	3.54	
Income (annual) [a]			
Denver	1.8	.84	5.05*
Ft. Collins	1.25	.50	
Weld County	3.0	0.0	
San Luis	2.0	0.0	
Acculturation [b]			
Denver	2.08	.99	2.28

Ft. Collins	2.4	.97
Weld County	3.6	.53
San Luis	2.9	.70

Note: Denver (n = 6), Ft. Collins (n = 4), Weld (n = 2), San Luis (n = 2). [a] Income: 1 = <$5000, 2 = $5000 to10000, 3 = $10001 to 20000, 4 = $20001 to 40000, 5 = >$40000. [b] Acculturation: 1 = low acculturation level, 5 = high acculturation level.
*$p < .05$.

Procedures

Rationale for Location of the Study

The locations of the interviews and focus groups were chosen based on the density of Latinas in both rural and urban areas throughout Colorado (Denver, Ft. Collins, Weld County, and San Luis). According to the 2000 Census, Weld County and San Luis had the highest population of Latinos per capita for rural areas (www.census2000.org). Of the urban areas in Colorado, Denver had the highest population of Latinos per capita. Although Fort Collins and Colorado Springs had comparable populations of Latinos, Fort Collins was chosen as a convenient location to conduct all three phases of the study.

Key Informant Interviews

In each community four or five key informants were interviewed separately. The fifth interview typically adds no new information over that already obtained in the first four interviews, but if it does and more clarification is needed then a sixth interview would be conducted and so on. Two additional interviews can be conducted when data from the original five interviews are inconsistent in any regard. Recent TEC experience in conducting the Community Readiness Interview in over 600 similar-sized communities has shown that only rarely are more than five interviews necessary (Edwards et al, 2000).

An interviewer telephoned community agencies to identify potential key informants. Upon contacting these individuals, the interviewer further assessed their leadership involvement with Latinas in the community. Based on this assessment, the interviewer decided the appropriateness of this leader as a key informant and an appointment was made. Once an initial contact was made in each community, each key informant was asked to provide referrals of possible other key informants. This process led the investigators to interview individuals who work closely with the Latino community and who provided insight into how the community members worked with community leaders to address the issue of BC prevention and control.

The Community Readiness Model interviews addressed the following six dimensions: community climate and attitudes about BC; community knowledge about the lack of Latinas' participation in BC clinical trials; community efforts to encourage participation in prevention programs and activities; community knowledge of these efforts; the knowledge and involvement of leaders; and what resources (e.g. money, transportation) are available to facilitate BC prevention and control activities (see Appendix A).

The information gathered from the interview acknowledges the extent of the problem by first examining the key informants knowledge and perceptions of BC prevention and control. Next, participants were asked how willing community leaders are to address and remedy a particular problem. If leaders are not willing to work towards problem solving, it provides obstacles to community members to initiate strategies themselves. Key informants were further probed for what resources were available in the community to address the issue of BC prevention and control. Throughout these discussions, participants were asked additional questions to get a better sense of how willing the community was to integrate any programs that facilitate BC prevention and control in their community. Each interview followed a similar format, however when possible, key informants were probed further for cultural barriers often not considered in addressing health issues with ethnic minority women.

The interviewer met the key informant at a location most convenient to them (e.g. the agency, home, or nearby coffeehouse). Each key informant interview took approximately 20-40 minutes to conduct, depending on how expansive interviewees were in their answers. The interview transcript took approximately 15 minutes to score. Interviews were conducted in either Spanish or English, depending on the preference of the key informant. Three of the interviews were conducted in Spanish while the remainders of the interviews were conducted in English. Key informants were not reimbursed for their time. Instead, their service was considered a benefit to their role as a community service provider. These interviews were seen more as a collaborative effort for data gathering to benefit the community.

Each interview was transcribed and scored using the Community Readiness Model (see Appendix B & C). Two graduate research assistants were trained by the Community Readiness Specialist at the Tri-Ethnic Center on how to score each of the interviews. These interviews were further analyzed for themes that provide explanations for the cultural variables or factors that influence

After completion of the interviews for each community, the interviewer spent approximately thirty minutes with the Community Readiness Specialist, Barbara Plested, one of the developers of the scale, to review the key informants' responses and confirm the scoring. At this time, a decision was made about whether more interviews were necessary. After scoring of the key informant interviews was complete, no additional interviews were deemed necessary. Although the interview process itself was relatively quick and efficient, considerable time was spent in identifying and contacting key informants and setting up times when the person was available for an uninterrupted interview.

Focus Group Interviews

The focus group is a unique group in regards to its purpose, size, composition, and procedures. Focus groups generally include seven to ten participants who may or may not have been acquainted with each other prior to the group's meeting (Krueger, 1988). Although earlier research suggested that prior relationships between focus group members was detrimental to the nature of the group, later research demonstrated no significant output difference between groups which include acquaintances and strangers in terms of the quality or quantity of the group output (Nelson & Frontczack, 1988). Focus group participants are typically selected according to the research question at hand. In this study, focus group participants were selected according to their ethnic identity as being Latina, their age being over 50+ years old and being considered representative of the community by community leaders or previously interviewed key informants.

The investigator collaborated with previously interviewed key informants to recruit approximately 8-12 women from each community. Considering the established relationship with the community, the key informant often contacted and recruited potential participants of the focus group according to established criteria, while the investigator managed the logistics of the group such as meals, transportation, childcare, and incentives. However, when needed the investigator retrieved a list of referrals from key informants or community leaders and recruited participants via telephone.

Recruitment was conducted in either English or Spanish, and depending on the preference of the participants, they were assigned to either an English or a Spanish group interview. Participants were informed about the purpose of the study, what was required of their participation, the incentives they would receive, and the date and location of the group. Focus group participants were primarily recruited through Catholic churches in each community. Considering the role the church plays in the Latino tradition, the church was seen as a convenient, familiar, and safe meeting place in the community. While participants were individually recruited, additional reminders such as flyers posted at the church and announcements made during Sunday mass were used to increase the likelihood of participation in the groups.

Possible barriers to participating in the focus group may have been time, transportation, and childcare. The time of the focus group was occasionally changed to better suit the participant's schedules. If a lack of transportation inhibited interested women from participating in groups, efforts were made to arrange for pick-up and drop-off. Often recruited participants were acquaintances of other members of the group and car-pools were arranged to transport individuals who required assistance. If needed, the focus group was conducted at the residence of the individual without transportation and those with transportation met at this residence rather than at the church. Lastly, if childcare inhibited participation in the focus groups, participants were encouraged to bring the child to the group and a research assistant provided childcare for them at no charge.

Focus groups were conducted in an environment that could be considered safe by the participants. Because of the strong involvement of the church in the Latino community, churches' dining halls or gathering rooms were often the locale for the groups. The environment during the focus group was created to be an open dialogue between the focus group participants and the interviewer.

Two researchers attended each focus group. The moderator of the focus group interviews (FGIs) was primarily concerned with directing the discussion, keeping the conversation flowing, and taking minimal notes. An assistant investigator took comprehensive notes of the focus group participants' comments. The assistant was in charge of handling the environmental conditions and logistics (e.g., lighting, and seating). In addition, the assistant was cautious of the time during the focus groups to ensure coverage of all the questions of interest. Lastly, the assistant operated the tape recorders and placed the microphones in non-intrusive areas of the room. Two tape recorders were used to ensure a more comprehensive record of the focus group sessions.

The focus groups were approximately two hours in length and were conducted in Spanish or English depending on the personal preference of the group. The time of the group was tentative until a time that was convenient for a majority of the women interested in participating was confirmed during recruitment conversations. Once a final date and time of the group was set, participants were contacted by phone and their participation was confirmed.

As participants arrived they were asked to wear a nametag and to complete a two-page demographic questionnaire written in English or Spanish (described below in the measurements section, p.41). If the participant was unable to read, the investigator orally asked the questions on the form and completed the form in their stead.

Each group began by serving a meal and refreshments. Food was prepared by the investigator or catered by a local restaurant recommended by the key informant who helped plan the group. This time provided an opportunity for the focus group leaders to build rapport with the participants. The building of rapport is valuable for the focus group discussions to be open and honest. Considering the sensitivity of the topic of BC, a level of trust should be established prior to in-depth discussions concerning personal experiences and perceptions of BC and BC prevention. Next, the focus group leader reviewed the informed consent procedure and responded to any questions participants had concerning the purpose and procedures of the study (See Appendix D & E).

Rules concerning group conduct were established at the beginning of the FGI to facilitate the group discussion. These rules included 1) all women are invited to participate; 2) only one person speaks at a time; 3) make sure comments address the issue; 4) every person's comments are important; 5) everything said will be kept confidential. The focus group began with less intimidating questions and progressed by probing for more specific information to answer the research questions. Initially each participant was called by name to respond to an icebreaker question and eventually the flow of the group discussion was such that women contributed their opinions to questions asked in a systematic and orderly fashion. While questions for each focus group were similar in format, minor modifications were made in future groups according to theoretical sampling procedures to facilitate the answering of the research questions.

The group ended with an information and question session concerning BC. This time allowed the participants to provide their opinions regarding current BC prevention programs in their communities as well as increase BC awareness. Each interviewer, knowledgeable about STAR, provided verbal and written information about the STAR clinical trial to all women regardless of their BC risk factor. The information provided included brochures about the clinical trial as well as phone numbers and addresses of people to contact from Colorado Cancer Research Program, CCRP. Providing information regarding the STAR clinical trials provided an opportunity to increase awareness about BC prevention. Considering that many Latinas become informed about health via social interactions, it was anticipated that women in the focus groups would share BC information provided during the group with their peers who may be at a high risk for BC. However, the focus groups were not designed to recruit participants for the STAR trial, therefore names of participants in the FGIs were not given to CCRP.

Lastly, incentives worth $25 dollars were distributed to each participant and when appropriate to the facilitators of the focus groups (e.g. a community organizer from Denver assisted in forming the group and hosted the group at her residence). Incentives included a tote bag, an apron, and a T-shirt with the CSU logo. In addition, literature on BC risks, prevention, and information about the STAR clinical trial was included in the tote bag. Literature was distributed in the language in which the focus group was conducted.

Questions and Probes for Discussion during Focus Groups. Data collection from the focus groups supplemented the key informant interviews by providing target community members' perceptions on issues related to BC prevention and control. Discussions included topics such as: beliefs about aging and BC; awareness regarding the incidence of BC in their communities; prevalent perceptions among Latinas about their own risk for BC development; the cultural beliefs regarding the nature, prevention, and treatment of BC; women's perceptions and knowledge about BC and BC prevention clinical trials; community's perception, attitudes, and acceptance of women's participation in clinical trials; perceived barriers (cultural, psychological, physical) to participation in clinical trials; women's willingness to participate in clinical trials; and the reasons given by women at high risk regarding their lack of participation.

Discussions were also geared to explore Latinas' perceptions of potential barriers (psychological, cultural and physical) to participation in both BC control (e.g. mammogram) and prevention (e.g. clinical trial) activities. The use of open-ended questions was intended to provide liberty among discussants in expressing their personal views (See Appendix J). An example of a focus group question and probe is:

If you heard that a group of doctors created a pill that could keep you from developing BC, would you take it?

(Probe: What if that doctor thought that this pill could prevent BC but were testing it with some women to see if it really worked? Would you be willing to be part of such experiment/tryout?)

(Probe: What if you had indeed developed BC, would you be willing to take a pill that they were testing to see if it could cure your cancer? Would you be willing to be part of such an experiment/tryout?)

As the researchers discussed the answers obtained in each FGI's during a processing meeting, the questions were modified for future FGI's in order to clarify inconsistencies or topics not fully understood based on the information obtained. In addition, theoretical sampling was conducted after each focus group to determine the sociodemographic profile of the participants that would be recruited in future groups.

Semi-structured Interviews

Semi-structured interviews were used in the last phase of grounding and strengthening the evolving theoretical framework that began with the key informant interviews and FGIs. We conducted interviews in communities where readiness level was below the *preplanning* stage and where there was an indication that the problem of lack of participation in BC clinical trials exists. Although unlikely in these populations, it was possible that in some communities there may be what appears to be a low readiness level because the problem truly is rare and a community-wide prevention effort would be superfluous.

The target population for interviews was Latina women living in the four communities where the key informant interviews and focus groups were conducted. The individual interviewees were selected according to what data were further needed after conducting the first round of phase two interviews. Although the primary goal of this project was to understand the barriers that women at high risk may face, we did not recruit women who were known to have a high risk of BC (e.g. based on family history, personal history of cancer, etc). However, it is possible that participants may have included women who are at high risk or who might have had some form of cancer.

In order to examine the social-cultural influences of Latinas' participating in BC control and prevention activities within each Hispanic community, levels of acculturation and SES were accounted for by using the same demographic questionnaire that was distributed during the focus group interviews (see measurements section, p. 41).

The questions included in the semi-structured interviews were more focused and guided by theoretical sampling (Strauss & Corbin, 1990). The use of close-ended questions followed by probes provided a structured interview and guaranteed that specific research questions would be answered (See Appendix K). An example of a semi-structured interview question and probe is:

> Do you believe that this pill developed by scientists and doctors can *indeed* keep you (or women at "high risk") from developing BC?
>
> (Probe: that it really works to prevent that you will develop BC?)

All interviews were transcribed and then responses were constructed or bounded into a preliminary set of categories based on established procedures for qualitative data reduction (Denzin & Lincoln, 1994; Miles & Huberman, 1984; Spradley, 1979).

Measurements Used

Participants in the focus groups and semi-structured interviews were asked to complete a socio-demographic questionnaire (see Appendix H & I). This questionnaire probed for the following: a previous history of cancer in themselves or any blood relative; health education concerning BC and clinical trials; sociodemographic information (e.g. age, level and locale of education, health insurance coverage, and personal income,); BC screening behavior (e.g. frequency of BSE, mammograms, pap smear); participation in clinical trials (e.g., prevention and treatment trials); and level of acculturation.

Participant's level of acculturation was assessed using Elder et al. (1991) modified version of Cuellar et al. (1980) Acculturation Rating Scale for Mexican Americans (ARSMA; Cuellar, Harris, & Jasso, 1980). This scale assessed four main dimensions to measure acculturation as a uni-dimensional construct. These dimensions included: the language participants prefer to speak and read (Spanish, English, or both); the geographic area where they were raised (Latin America, United States of America, or both); the ethnicity of their social network (Hispanic, non-Hispanics from the U.S.A., or both); and how much pride they have in their Latina heritage. The items of the ARSMA appeared to be a valid measure of acculturation with this sample. Elder et al.'s (1991) modified five-item acculturation scale had an alpha internal consistency of .80. In this study, one item that had little variability in responses among the participants (rated at the high end by almost all participants) was deleted to obtain an internal consistency of .89.

Data Analysis

Descriptive Analyses

The demographic questionnaires were analyzed for means and frequencies of the sociodemographic variables and BC screening behaviors. Mean scores from the ARSMA from focus group and semi-structured interview participants were used to provide a level of acculturation to mainstream or dominant US society. These quantitative data allowed for demographic comparisons between census data and the representativeness of the focus group sample. An ANOVA of the differences between the participants of the focus groups and the semi-structured interviews only revealed a significant difference between the time participants received their last pap smear (F = 14.19 (1,50)). Therefore, to explore the relationships between age, SES, acculturation, and screening behaviors, the data from both the focus groups and semi-structured interviews were merged (see Table 3.)

Table 3.

Relationships Between Sociodemographic, Acculturation, and BC Screening Variables

	BC Screening Behaviors			
Demographic Variables	1	2	3	4
Age	-.14	.08	-.01	.21
Education (years)	.25	-.32*	.02	.23
Salary	-.02	-.23	.02	.07
Acculturation [a]	.10	-.30*	.14	.36**

Note: n=50. BC screening variables: (1 = BSE past year), (2 = BSE past month), (3 = last mammogram), (4 = last pap smear). [a] Acculturation score is an average score of the five items from the ARMSA scale. *p = < .05, **p = < .01.

Analysis of Key Informant Interviews

Key Informant interviews were scored using the Community Readiness Model. Each of the six dimensions assessed were scored on a scale of 1-9 for a stage of readiness. These nine stages include 1) no awareness; 2) denial; 3) vague awareness; 4) preplanning; 5) preparation; 6) initiation; 7) stabilization; 8) confirmation/expansion; 9) professionalization. All the key informant interviews for each community were averaged to arrive at one score for each dimension. Based on the training received, the two trained raters compared their assessments to arrive at an agreed score. The average of the two raters' scores should provide a valid assessment of the level of readiness of each community revealed by the key informant interviews. Each community was assessed for its respective stage of readiness along the six dimensions of the CRM (e.g. community climate; knowledge of BC; efforts towards prevention; knowledge of these efforts; involvement of community leaders; and available community resources).

Qualitative Analysis

The grounded theory approach developed by Strauss and Corbin (1990) was used to reveal themes that evolved from the focus group interviews. Grounded theory is a method of developing theory that is grounded in the data systematically and analyzed. Through the various stages the process of grounded theory involves making constant comparisons, asking of theoretical questions, coding and developing theory. While Strauss and Corbin (1999) provide a general outline of the method of grounded theory analysis, the process is not linear, rather it requires flexibility between stages. However, the main procedures involved in grounded theory will be explained here to illustrate how the interviews were analyzed. This process aimed at revealing themes that encompass the cultural as well the human aspects embedded in Latinas' perceptions of and decision to participate in BC clinical trials.

Stage 1: Data Collection. The process of grounded theory begins with collecting data from which theories emerge and guide further areas of exploration. The concept of Symbolic Interactionism (Blumer, 1969) suggests individuals organize thoughts based on social interactions with others and past experiences. Therefore, theory should be understood within an interactional social context to grasp the phenomena in question. Focus groups are effective methods of providing a social arena in which participants can process and organize questions posed to them. Focus groups were the primary source of data collection in this study to understand the variables that influence Latinas participation in BC clinical trials within the social context of their communities.

Stage 2: Transcription of Data. Transcription of data involves the arduous task of listening to the tapes of the interviews and transcribing the content into written words. This stage of the project was time consuming and required many hours. Debates have occurred questioning what parts of the data should be transcribed. Considering that on average each two-hour interview produced 40-50 pages of transcriptions, Millward (1995) suggests that only the parts of the interview that illustrate the question at hand should be transcribed. However, others (Bartlett & Payne, 1997; Strauss & Corbin, 1990) suggest that the whole interview should be transcribed, particularly in earlier stages of theory development so as to consider the interview as a whole as an illustration of responses to the phenomena in question.

In this study, the full interviews and focus groups were transcribed throughout the data collection process. Graduate and undergraduate research assistants collaborated with this stage of the process using identical format to provide consistency among transcriptions. Transcribers assigned numbers to each speaker to distinguish between speakers for future reference. In addition, each line of transcription was numbered to facilitate the future coding process. The coding process used photocopies of each transcription to cut and paste comments that reflect themes related to core concepts. A manual coding process was utilized as opposed to a computerized coding process.

Stage 3: The Development of Categories. This process lies at the core of data analysis using grounded theory. This stage involves the identification and definition of the main categories that have emerged through the data. Categories are developed using a method called "open coding." Open coding techniques as specified by Strauss and Corbin (1999, pp. 101-121) were utilized for this study to identify "meaningful concepts." Concepts are defined as "the building blocks of theory" that can be interpreted independent of context.

After these concepts were identified, groups of concepts were compiled to develop categories. Categories conceptualize the phenomena at a higher level. Appropriate labels attempt to capture the phenomena beyond the descriptive level to a more abstract, but conceptual level. To assist in categorizing concepts, Strauss and Corbin (1999) provide a number of techniques to enhance theoretical sensitivity (pp.113-119). These techniques encourage the researcher to analyze the data at an abstract level rather than merely describing or rephrasing what the speaker is saying. Furthermore, these strategies influence the researcher to ask a number of questions about the data to ensure that personal bias and assumptions do not impact the analysis of the data. Categories are further defined or supported by the identification of subcategories, properties, and dimensions. Strauss and Corbin (1999, pp. 101) define subcategories as "concepts that pertain to a category, giving it further clarification and specification." These subcategories are further analyzed for particular properties or characteristics that provide meaning and definition to the phenomena. In some cases interviewees inadvertently in their discussions can suggest a dimension to the phenomena or a range of general properties of a category. The identification of subcategories, properties, and dimensions gradually provides further depth and definition of the category identified.

Throughout this process of identifying and defining categories, the researcher can make comparisons between concepts and categories to enhance theoretical sensitivity. This process involves comparing concepts and categories attending to similarities and differences. This technique is suggested to protect the researcher from contributing personal biases while analyzing the data and providing reliable and valid analysis because categories are constantly being verified, refined, or rejected when new data suggests alternative categories, or depending on how pervasive the category defines the phenomena.

Stage 4: Saturate Categories. Open coding provides an initial assessment of phenomena that exist in the data and may reach a stopping point where no additional differential categories can be identified. This situation has been described as "theoretical saturation" (Strauss, 1987). During this stage no action necessarily takes place, rather it is indicative that any further categories would merely add bulk and redundancy to the analysis and therefore, no additional data need to be gathered.

Stage 5: Abstract Definitions. During this stage the researcher formulates a more conceptual and thus, more abstract definition of each category according to their subcategories, properties, and dimensions. After saturation of the categories has occurred, the researcher now must explicitly create an abstract definition of each category by integrating respective properties that have been implicitly identified each time the category reappears in the data. This defining process is fairly detailed and demanding however; it provides a deeper and more precise understanding of the phenomenon and may lead the research to decide that theoretical saturation has not been reached (Turner, 1981).

Stage 6: Theoretical Sampling. Theoretical sampling involves deciding what data should be gathered next to further develop emerging theory. This is a discrete process in that it occurs once open coding begins until the final stages of filling in the gaps occur. Theoretical sampling may involve adding questions to interviews or recruiting participants who meet particular demographic criteria. Throughout the FGI's the investigators discussed the major themes that were revealed in the discussions. After analyzing the group notes additional questions were added to future groups to gather additional information.

Stage 7: Axial Coding. Axial coding refers to "the process of relating categories to their subcategories, termed 'axial' because coding occurs around the axis of a category, linking categories at the level of properties and dimensions" (Strauss & Corbin, 1999, p. 129). Strauss and Corbin (Strauss & Corbin, 1999, p. 126) describe a four-step process in axial coding as:

1. Laying out the properties of a category and their dimensions, a task that begins during open coding.
2. Identifying the variety of conditions, actions/interactions, and consequences associated with the phenomenon.
3. Relating a category to its subcategories through statements denoting how they are related to each other.
4. Looking for cues in the data that denote how major categories might relate to each other.

During axial coding, data are analyzed on two levels. Analysis looks at the actual words or phrases the respondents' use as well as the conceptualization of these words. By answering the questions of how, why, who, and where, the researcher attempts to relate structure (e.g. why the phenomenon is occurring) with process (e.g. how the phenomenon is occurring). To facilitate the understanding of the relationship between structure and process, Strauss and Corbin (1999) suggest working within an organizational scheme or a "paradigm." Simply stated, "the paradigm is nothing more than a perspective taken toward the data, another analytic stance that helps to systematically gather and order data in such a way that structure and process are integrated" (Strauss & Corbin, 1999, p. 128). This process provides structure in making these connections and provides further dimensionality of the category by examining the degree or intensity of the dimension.

Strauss and Corbin (1990) indicated that the paradigm model is used to specify categories according to the *conditions* that give rise or support it; the context (or properties) in which it is embedded; the *action/interactional* strategies under which it is managed; the intervening conditions that facilitate or constrain the strategies taken within a specific context; and the *consequences* of those strategies. While particular words or phrases were labeled as conditions, actions/interactions, and consequences, the goal in axial coding is to code for *explanations* that enhance the researcher's understanding of the phenomena and not for terms that organize the data in a rigid linear fashion.

In describing the process of axial coding, Borrayo and Jenkins (2001a, p. 814-815) provide an example of how they analyzed the relationship between the categories "symptomatic illness" and screening behavior using axial coding:

> I go [obtain a mammogram] because I have to {action strategy – BC screening], because I have this cyst {intervening condition – symptomatic illness} and if I don't go get it checked {causal condition} then it [BC] can develop {consequence – BC development}.

This example illustrates how the process of axial coding is fluid and not only labels conditions, actions/interactions/ and consequences, but illustrates how they all web together to foster a particular phenomenon or theme.

Once axial coding was complete the most salient themes influencing Latinas' decision to participate in BC prevention activities were identified. To illustrate the decision-making process quotes derived from each focus group will be extracted. The axial coding will go beyond a descriptive theme analysis to explain how each theme interacts with the context in which health decisions are made in these communities.

Throughout the coding process undergraduate and graduate research assistants worked together as a team. Dr. Evelinn Borrayo trained research assistants on the theoretical foundations and process of grounded theory. During the training, research assistants worked in pairs to foster a similar understanding of how to code each transcript. Initially, the whole team conducted open and axial coding of the same transcript. Once the research team reached a consensus of how to code the data, and each research assistant was coding the data in a similar fashion, then each research assistant worked individually on a separate transcript. Throughout the coding process, the research team met to discuss any difficulties experienced while coding a transcript and to ensure that the transcripts were being coded objectively. A more experienced analyst oversaw the coding process and facilitated the research meetings. To account for personal bias in the coding process, a research team of four to six undergraduate research assistants and a graduate student discussed categories and relationships found in the data. A list of categories were constantly revised and examined for overlapping categories and the use of labels that reflect personal biases rather than a raw conceptualization of the data. Research assistants met regularly to discuss the coding process, compare similar categories, and examine anomalies between transcripts.

Analysis of the Semi-Structured Interviews

Content Analysis (Holsti, 1969; Krippendorf, 1980) was used to examine how the study's participants appraised their potential enrollment and adherence to BC prevention clinical trials. The main purpose of the analysis was to provide descriptive information. There were two broad components to the data analysis using this methodology: a mechanical and an interpretative component. The mechanical aspect involved physically organizing and subdividing the data into categories while the interpretative component involved determining which responses were meaningful in terms of the questions of interest. The eight SSI questions were used as the initial guiding frame to organize the data and the probes that accompany the questions helped to understand women's responses with more depth in order to make interpretations regarding women's reasoning, feelings, apprehensions, and motivating factors. Because most of the questions required that the interviewee first responded with "yes or no," responses were classified using these categories. However, during the interview there were some respondents who did not know what they thought about the issue that we were asking. As a result, an extra category of "don't know" was added. For example, the first question asked participants whether they would be willing to participate or not in a clinical trial. While some women were certain about their position, there were many who were uncertain because they needed more information before they could decide either way.

Other questions asked the SSI participants to opt among choices such as choosing which medication side effects they were willing to take or not if they were to participate in a clinical trial. Their responses were coded as "minor side effects" or "major side effects" that they were willing to "to take" or "not to take." While other questions asked for an estimate of some degree related to their responses, such as the how much women thought participating in a clinical trial would interfere with their daily lives. Their responses were coded as "high interference" or "low interference." All the categories developed were exhaustive (every instance was assigned to a category) and exclusive (every instance was assigned to only one category). Responses to questions' probes, however, were not exhaustive or exclusive given their exploratory nature. For this reason, there were answers to some probes but not to others or some women might have been asked to respond to a probe while others were not. As mentioned earlier, probes helped to elaborate on women's responses and to make interpretations about their meaning.

Once the data were organized using the coding frame, we began to look for running themes in women's responses. For example, efforts were taken to search for the reasons why women were willing or not willing to participate in a clinical trial or why they did not know if they would participate. Because a few of the women's responses to some questions became clear in the context of their responses to other questions, a certain degree of interpretation was required on the part of the coders. The overall goal was to determine which responses were meaningful in terms of the questions of interest.

Two coders conducted the content analysis of the SSI transcripts. The mechanical coding for the study resulted in an inter-rater reliability of Cohen's alpha of .91. Content analysis was further interpreted using Grounded Theory (Strauss & Corbin, 1990) coding procedures (e.g., open and axial coding).

All of the analyses conducted were compiled in order to answer the study's primary research question. The key informant interviews, focus groups, and the semi-structured interviews were used to identify factors that influence Latinas' participation in BC prevention and control activities in one conceptual framework.

RESULTS

Key Informant Interviews

Nineteen key informants were interviewed in four Latino communities in Colorado to assess their perceptions of BC as a health problem for Latinas, as well as their readiness to address the problem by increasing participation in BC prevention activities, specifically clinical trials. Averages across each of the six dimensions of community readiness are displayed for each community in Table 4. Using the Community Readiness Scale, it was determined that the modal stage of readiness is "vague awareness." The two rural communities and one of the urban communities were in this stage. Consistent with the stage of vague awareness (Jumper-Thurman, Edwards, Plested, & Oetting, 2003), the three communities were characterized by a general sense that BC is a health problem and that something ought to be done about it, but there was no immediate motivation to take action. For the most part, there was no identifiable leadership from health care professionals or other health authorities for dealing with the problem of lack of BC prevention programs for Latinas living in the three communities.

Only one of the urban communities was at the "preplanning stage" (Jumper-Thurman et al., 2003) of addressing the problem of lack of prevention programs targeted at Latinas. According to the key informants from this community, at least some leaders in the community recognized that BC is a health problem for Latinas and that some sort of prevention ought to be done. In particular, there was awareness that the incidence and mortality of BC among Latinas could be lowered by participation in BC prevention interventions, such as those being currently tested in clinical trials. It was also recognized that Latinas are not fairly represented in these activities. Overall, leaders in the community at the preplanning stage were interested in increasing Latinas' participation in BC prevention and control activities, but their efforts were neither focused nor detailed. There was discussion among leaders but no plan of action to address the problem.

Table 4.

Averages of Community Readiness Scores by Dimension for Each Community

Dimension	Rural 1	Rural 2	Urban 1	Urban 2
Climate	4.3	5.2	5.6	4.4
Knowledge of BC	3.2	3.6	4.2	3.6
Efforts	2.5	3.5	3.5	3.4
Leadership	3.0	3.4	4.1	3.6
Knowledge of Efforts	3.4	3.5	3.8	3.5
Community Resources	3.5	3.3	3.8	3.6
Average	3.3	3.8	4.2	3.7

Note: n=9. CR scores: 1= no awareness; 2 = denial; 3 = vague awareness; 4 = preplanning; 5 = preparation; 6 = initiation; 7 = stabilization; 7 = confirmation/expansion; 9 = professionalization.

Community Climate

Community climate refers to the motivation of community members at large, rather than the leaders alone, to address the problem of interest (Jumper-Thurman et al., 2001). Such motivation among general community members is an important engine for action and change in a community. If the community climate does not recognize or favor change, any effort will not successfully affect the problem and no movement to higher stages of readiness is possible. When we assessed the climate in the four target communities, it was not surprising that the perceived climate in each community paralleled their level of readiness to take action to address the problem of BC. Specifically, the climate in all four communities among Latinas was one of indifference, even in the one at the “preplanning stage.” In other words, BC was not perceived as a health problem that affected Latinas in these communities. Concurrently, there was no perceived need for Latinas to participate in BC clinical trials where prevention measures are being tested. Key informants described how communities had many other issues to consider; thus, BC prevention was not an immediate concern. A key informant in an urban setting explained, “they [community members] don’t deal with it [BC] unless something crops up. . . . I’m sure yeah people think it’s a problem, but it’s not a problem right now because I am fine. . . . I’ve got to get to work . . . but to make [a priority] the annual prevention stuff is hard.”

According to key informants, community members do not seem to perceive BC prevention as an immediate need and hence, have not approached leaders in the community to address the issue. In order for community leaders to address a particular problem, community members must lobby their concerns and demonstrate the need for action. A key informant said that she has heard some Latinas voice that, “somebody should do something about it, but not me. I’ve heard that a lot . . . Why, what, and where, but not me.”

Community Knowledge about Breast Cancer Prevention

In the three communities at the “vague awareness” stage, community leaders perceived that Latina communities lack knowledge about and have little interest in participating in BC prevention activities, specifically clinical trials. One key informant from the urban community stated, “this little bit of prevention that there is out there, it’s not known by everybody that can access it.” Another key informant from a rural community who works with many Latino migrant workers suggested that transient lifestyles inhibit this population from knowing about or accessing health programs. She explained, “I’m not sure they [migrant workers] would be aware of all these efforts . . . They’re not in one place long enough to follow through or have a primary care physician." In the other rural community, it appears that daily responsibilities demand people's attention more and BC prevention is not a high priority. One key informant exemplified this rationale with her comments, "I think that it [BC] is a concern, but it's not a top concern. Right now families are concerned about how they can pay their gas bill, things like that, how they can make their house payment and you know how they can get health care for their children. They are more concerned with those types of issues. It's [prevention] not a priority down here."

Furthermore, key informants across all four communities believed that there is minimal awareness about the importance of BC control activities such as mammography and much less awareness about prevention activities that are currently being tested in clinical trials. One key informant from a rural community working in a community clinic stated, "Most of the Latino women have come from Mexico and have never had a mammogram, have no idea what it is, and so they would not know what their risks were or what their chances are of having BC." Because awareness of BC in general is low in these communities, the understanding about the importance of prevention is minimal.

Community Efforts to Engage Women in Prevention Programs

According to the key informants' report, health-care providers have made little or no effort to engage women in BC prevention activities, particularly BC clinical trials, in communities at the "vague awareness" stage. Although there are active BC control programs (e.g. mammography) in these communities, it is difficult to recruit women into the programs. Given this ongoing struggle, it appears that progress has not been made towards increasing BC prevention activities. A key informant from the state health department in an urban community cited several initiatives for BC control activities; however, when asked about prevention activities such as those tested in clinical trial, she could not recall any. A key informant in a rural community also recognized that BC control efforts have been long-standing, but that prevention efforts have been minimal. In the urban community at the “preplanning” stage, efforts among health-care workers have also focused on BC control. Although there has been a discussion regarding prevention activities, no real planning for these activities has begun.

Leadership

No key informant identified any real leadership at the state or federal government level to systematically address the lack of Latinas’ participation in BC prevention activities, and thus, community leaders have not been motivated to deal with this problem. It appears that community leaders, particularly those in health clinics, may be aware of the importance of BC prevention, but do not consider it a sufficiently high priority to develop prevention programs. A key informant working with the health department in a rural community stated, “I’m not sure that they’ve [leaders] really gone into specific BC prevention. And it’s probably just because they haven’t really thought about it. . . But a lot of them probably haven’t asked and just haven’t really thought about it, not intentionally that they don’t want to do anything about it.”

The urban community at the “preplanning stage” had identifiable leaders working with BC issues. In this community leaders meet regularly to discuss enhancement of BC control activities and to begin BC prevention initiatives, such as providing free mammogram screenings each month and funding for BC treatment for lower-income individuals. However, it was noted that post diagnosis funding resources were limited, which often leaves gaps in health-care coverage and often inhibited women from receiving treatment.

Community Knowledge of Efforts to Increase Breast Cancer Prevention

In all four communities, key informants believed that Latinas seem to be familiar with BC as an illness that typically affects women. However, despite education efforts, many of these

Latinas still lack adequate understanding of the symptoms, treatment, and, in particular, prevention of BC. When asked what community members know about prevention and treatment of BC, a key informant from the urban community at the "preplanning stage" responded, "I think they [community members] know that it [BC] or they think they know that it just affects women. Um, that it can be cured. My perception is that they think that if a women gets BC she's gonna have to have a mastectomy. That that's the treatment."

In all four communities, key informants reported that Latinas often had misperceptions about the causes, course, and treatment of BC. Some women believe that BC is fatal and that receiving a mastectomy is the primary treatment mode. One key informant from a rural community (who was a nurse at a community hospital) described how one of her Latina clients waited until her breasts were excreting fluid to consult a physician. This woman did not suspect BC as a possible source for her symptoms and, unfortunately, these symptoms were detected at a late stage. Furthermore, Latinas appear to be unaware that BC may be preventable. This key informant believed that many women embraced a belief in predestination: nothing can prevent BC from occurring if a woman is fated to have it.

Community Resources

Insufficient resources are available to address BC prevention in all four communities. Although all key informants interviewed perceived that community members would be supportive of prevention efforts, they thought that tangible resources, such as time and money, were lacking. For example, when asked what the community offers to support BC activities, a key informant from a rural community stated, "Both money and space are very tight. So um, I mean people probably are willing to help with a good cause, but at the same time their hands may be tied. Because everywhere the space may be very limited and is hard to come by and the funds, so many cut backs lately in funding, that also is a problem. So it is not necessarily that these people are willing to help, it is they are unable to."

In the urban city at the "preplanning stage," space was not perceived to be a barrier as one key informant stated, "space, uh, I think community agencies have been pretty helpful with space, if we really needed it." She further explained that churches and community centers are often willing to donate space for educational seminars or health fairs. She added that resources, specifically work force, are often lacking to organize educational programs and recruit participants. She cited that often Latino radio stations will publicize programs or special events in the community free of charge, but other advertising community services are often too expensive for community agencies. Alternative promotion strategies include announcements in church bulletins and booths at cultural events. Key informants from all the communities were unaware of any grants or funding opportunities to initiate prevention programs and no plans have been made to seek out funding.

Key informant interviews provided an assessment of the level of awareness among Latinas in each community regarding BC prevention and control from the perspective of community leaders. Key informants were chosen because they work closely with Latinas and understand the cultural as well as systemic factors that underlie each community's level of readiness. To further understand cultural and psychosocial factors that influence Latinas' participation in BC prevention activities, focus groups were conducted. Results from the KI interviews provide a community context in which Latinas' perceptions of BC prevention and control can be understood.

Focus Groups

Focus groups were used to assess Latinas' perceptions of BC prevention and, specifically, chemoprevention clinical trials. Focus group discussions began with discussing causes of BC and possible prevention strategies to assess Latinas' knowledge regarding the illness. Women expressed their thoughts of how Latinas are inflicted with BC and how one could control as well as prevent BC. In general, the emergent themes suggested that Latinas had minimal knowledge of BC prevention and control activities.

Women frequently demonstrated confusion between BC prevention and control activities. BC prevention activities aim toward preventing the initial onset of BC (i.e., healthy diet and consuming Tamoxifen), whereas BC control activities aim at controlling the progression of BC after one is affected by the illness (i.e., BSE and mammography). Throughout focus group discussions regarding BC prevention activities, women often used the term "prevention" they were referring to BC control activities. This confusion demonstrates the level of knowledge women had regarding the concept of prevention, particularly prevention of BC. Initially, women provided BC control activities as a means of preventing BC and required prompting to focus on prevention, not control strategies. The following example demonstrates this confusion and how it was clarified during the focus group:

> *Interviewer:* What do you think, how do you think that these women including yourself, can prevent getting BC? Prevent or avoid. How do you think a woman could prevent getting BC?
>
> *Speaker 1:* Taking your mammograms.
>
> *Interviewer:* Your mammograms, okay.
>
> *Speaker 1:* Prevent . . .

Speaker 2: I . . . am a person that I go . . . Year by year. Well in the beginning the doctor asked me, or two people ask me to go and now that I am older he told me to go annually.

Interviewer: Now, do the check ups help to prevent BC, but does not necessarily avoid it?

Speaker 2: No, but it can be detected in a. . . .

Interviewer: In an early stage.

Speaker 2: In an early stage is when it can be . . . block.

Interviewer: It is important. What I would like to know is what do you think you can do to avoid getting it. Everything you touched on is very important but what can you do to prevent from getting it.

Speaker 2: Don't smoke.

Interviewer: Don't smoke? What other things do you think you can do to prevent?

Speaker 1: Good diet, exercise, self-examination.

Participants also expressed how their perceptions of BC prevention clinical trials influence their decision to participate in such trials. As focus group discussions progressed, various themes arose regarding Latinas' perceptions of BC prevention and control. These themes should be evaluated within the context that Latinas' had minimal knowledge regarding BC control and prevention strategies in their communities. Specifically, the factors influencing Latinas' perceptions of BC prevention clinical trials surrounded four major themes: personal control over preventing BC (predestination versus free will); distrust of pharmaceutical interventions; distrust in health-care providers; and a fear of participation in a chemoprevention clinical trial. To better understand their perceptions, each theme will be discussed with excerpts from the focus group discussions. Excerpts were chosen from the four FGIs; however, because each group was asked slightly different questions for theoretical sampling purposes, some themes also vary slightly. In a few other instances, the themes did not emerge as clearly in some groups as they did in others or the discussion around a particular theme was too lengthy to be included in this section. Thus, excerpts were chosen from those groups that most clearly illustrate the themes.

Personal Control Over Preventing Cancer

In this study, many Latinas believed that BC was caused by predestination, their own free will, or personal life choices. The concept of predestination posits that an individual is destined to either have BC or not have BC, and there is nothing she can do to prevent this. "Predestination" is often used synonymously with "fate." For example, in the saying, "leave it up to fate," it is recommended that an individual inhibit him/herself from intentionally making a decision to act, for fate will decide the outcome. Latinas' belief in predestination or fate led many to believe that they had little control over preventing the onset of BC. For example, women from an urban community stated:

> *Interviewer:* What other way do you think that you can prevent it [BC] or avoid getting it?
>
> *Speaker 1:* If a woman is going to get it, she's going to get it [fate], no? There's no way of preventing it.
>
> *Interviewer:* Why do you think that way?
>
> *Speaker 2:* I think so too. If you're going to get cancer, you're going to get it, and I do not think that you can . . . you can't prevent it, no way.

Other Latinas from a rural community expressed similar sentiment that cancer is not preventable and that there is nothing one can actively do to prevent this from occurring:

Speaker 1: Because if you're going to get cancer, you're going to get it, anyway [fate], any time.

Interviewer: So, if it's gonna . . . if you're going to have cancer, you're going to have it.

Speaker 2: Yeah.

Speaker 3: Well that's what you think.

Prior research has suggested that Latinas believe that a higher power, (i.e., God) determines whether a woman becomes ill with BC (Borrayo and Jenkins, 2001). Many women in this study who endorsed predestination believed that a higher being or God predetermines whether or not a women is going to get cancer or not and that there was nothing one could do to prevent this. Latinas from a rural community demonstrated how their belief in predestination influences them to abstain from taking pharmaceuticals to prevent or cure an illness:

Speaker 1: Because if God sends me cancer, there isn't a pill that will get rid of it.

Speaker 2: Oh yes.

Interviewer: So, you think that if God is going to give you cancer anyways. . . .

Free Will. Although some women posited that BC was a predetermined illness, a minority of women endorsed the concept of free will and believed that indeed BC is a preventable disease. "Free will" posits that individuals determine their own fate, rather than having it determined for them. Advocates of the construct of predestination rejected BC prevention strategies, whereas those who endorsed the concept of free will were open to discuss measures one could actively engage in to prevent BC.

Prevention strategies Latinas identified included engaging in healthy lifestyle behaviors and avoidance of detrimental sources. Preventive lifestyle behaviors included not smoking, having healthy nutrition, not drinking alcohol, and exercising. Avoidance of *detrimental sources* included avoiding consumption of drugs, alcohol, synthetic and fried foods, and medications that have side effects that may eventually cause BC. Although some women stated that taking vitamins could prevent BC, they specified that only vitamins made from natural ingredients, not processed or synthetic chemicals, could prevent BC. For example, one woman from an urban community stated:

> *Interviewer:* If you heard that they already tested it on rabbits, with animals, and now they're testing it with women. What would you do, would you take it?
>
> *Speaker 1:* Since I don't believe much in chemistry. I would better look for an herb.
>
> *Speaker 2:* Yes, yes it's true. The natural medicine.
>
> *Interviewer:* That it would be the most natural.
>
> *Speaker 2:* Yes. Because the natural doesn't seem to do as much harm as . . . [pharmaceutical interventions].

Synthetic vitamins or pharmaceuticals were perceived largely as detrimental to one's health rather than preventive substances for BC. A few women noted the protective nature of estrogen in preventing BC, but the majority of women perceived this as another detrimental source that could cause BC. Furthermore, the negative perceptions of estrogen were also related to negative experiences Latinas had when physicians recommended taking hormones for preventive purposes. The speaker below shared a story of her friend who took hormones and developed lumps in her breasts. Learning of this event raised the speaker's suspicion of estrogen as a detrimental source that could cause cancer:

> *Speaker:* To me a friend of mine told me that they had given her some of these hormones to take, and that she would just take them and she stopped taking them. That she would get these lumps here, above her breasts that they pricked here.

> *Interviewer:* When she was taking birth control pills?
>
> *Speaker:* When she was taking the pills, no, not the pills, the hormones.
>
> *Interviewer:* The hormones.
>
> *Speaker:* She would say, I'm not going to take them. I would tell her to tell her doctor. She would say, oh, but how, she's going to scold me. No, [I] tell her. She says, I barely take them and some lumps here above the breasts I get. I grab the lumps like this and they prick me. She says, I am afraid to get cancer.

Witnessing her friend develop a lump after taking hormones contributed to this woman's concerns regarding the negative impact of choosing to take a preventive pharmaceutical. Although choosing to engage in healthy behaviors exhibits the positive benefits of free will, the above example illustrates how free will can lead to negative consequences as well.

As the focus group discussions progressed, women were educated about what BC prevention clinical trials entail and were asked for their views regarding whether they would participate in chemoprevention, specifically for prevention. These discussions encouraged women to discuss their perceptions of health care, specifically pharmaceuticals and health-care providers. The following sections discuss the second category of themes surrounding Latinas' participation in BC clinical trials and their distrust in modern interventions for prevention of BC. In particular, Latinas expressed distrust in the potential side effects and efficacy of pharmaceuticals.

Distrust in Pharmaceuticals for Prevention of Breast Cancer

In general, women in this study were opposed to using pharmaceuticals to prevent illness, particularly BC. Latinas perceived pharmaceuticals as a foreign chemical compound that is not natural and thus harmful to the body. Therefore, women believed that taking a pharmaceutical when not ill was unnecessary and potentially harmful. One woman from an urban community demonstrated her skepticism of the chemical nature of pharmaceuticals and her preference for natural remedies in the following dialogue:

> *Speaker:* Since I don't believe much in chemistry, I would better look for an herb, some . . . Yes, yes it's true. The natural medicine.
>
> *Interviewer:* That it [taking herbal medicine rather than synthetic medication] would be the most natural.
>
> *Speaker:* Yes. Because the natural doesn't seem to do as much harm as [preventive pharmaceuticals]. . . .
>
> *Interviewer:* If you already had it [BC]? You wouldn't take it [preventive pharmaceuticals] anyways.
>
> *Speaker:* No, no [she would not take the pharmaceutical].

This speaker appears more inclined to trust herbal remedies over chemical remedies because she perceives the former as more benign and less threatening.

Latinas' distrust in preventive pharmaceuticals was maintained by two main concerns regarding the possible side effects of the medication and how a pharmaceutical is proven effective. Further analysis of the FGIs revealed the context of Latinas' negative perceptions and distrust of preventive pharmaceuticals.

Perceptions of the Side Effects of Pharmaceuticals. Across the focus groups Latinas expressed concern regarding possible negative side effects of preventive pharmaceuticals. Latinas' perception that all pharmaceuticals have negative side effects influences their belief that taking a preventive pharmaceutical could cause a healthy individual to become ill. Regardless of whether they were informed or not of possible side effects, women generated various side effects that supported their unwillingness to take preventive pharmaceuticals. For example, a participant from an urban community provided possible side effects as a barrier to participating in prevention activities. However, she was evasive as to what type of side effects might occur. It appears that the possibility of side effects in and of itself is a barrier to taking preventive pharmaceuticals as demonstrated by the following comment:

> If it [a preventive pharmaceutical] had . . . I wouldn't, I do not know, because if it [preventive pharmaceutical] had a, like a side effect, that they say that it's good for this, but it's going to do damage in this [another health condition]. Because of that I do not take anything that they give me, because, they say, "Well we are going to give you this [negative physical side effect], but it's going to do damage in the kidneys, or around that." So, I do not want anything.

Other women provided more detail to the rationale behind their decision to abstain from chemoprevention interventions. Some women believed that it was unwise to take a pharmaceutical that could possibly make a person sick. Because women perceived that they were in no immediate threat of developing BC, they saw no need to take pharmaceuticals that could potentially cause them to become ill. Women suggest that if a healthy individual takes a pharmaceutical, he or she could possibly become ill solely because of this decision. The following comments from women in an urban community illustrate Latinas' belief that participating in chemoprevention could lead to a negative side affect, specifically, cancer:

> *Speaker 1:* Well I say no because, if I was OK why would I put myself at risk of. . .
>
> *Speaker 2:* So that they don't give it [cancer] to you.
>
> *Interviewer:* Then you all think that taking that pill means that you get BC?
>
> *Speaker 1:* It could be that it [the pharmaceutical] starts cancer.

> *Interviewer:* You think that.
>
> *Speaker 1:* In the tests.
>
> *Speaker 3:* [Pharmaceuticals] do one damage for another thing.
>
> ---
>
> *Speaker:* I say, to myself yes, that if perhaps, yes I would take it, but it would also be with, that way because if another thing happens to me, and if I did not have cancer and later I if was going to get it. . .
>
> *Interviewer:* You think that it could be that this pill could give you BC?
>
> *Speaker:* Well, if maybe they are barely testing it, I mean, they . . . one does not know what they are testing it for. Maybe they are testing to give more strength to the cancer. We don't know.

Some women went on to say that it would be unwise for a person to take a pharmaceutical that could cause her to have side effects that she or researchers may not be aware of. A woman from an urban community believed that she and others in the community would see it as a "foolish" endeavor to take a medicine that could possibly make you sick:

> *Interviewer:* What would you think that other people in the community would say if they heard that there is a woman that is taking, or that is participating in this pill that the doctors are testing? What would the community say?
>
> *Speaker:* What a foolish woman.
>
> *Interviewer:* How foolish? Do you think that there would be people that would think how foolish? Why, do you think that there would be someone that would say how foolish?
>
> *Speaker:* Well, she doesn't know what she is doing, or she doesn't know what they are going to do to her, or what is going to happen.

> *Interviewer:* Because of that you think that they would say maybe how foolish, because she does not know? OK.

In addition to worrying about the possible side effects of pharmaceuticals, Latinas worried about the efficacy of pharmaceuticals. As discussed earlier, the concept of clinical trials was unknown and almost foreign to most women. Therefore, it was inconceivable that pharmaceuticals could be used to prevent an illness that one might not acquire. Latinas questioned the efficacy of pharmaceuticals, particularly in preventing BC.

Perception of the Efficacy of Preventive Pharmaceuticals. In addition to the possibility of side effects, women's concern regarding the efficacy of a preventive pharmaceutical was another barrier to participation in chemoprevention strategies. Women had difficulty understanding how a pharmaceutical is proven effective if it is preventive and not curing an illness or minimizing a physical symptom. For example, one woman from an urban community challenged how researchers determine the efficacy of pharmaceuticals in her following statement:

> *Speaker:* But um look. If I'm healthy, and I take a pill, how am I going to prove to Antonio [speaker's husband] that it did some kind of effect in me.
>
> *Interviewer:* That it did have an effect on you?
>
> *Speaker:* Because I'm healthy, and it [preventive pharmaceutical] could have been that I wasn't going to get it. And, how do I know if it [the preventive pharmaceutical] prevents it [BC]?

If a person who participates in chemoprevention is cancer-free throughout their life, it is likely that this woman would attribute being cancer-free to being healthy, rather than believing that the pharmaceutical lowered the person's risk of acquiring BC. Rather than treating an illness that has already developed, like traditional therapeutic pharmaceuticals do, preventive pharmaceuticals aim to prevent the onset of the illness. This woman is having difficulty appreciating the preventive nature of pharmaceuticals and questions how researchers determine if it is the pharmaceutical or another factor that deterred the onset of BC.

Not all women questioned the efficacy of preventive pharmaceuticals. A minority of women understood the purpose of preventive pharmaceuticals and believed it could be efficacious in preventing the onset of a particular illness. This next example demonstrates how a woman's understanding of calcium in preventing osteoporosis parallels her understanding of chemoprevention (Tamoxifen or Raloxifen) in preventing BC. In making this comparison, the woman is able to understand the purpose of taking preventive pharmaceuticals for BC, and believes it could be effective.

> *Speaker:* I'm thinking, okay, like we take calcium to prevent bone disease.
>
> *Interviewer:* Right!
>
> *Speaker:* Okay, but with BC I tend to look at it a little different, you know.
>
> *Interviewer:* How?
>
> *Speaker:* As a very deadly disease, you know whereas the bone disease you might deteriorate, you know, slowly.
>
> *Interviewer:* Aha!
>
> *Speaker:* Or something like that, but cancer it is deadly, you know.
>
> *Interviewer:* So, would you take it then to prevent [BC], if it [preventive pharmaceutical] was approved?

> *Speaker:* If it was approved and it would be like taking a calcium or taking a certain thing for your eye sight, that kind of thing, you know I can take ah . . . ah . . . vitamins that help prevent but, um?

Despite the knowledge Latinas had regarding the benefits or risks of prevention pharmaceuticals, women also identified their distrust in the physicians prescribing these pharmaceuticals as a factor in their decision-making. Latinas' distrust in physician influenced their willingness to believe medical information and follow physicians' recommendations to engage in prevention activities, particularly when these activities involved pharmaceuticals.

Distrust in Physicians

In addition to distrusting pharmaceuticals, Latinas also distrust the physicians prescribing these pharmaceuticals. Across all groups Latinas shared their jaded perceptions of physicians that stemmed from negative experiences in the past that instilled a sense of distrust of physicians that, in turn, discouraged them from taking experimental pharmaceuticals. Women reported feeling misinformed and faulted their physicians for not providing adequate information that may have influenced their decision to consume the prescribed pharmaceutical. The following example demonstrates a woman who discontinued taking a pharmaceutical after learning that it was experimental and that it had possible negative side effects:

> *Speaker:* Because they already tried to give me some pills for diabetes. They were called Reslin. And I started to take them, and then I read up on them. And I stopped taking them. I told them I'm not taking these.
>
> *Interviewer:* What did you read?
>
> *Speaker:* That you get um . . . What is that alcoholics get…?
>
> *Interviewer:* Um, cirrhosis. . .

Speaker: Oh, cirrhosis of the liver, or something like else…

Interviewer: Is that what it said, that you could get that?

Speaker: And then they check you every time, take out your blood to check it. So I didn't take it.

Interviewer: So they were experimenting with this drug for diabetes.

Speaker: Yeah they were but they didn't tell me.

Interviewer: Oh, they didn't tell you. OK.

Speaker: So I read up on it. I said, "I ain't taking this stuff."

In this situation, this woman distrusted her physician because she felt misinformed which in turn, influenced her to discontinue taking the experimental pharmaceutical.

Other women distrusted physicians because they witnessed errors that led to negative consequences. A woman from a rural community illustrated how a medical error caused her to distrust physicians and discouraged her from taking experimental pharmaceuticals:

> *Speaker 1:* Because many times, in the same blood tests, they [physicians] make mistakes. It has happened to me. They [physicians] told me I had diabetes, and it belonged to another person, and I didn't have diabetes.
>
> *Interviewer:* Wow. Then you have a certain type of uncertainty to participate in studies of that type?
>
> *Speaker 1:* Precisely because of that. They [physicians] themselves make you not trust.
>
> *Interviewer:* So they [physicians] were experimenting with this drug for diabetes.
>
> *Speaker 2:* Yeah they [physicians] were but they didn't tell me.
>
> *Interviewer:* Oh, they [physicians] didn't tell you. OK.
>
> *Speaker 2:* So I read up on it. I said, "I ain't taking this stuff."

In the above example, the participant might have not only felt misinformed, but also somewhat betrayed. The mistakes physicians have made in the past appear to have influenced this woman's ability to trust pharmaceuticals prescribed by physicians. These negative experiences may cause women to distrust physicians in the future, to the extent that they would not trust information regarding pharmaceutical administration and their possible side effects.

In addition to Latinas' perceptions, emotional factors contribute to their decision to participate in BC prevention activities, specifically chemoprevention. Regardless of Latinas' knowledge about BC prevention or control, their decision to participate in a chemoprevention clinical trial appears to be guided by their emotions or instinct.

Fear of Participation in a Chemoprevention Clinical Trial

The minimal knowledge of BC clinical trials among Latinas seems to lead them to perceive chemoprevention as an ambiguous and ominous process. Due to the complexity of the medical procedures involved in chemoprevention strategies, there are many opportunities for confusion when learning about BC chemoprevention. In addition, the preventive purpose of chemotherapy in clinical trials adds another dimension that makes this process difficult to understand. Finally, the experimental nature of clinical trials and not knowing the results of the experiment creates another layer of ambiguity. Therefore, women perceive participating in a chemoprevention clinical trial as placing themselves in an ambiguous situation, and a sense of fear of the consequences of this participation seems to be evoked. This fear may serve as a barrier to participating in chemoprevention clinical trials. The following dialogue exemplifies the common fear of experimental pharmaceuticals expressed across all groups. The speaker describes her fear of participation in chemoprevention without specifying what she fears and why this fear exists; however, she appears certain that she does in fact fear that chemoprevention may cause cancer:

> *Speaker 1:* Um, because I wouldn't [participate in experimental chemoprevention]. I would, I don't know, I wouldn't take it though.
>
> *Interviewer:* Why do you think you wouldn't take it? Is it odd, or what's going on?
>
> *Speaker 1:* I think that it would, I was gonna get it [cancer].
>
> *Interviewer:* OK, so even if they said this can prevent it [BC], you would be afraid that instead of preventing it, it may actually cause it?
>
> *Speaker 1:* Um hmm.
>
> *Speaker 2:* Um hmm.
>
> *Interviewer:* So, you would be somewhat afraid?
>
> *Speaker 1:* Yeah.

This participant's initial ambivalence regarding taking the experimental pharmaceuticals combined with the ambiguity surrounding the possible side effects inhibited her willingness to take the pharmaceutical. Other women echoed these thoughts, stating their fear that taking the experimental pharmaceuticals could give them cancer. The following excerpt provides another example:

> *Speaker 1:* No I wouldn't take it, not me.
>
> *Interviewer:* Why not?
>
> *Speaker 2:* Well because I would be afraid that it would give me cancer. Listen, like one of the girls said, that it's better if they give it to the dog to see.

The fear surrounding taking experimental pharmaceuticals, particularly preventive pharmaceuticals, serves as a barrier to Latinas' participation in clinical trials. It is possible that the ambiguity surrounding chemoprevention is evoking a sense of fear. One woman clearly states the linear relationship between the unknown, ambiguity, and fear in her statement, "The fear of the unknown, of what the backlash is going to be."

Results from the focus groups provided a more in-depth understanding of Latinas' decision-making process in participating in chemoprevention clinical trials. Because the level of awareness regarding BC prevention, according to the CR model, amongst these communities was relatively low, these themes further explain Latinas' hesitancy to participate in BC prevention and control activities. Although FG discussions involved both BC prevention and control, we wanted to specifically assess Latinas' willingness to participate in BC prevention clinical trials and therefore semi-structured interviews were conducted.

Semi-Structured Interviews

To specifically assess Latinas' willingness to participate and adhere to clinical trials we conducted 14 semi-structured interviews (SSI) across all four communities. Upon analyzing the demographics of the four focus groups, we discovered that the participants of the focus groups were not necessarily representative of all the Latina subgroups in each of the respective communities. For example, the participants in one of the rural communities were composed of relatively highly educated individuals. After speaking with community leaders regarding these demographics, we learned that we were unable to access the underprivileged Latinas in this community because they had no telephones in their home and lived far from the town where the focus groups were held. Therefore, we conducted one-on-one semi-structured interviews to target underrepresented individuals and made every effort to accommodate the participants needs, including interviewing them in their homes.

Fourteen semi-structured interviews were conducted in four communities throughout Colorado. The participants of the SSIs were all of Mexican descent and on average were 66 years old. Their average education was 7.79 years, and had an individual income that averaged less than $20,000 each year, which is below federal poverty level (U.S. Department of Health and Human Services, 2001). According to the ARSMA measure of acculturation, the women in this sample were bicultural.

The SSIs were organized into three sections. Initially, interviews attempted to assess awareness of prevention clinical trials and willingness to participate. Next participants received a brief education regarding the risks and benefits of BC prevention clinical trials and the procedures involved. Information on the STAR clinical trial was used to illustrate to participants what such a trial might entail. After providing this education, participants were asked about their perceptions about their potential participation in a similar clinical trial. Last, we assessed these women's willingness to comply with each the procedures involved in a BC prevention clinical trial.

Specifically, a total of eight questions tapped into six main areas about participants' views concerning 1) potential participation; 2) chemoprevention interventions, including perceived benefits, costs, and possible side effects; 3) their perceived commitment and adherence to clinical procedures that would likely include regular consumption of medications and participation in medical check-ups; 4) their anticipated trust in medical professionals and characteristics of these professionals that would encourage women's trust in them; 5) their ability to overcome access barriers, such as finding transportation and navigating medical settings and procedures; and 6) their appraisal of how their participation could potentially contribute to their family's and society's well-being. The section that follows explains in detail the themes that emerged under each of these content areas.

Knowledge and Willingness to Participate

Of the 14 study participants, none had ever been educated or had a health-care professional educate them about BC clinical trials or refer them to one. Likewise, none of the women had ever participated in either a treatment or a preventive BC clinical trial. There were three women who indicated that they would be willing to participate in a BC prevention clinical trial, whereas eight said that they would not participate and three did not know if they would or not. After further probing of the women who hesitated or would not participate, four women said that they would participate if their physician told them that they were at high risk of BC and two said they would participate if the intervention was already approved rather than in its experimental stage. Among the reasons for not being willing to participate were that women did not want to run the risk of taking something that might turn out to be harmful to their health or simply because they did not like taking medication. Other women were unsure about whether they would participate in a clinical trial because they did not have enough knowledge about the intervention, such as what type of effect it might have if it interacted with other medications that they were taking. A woman said: "I don't know because I am taking several pills from the doctor and I don't know if they would counteract."

After the initial question about Latinas' willingness to participate in a BC prevention clinical trial, they were asked to assume that they would participate in one, even if some women had said that they would not participate. They were asked their opinion about the various aspects and procedures that women in a clinical trial experienced. With this scenario, we obtained Latinas' views about chemoprevention interventions (Tamoxifen and Raloxifene), clinical procedures, health-care professionals, access barriers to clinical trials, and potential contributions of women's participation to family and society.

Perceived Benefits and Costs of Chemoprevention Interventions

The belief that an intervention can actually prevent the development of BC was prevalent among 10 of the Latina participants, primarily because they believed that with medical advances a preventive medicine could be created. Nonetheless, three participants did not believe in the development of such medication based on their conviction that BC cannot be prevented. Only one woman said that the medication would have to be tested first before she could believe in its preventive properties. With regard to the opposite belief, five did not believe that the intervention could cause BC, whereas two believed that it could and seven did not know if it could or not cause BC. In addition, 11 women had concerns about health harms related to its consumption. In general, they were concerned about potential damage to internal organs like the kidneys, stomach, liver, and heart, or that it might aggravate other illnesses. For example, a woman explained "because I have diabetes and high blood pressure, I would not know if it [chemoprevention intervention] could be harmful or not."

Information exists about potential side effects related to taking Tamoxifen and Raloxifene. Thus, we asked Latinas what minor and major side effects related to the medication they were willing and unwilling to take if they participated in a BC prevention clinical trial. For the most part, the participants were unwilling to take the major side effects (nine women), even though women were told that only about two to three women out of 1,000 were likely to experience them. The major side effects were endometrial cancer, stroke, heart attack, clogging of veins, and increased cholesterol. Participants were more willing to take minor side effects (nine women), which included leg cramps, hot flashes, vaginal discharge, and cataracts. Of the remaining participants, three did not want to take even the minor side effects and two did not want to take any side effects.

Commitment and Adherence to Clinical Procedures

STAR is a randomized clinical trial where some women receive a pill that contains either Tamoxifen or Raloxifene. Participants in this trial are asked to take the pill for five consecutive years, as indicated by their physician. Because the literature on medication compliance suggests that it would be difficult for various participants to adhere to such regimen, we were interested in inquiring about Latinas' perceived medication compliance as part of the procedures involved in a BC clinical trial. In response to this question, six women said that they would be committed to taking a pill for five years; four said that they would not be committed; and four did not know either way. Lack of commitment was expected for various reasons, including some women do not like trying any new medicines; would rather take herbal remedies; others do not like taking "pills"; or are already taking a lot of them. A woman who said, "I think I am taking enough medicine right now, I wouldn't want to take anymore" gave a clear example.

Many clinical trials also require pre-entry and regular medical examinations once participants are accepted. In STAR, the examinations include yearly Pap smears, mammograms, blood tests, and breast exams, and these most be performed at least for seven years, even though the intervention only lasts for five years. After explaining the required clinical procedures, we asked participants about their anticipated adherence to them. Unlike their responses to the medication compliance question, 11 women expressed that they would be likely to comply with the yearly medical exams for seven years, mostly because they are already participating in some form of medical examinations. However, only four of these women anticipated that doing so would be rather easy, whereas the rest thought it would be difficult or that it would "highly interfere" with their daily lives but that they could work around the obstacles. Only one woman said that she would not be compliant because she thinks that medical examinations are unnecessary at her old age (80 years old). There were two participants who could not estimate whether they would be compliant with the clinical trial's required medical procedures, mostly because these examinations would "highly interfere" with their chores and responsibilities.

Routine medical exams in a clinical trial are usually covered by sources like Medicare, Medicaid, or private health-insurance companies. For women who do not have any form of insurance, funds to cover medical procedures involved in the clinical trial are unfortunately scarce. We wanted to find out how willing women were to participate and adhere to a clinical trial if they had or did not have health insurance coverage. As expected, 10 women did not want to participate if their health insurance would not cover it or if they did not have a source of insurance, even when other sources could be sought. Among women who had insurance, two said they would not participate. Two said that they would participate even without health insurance. In addition, participation in a clinical trial might have some indirect financial costs to women. The health insurance deductible and the costs of treatment for side effects were the only indirect financial costs mentioned by three participants.

Ability to Trust Medical Professionals

Because of the state-of-the-art procedures involved in a clinical trial, a woman's primary physician has to sometimes refer her to a specialized group of health-care providers. In other words, in some clinical trials participants are required to trust someone that is not their regular health-care provider. When we asked Latinas whether they would trust such a group, 10 women said that they would trust them because the specialty physicians were likely to be more knowledgeable and prepared than their primary care physicians. Trusting them was more difficult for two women who only trust their current physician, whereas two were unsure about their level of trust in a group of new health-care providers because they were likely to be males.

Based on previous findings from studies with the target population (Borrayo et. al., 2001), we anticipated that the gender of the health-care provider was likely to be an issue for older Latinas of Mexican descent. Upon asking women about it, a majority of 10 women said they would prefer a female physician to a male physician. Primarily, women feel more comfortable with a female because of their shared anatomy, their ability to communicate better, and because women would feel more *confianza* (equivalent to trust) with another female. "They [female doctors] would know more a woman's body. I think, and you could talk to them how you feel, how you think, and more than a male doctor," said a woman, which illustrates most of the women's stance. Three participants voiced no preference for either a female or a male physician and only one said that she would prefer a male physician.

On the other hand, most of the participants (13 women) had no preferences for the ethnicity of the health-care providers in a clinical trial study, and only one indicated that she would prefer a Latino/a provider. A more important issue for five of these women was that the health-care providers could communicate with them in Spanish or that they would have a translator to communicate more effectively.

Ability to Overcome Medical Access Barriers

Access to the medical facilities where BC clinical trials are conducted is necessary for the successful enrollment and adherence of community-dwelling Latinas. That is, women must be able to travel to these facilities and once there, they must be able to navigate the medical system and its procedures. Learning about Latinas' perceived ability to overcome medical access barriers was an important goal of the interview. We asked them about their ability to travel to medical appointments and about their comfort level navigating unknown medical settings. Participants' responses to questions about their ability to travel were equally split, with seven women indicating that they would be able to find transportation and seven women indicating that they would not be able to find it. Those who anticipated that transportation would not be an issue were more likely to use public transportation or to ask a family member to drive them. On the other hand, those for whom transportation was an issue were less likely to have a reliable source of transportation or if they had one, such as owning a car, costs associated with gas prices or inability to drive far were of concern. Women residing in rural settings perceived transportation to be even more difficult, as illustrated by a woman who said "but I don't like driving to doctors out of town because I can't afford the trips." Level of difficulty finding transportation, however, was not less difficult for participants living in urban locations.

Navigating a large medical setting such as a local or university hospital requires one to find a specific clinic, sign in, and talk to several health-care professionals (e.g., physicians, nurses, radiologists). Women's perceived and actual ability to navigate such a system might serve as an access barrier. Indeed, seven women confirmed that it would be. They reported that they would find the process of navigating a large medical setting to be complicated, intimidating, and confusing, particularly if they could not read or speak English. An immigrant Latina explained, "because I don't understand English very well . . . to find buildings, where offices are, everything, everything gets much, much harder." All of these seven women, however, indicated that having a Spanish-speaking person (a system navigator) who would meet them at the hospital entrance and stay with them throughout their hospital visit to guide them on where to go and what to do would be extremely helpful. Equally encouraging was to find that the other seven women did not anticipate having as many difficulties navigating a large medical setting, mostly because they had or they were currently attending one and could read and speak English without a problem. Participants across the two groups relied heavily on help from a family member in accessing health services.

One aspect of clinical trials and other studies that is especially problematic is obtaining participants' consent with assurance that their consent is in fact fully informed. Part of the difficulty is that consent forms and verbal explanations are usually written above participants' literacy levels and rely heavily on medical terms. When asked whether women 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 hospital or medical setting, nine women anticipated that they would be able to read such information without major problems. They acknowledged, however, that they have had some difficulties in the past with medical jargon but that they have asked questions to make sure they understand difficult terms. The other five women did not think that they could understand any of the medical information given to them, mostly because of previous experiences. They expected that the information would likely be written in English, which has made it more challenging for them to understand in the past. Other problems not related to literacy levels were also mentioned. An older participant explained, "Because I do not know the language and because my capacity no longer helps me very well, girl. For example, reading what I am going to sign. Give me a person that goes with me, accompanying me. [A person went with me] and was telling me and explaining to me what I was going to sign because I was going to sign just for signing. Well, I would not even know what I was going to sign."

During the interview we asked participants how difficult it would be to fill out forms that asked for personal information (e.g., medical history, how the medication was working). Eight women did not anticipate that completing the forms would be difficult for them or trusted that they could ask for some help if they need it. However, six women said they would absolutely have problems giving personal information, unless they received helped from a family member.

Perceived Contributions to Family and Society

Embracing the nuclear and extended family and close friends as central in life is a Latino value known as *familismo.* Among Latinas who hold this value, it is likely to serve as a powerful motivator for individual actions and important decisions. On this assumption, we asked our study participants to what extent *familismo* would be influential in their decision to participate or abstain from a clinical trial. Indeed, eight women confirmed that they would be motivated to participate in a BC prevention clinical trial if the medication could prevent them from developing and dying from BC and allow them to be there for their children in years to come. The same number of Latinas said that they would also like to participate in a clinical trial if their participation could help in the discovery of a "pill" that proved to be effective in preventing BC and could help save lives of future generations of women in their family and community. Surprisingly, a number of participants (six women) considered the benefits as ambiguous and had difficulty believing in the intergenerational benefits from their individual participation in clinical trials. Thus, they were not motivated to participate. "How would they benefit [other women] if I was the one taking it? Unless it worked, unless it worked then they would benefit, you know? I don't know if it is going to work," said one skeptical participant.

In general, there were minimal efforts to engage Latinas in BC prevention strategies, specifically clinical trials. Considering the minimal (or lack of) education, Latinas' knowledge of BC prevention strategies was poor. Women's perceptions appear to be influenced by this lack of knowledge and the majority of women are hesitant to engage in chemoprevention clinical trials. FGs demonstrated how Latinas' perceptions of pharmaceuticals and physicians influence their willingness to participate in chemoprevention clinical trials. The SSIs revealed that when specifically asked to participate in chemoprevention clinical trials the majority of participants would choose not to participate and would have difficulty adhering to the protocol of the study. These interviews answered specific questions regarding chemoprevention clinical trials within each community. The three phases of this study provided insight into Latinas' decision-making process at both the community leader and member level. The accumulated results from the KI, FG, and semi-structured interviews provide an understanding of how Latinas' decide to participate in BC prevention and control activities and the context in which these decisions are made.

DISCUSSION

Overview of Research Process and Findings

Research Question

This study examined Latinas' perceptions of BC prevention activities and, specifically, chemoprevention clinical trials. The research question is: How do psychosocial and cultural factors influence Latinas' participation in BC prevention and control activities, and, in particular, clinical trials? In answering the question, it was necessary to provide not only a description but also an explanation of how these factors exert influence women's decision to participate in BC prevention. Although a description would provide a broad understanding, an explanation of the decision process more fully captures the dynamic process between culture, psyche, economics, and community behavior. The explanation was addressed using a conical approach, beginning with a broad community perspective and continuing with a focus on the target groups and individual perspectives.

At the community level, the Community Readiness Model (CRM) guided analysis. Accordingly, leaders in the community who work closely with Latinas were first interviewed to gauge the level of awareness regarding BC prevention and clinical trials in the four Colorado communities. These interviews assessed the current level of community readiness regarding BC prevention and provided insight regarding how to increase in the future the level of awareness of BC prevention among community members. The CRM findings revealed that communities were in the "vague awareness" and "preplanning" stages of readiness to address the issue of BC prevention.

The next phase of the study examined the psychosocial and cultural factors that Latinas considered influential in their decision to participate in prevention clinical trials and utilize chemoprevention interventions. Focus groups were conducted in each community and Latinas were asked their opinions regarding BC prevention interventions in general and clinical trials in particular. Analysis of the focus group interviews using grounded theory provided in-depth understanding of the decision-making process beyond descriptive analysis. Comparisons of participants' collective thoughts and opinions revealed a number of themes in Latinas' perception of BC prevention activities.

After learning about the group's perceptions of the various psychosocial and sociocultural factors that influence Latinas' participation in BC prevention activities, semi-structured interviews were conducted to assess individual perspectives on how these factors might influence one's willingness to participate and adhere to the specific procedures involved in BC prevention clinical trials. Attempts were made to interview Latinas' from socioeconomic backgrounds underrepresented in the focus groups.

By addressing the issue of BC prevention at the community, group, and individual levels, we tried to gain an understanding of the factors that influence Latinas' decision to participate (or not) in BC prevention clinical trials. The first section provides a summary from each phase of the study, followed by the implications, future research directions, and the strengths and limitations of the study.

Key Informant Interviews

Nineteen key informant interviews were conducted with community leaders to obtain their perceptions of how their community addresses the issue of under representation of Latinas in BC prevention and control activities. Key informants from two rural and two urban communities included representatives from the health department, the church, *curanderas* (folk healers), and schoolteachers. Across all four communities Latinas' knowledge of BC prevention activities was minimal or almost nonexistent.

Using the scoring guidelines of the CRM, it was determined that the modal stage of readiness is "vague awareness." The two rural communities and one of the metropolitan communities were in this stage. Consistent with the stage of vague awareness (Jumper-Thurman, Edwards, Plested, & Oetting, 2003), the three communities were characterized by a general sense that BC is a health problem and that something ought to be done about it, but there was no immediate motivation to do anything to address this health problem. For the most part, there was no identifiable leadership that directly dealt with the problem of lack of BC prevention programs for Latinas living in the three communities and no resources had been allocated.

One urban community was found to be in the "preplanning" stage for BC clinical prevention activities. This community differed from the other communities in that there were identifiable leaders working with BC issues. However, leaders' efforts were more focused on BC control rather than BC prevention. Leaders had begun discussions to address BC prevention in this community; however, no concrete plans had been made. In this community, a lack of labor and funding were identified as tangible barriers to BC intervention programs.

Focus Groups

Four focus groups with Latinas were conducted in the two rural and urban communities included in this study. Participants revealed a general lack of knowledge regarding BC prevention activities, specifically chemoprevention clinical trials. The majority of participants were unfamiliar with the differences between BC control and BC prevention. The concept of BC prevention was unfamiliar to these women and upon receiving education regarding BC prevention strategies; many women questioned its value and efficacy.

Theme analysis using grounded theory revealed themes in four main areas: personal control over preventing BC (predestination versus free will); distrust of pharmaceutical interventions; distrust in health-care providers; and a fear of participating in a clinical trial. In the first category, the majority of Latinas believed that the onset of BC was determined by a higher power, whereas a minority of women believed that an individual's behavior could influence whether one would get BC. Those who believed in predestination suggested that if a higher being decided that an individual were to have BC, there was nothing a woman could do to prevent this. In turn, these women did not believe in the efficacy of BC prevention activity, particularly those that required pharmaceutical interventions. Alternatively, a minority of women believed that an individual could have control by engaging in behaviors that could influence whether they were to be inflicted with BC. In general, negative health behaviors such as smoking tobacco were seen as contributing factors of BC, whereas exercise was seen as a preventive strategy.

The second theme, Latinas' distrust in pharmaceuticals, specifically for prevention purposes, highlighted Latinas' unfamiliarity with the concept of BC prevention. Thus, the majority of Latinas tended to distrust pharmaceutical interventions for BC. Perception of potential harmful side effects, as well as the questionable efficacy of chemoprevention, fostered this distrust. Many women shared negative past experiences, which tended to shade their perceptions of pharmaceuticals, particularly if they are experimental in nature. Women defended their decision not to participate in chemoprevention because of their concern that it could cause cancer instead of preventing it.

Latinas also distrusted the perceived efficacy of the chemoprevention. Women challenged how researchers determine if chemoprevention interventions prevented the onset of BC if an individual was never going to be inflicted with the illness. Regardless of whether women believed in predestination or not, they questioned how researchers could attribute not having BC to the efficacy of a particular pharmaceutical and not a host of other factors. It is interesting to note that although the women had little or no familiarity with BC prevention clinical trials or other research protocols, their views demonstrated how negative perceptions of pharmaceuticals potentially expand onto chemoprevention clinical trials.

The theme of distrust in health-care providers also arose among focus group participants. The majority of the Latinas in our sample shared negative past experiences with physicians, which included being prescribed the wrong medication or being misdiagnosed. These negative experiences shaded the lens through which these women perceive health-care providers associated with clinical trials and encouraged feelings of distrust in them. Consequently, Latinas expressed their discomfort in volunteering for a study conducted by health-care providers they distrust.

Throughout various discussions regarding chemoprevention, Latinas seemed to have had difficulty grappling with the concept of chemoprevention. Their unfamiliarity with the concept and practice of chemoprevention made some women perceive these interventions as ambiguous. The uncertainty of the chemotherapy process, how the chemoprevention works, and the potential risks of participation all added to this sense of ambiguity. When considering such an ambiguous situation, women experienced fear just thinking about potentially participating in a BC prevention clinical trial. Ultimately, it appeared that it was this sense of fear that inhibited their willingness to participate in BC chemoprevention clinical trials.

Semi-Structured Interviews

Fourteen semi-structured interviews (SSI) were conducted in the four communities to assess one-on-one Latinas' willingness to participate and adhere to clinical trial protocols.

Interviews were organized into three phases: assessment of knowledge of clinical trials and willingness to participate; education regarding clinical trials; and assessment of adherence to clinical trials assuming participants would participate in the study.

Results revealed that none of the participants had ever been referred to a BC clinical trial, particularly a preventive clinical trial. Of the 14 women, only 3 were willing to participate in a clinical trial, 8 were unwilling, and 4 were ambivalent in their decision. Upon receiving education regarding the procedures involved in a clinical trial and the potential risks and benefits of participation, 10 of the 14 women believed that a chemoprevention intervention could be invented to prevent the onset of BC. After women were asked to assume that they would participate in a clinical trial, 10 women expressed commitment to participating in the initial medical procedures for the study, but of these women only 6 committed their compliance until completion of the study. Because some of the medical procedures of the study may not be covered by insurance, 10 of the women refused to pay for these procedures out of pocket.

Ten women stated their ability to trust physicians conducting the study; however, they preferred that the physician be female. Half of the women (seven) felt confident that they could overcome barriers related to navigating the health-care system, such as finding their way in an unfamiliar hospital. Finally, participants were asked if they believed their participation in clinical trial could benefit their family and community, and how much would this influence their decision to participate. Eight of the 14 women stated they would participate in the study to live for their children or to protect them in the future.

Implications of Study

The participation of ethnic minorities in cancer clinical trials continues to be considerably small. In the case of prevention clinical trials, Latinas' have constituted less than 2% of the participants (Fisher et al., 1998). The factors that are specifically influential in the under representation of Latinas have not been identified, although they are likely to be similar to the factors that influence the participation of other medically under-served populations. For example, the evidence in the literature is convincing regarding the role that low SES and access barriers play in impeding the fair participation of ethnic minority populations in clinical studies. Less is known, however, about the social, psychological, and cultural factors that are also likely to play a role in ethnic minority women's participation in clinical trials. A review of the literature suggests that the majority of the research studies that have examined Latinas' perceptions of the factors that influence their enrollment and adherence to BC prevention clinical trials have used quantitative approaches. This study is an initial attempt to expand understanding of this issue qualitatively by exploring, from community leaders and members' perspectives, some of the factors that need to be considered and incorporated into programs for the successful recruitment and retention of Latinas in BC prevention interventions.

Results of this study demonstrated several factors that influence Latinas' decision to participate in BC prevention and control interventions. These factors stemmed from individual, cultural, and systemic dimensions. In this section the three phases of the study will be considered together to discuss the factors that influence Latinas' decision making. Recommendations to increase Latinas' recruitment and retention in BC prevention interventions will be offered. Addressing Latinas' knowledge of BC prevention interventions will provide a context in which to understand their perceptions of pharmaceuticals, relationships with health-care providers, and views regarding clinical trials. Finally, systemic barriers that affect retention in clinical trials will be addressed to inform future recruitment and retention strategies.

Knowledge of BC Prevention

Using the CRM results demonstrated that the majority of the communities were in the "vague" awareness stage of readiness. In this study both community leaders and members were aware that BC is a problem; however, they had minimal knowledge about how to control or prevent BC. Much of women's knowledge regarding responsibility for cancer, and in turn the prevention and control of cancer, lie within a context of strong religiosity and faith in a higher power. Women were divided in their perception of whether predestination versus free will affects the onset of BC. The majority of women endorsed the concept of predestination, suggesting that a higher power, God, determines whether one is inflicted with cancer. Only a minority of women believed that BC was preventable. Participants in this study who believed in predestination were less likely to endorse allopathic interventions as possible prevention strategies. These results parallel those of a similar study that utilized focus groups to assess perceptions of the causes and the nature of BC among women of Mexican-descent (Borrayo & Jenkins, 2001). These women believed that it was "God's will" or "fate" that determines the onset of BC. Consistent with these beliefs, women sited religious practices as possible strategies to prevent BC rather than participation in pharmaceutical interventions.

To increase Latinas' participation in BC prevention and control activities, education efforts should acknowledge these beliefs rather than challenging them while increasing awareness of the impact of under-representation of Latinas in BC prevention activities. If community interventions threaten the cultural integrity of a target population in effort to promote change, success is unlikely (Jumper-Thurman et al., in press). Furthermore, if interventions are congruent with cultural beliefs, community members are more likely to contribute to the change process and enhance the feasibility of the intervention.

Previous research with the CRM (Plested et al., 1998) suggests that the use of surveys may be helpful in assessing community awareness about BC among Latinas and the negative implications of their under-representation in prevention interventions. The survey should be tailored specifically to the community so results have personal relevance and foster motivation for moving the communities towards a higher level of readiness to increase Latinas' knowledge of BC prevention, as well as identifying what resources are needed to initiate these efforts in a particular community. These surveys not only serve as an assessment tool, but also provide an opportunity to inform respondents of the importance of BC prevention and control.

Another strategy involves distributing material that includes both information about BC and how it is prevented. Media exposure through radio and television public service announcements would be an efficient means of distributing information throughout the community. The announcements should be culturally sensitive and guided by an empirical understanding of Latinas' perceptions of BC prevention and control. Brochures, pamphlets, billboards, and fliers could also be circulated throughout the community to increase awareness of the importance of BC prevention.

An ongoing assessment could be conducted to assess who benefits from current BC prevention education efforts and how much impact it has had on the community's level of readiness to address Latinas' under-representation in BC prevention activities. Focus groups, as well as telephone and mail surveys, can be effective ways of assessing the community impact of these interventions. Results from the evaluation research can then be used to develop additional intervention strategies. This information could be distributed in locations such as churches, drug stores, clinics, and community health and recreation centers.

Perceptions of Pharmaceuticals

Overall, most of the women's concerns in this study were related to their lack of knowledge about the interventions and its potential side effects. When informed and probed about the potential minor and major side effects, none of the women were willing to accept major side effects. Although their apprehension is understandable, perhaps their low levels of health literacy prevented them from comprehending how to weigh the costs against the benefits. For example, it was explained to SSI participants that in a previous clinical trial (testing Tamoxifen), 50% of the women at high risk of developing BC had a significantly reduced risk. In addition these women were informed that about 2 to 3 women out of 1,000 (.30%) became at risk of developing side effects such as endometrial cancer, stroke, heart attack, and increased cholesterol. Possibly, the women in our sample did not appreciate that the benefits of participating in a clinical trial outweigh the costs of not. However, these women were not alone in their decision. Despite being at high-risk for BC, using a published algorithm (Gail et al., 1999) to calculate the benefit of participating in chemoprevention, all of the 16 (out of 346) women demonstrated a numerical benefit from chemoprevention denied the intervention (Taylor & Taguchi, 2005).

An alternative hypothesis is that these women have a certain level of distrust in modern medicine that made them apprehensive about the harmful impact of chemoprevention in their health. Overall, Latinas in this study were distrustful of pharmaceuticals. Women feared the possible negative side effects of pharmaceuticals and perceived this as a primary barrier to taking them, particularly if they were experimental. In general, women were suspicious of pharmaceuticals. Concerns for the safety of pharmaceuticals have been demonstrated in previous research (Traulsen et al., 2002). Traulsen and his colleagues (2002) conducted seven focus groups to explore laypersons' perceptions of the quality of pharmaceuticals. Participants criticized both the pharmaceuticals and the providers for not providing enough safety surrounding their consumption. Another qualitative study that included African American men and women in focus groups (Freimuth et al., 2001) also identified the possibility of side effects as a barrier to participation in research. They quoted a participant's statement, "no side effects, no side effects, it's not life threatening, no side effects" (p. 804) explaining his reluctance to engage in medical research. Latinas in this study expressed similar concerns, that a chemoprevention could have detrimental side effects that could in fact cause cancer. The fear of harmful side effects appears to be a primary factor for distrust in pharmaceuticals.

In 1990 individuals living in the United States made an estimated 425 million visits to alternative health-care providers, exceeding the number of visits to allopathic primary-care physicians (Eisenberg et al., 1993). Compared to Chinese, African American, and Caucasian women with BC, Latinas (22% of the sample) were most likely to utilize dietary therapies and spiritual healing (Lee et. al., 2000). In general, Latinas in this study showed a similar preference for natural or herbal remedies over allopathic remedies. Individuals of Mexican descent who held traditional health beliefs have been shown to be more likely to rely on herbal or home remedies than seeking Western allopathic remedies (Gordon, 2004). Considering that on average Latinas in this study considered themselves bicultural; perhaps, these women held more traditional health beliefs that contribute to their distrust in pharmaceuticals and preference for herbal remedies.

Relationships with Health-care Providers

Previous literature has identified distrust in health-care providers as a factor inhibiting ethnic minority participation in research (Corbi-Smith et al., 2002; Roberson, 1994; Mouton et al., 1997). Corbi-Smith and colleagues (2002) surveyed one thousand African American and Caucasian individuals via the telephone regarding their trust in health-care providers and clinical research. The development of a Distrust Index found that compared to Caucasians, African Americans were more likely to believe that they would be asked to participate in harmful studies or exposed to unnecessary risks. African Americans were also more likely to believe that physicians would not fully explain research or would treat them as part of an experiment without their consent. These authors discussed these findings within the historical context of the mistreatment of African Americans throughout U.S. history, including during research endeavors, primarily citing the Tuskegee syphilis trials. They suggested that the publicity of African American's mistreatment heightens their distrust in the health-care profession. Latinas in this study also described feelings of distrust towards health-care providers stemming from previous negative experiences with health-care providers. These experiences have created a sense of dissatisfaction in provider care and a reluctance to trust health-care providers, particularly in reference to how they utilize experimental pharmaceuticals.

Latinas' distrust in health-care providers may stem from their dissatisfaction with prior treatment. The 2002 CAHPS Medicare Managed Care Survey of 125,369 Medicare adult enrollees (Hays, 2004) across the United States, including 8,463 Latino/as and 13,264 "other" racial ethnic minorities, found that English-speaking Latino/as reported worse experiences with care than Caucasians regarding pharmaceutical care, home healthcare, access to physicians, planned services, staff helpfulness, and timeliness of medical care. According to the participants of the SSIs, Latinas tend to communicate better and be more satisfied if the physician is able to communicate with them in Spanish. Considering the growing population of Spanish-speaking patients who utilize health-care services, there is an unfortunately small minority of physicians that has been identified as Spanish speaking (Yoon, Grumbach, & Bindman, 2004). Morales (1999) demonstrated that among 6,911 adults, Spanish-speaking Latina/os had more negative perceptions of provider communication than that reported by English speaking Latina/os or non-Latina/o Caucasian respondents. Individuals with limited English-speaking proficiency have also been shown to have limited access to health care (Fiscella et al, 2002), lower rating of care (Weech-Maldonado et al., 2003), and less satisfaction with care (Morales & Cunningham, 1999; Borrayo et al., 2001). It is likely that Spanish-speaking health-care providers would facilitate Spanish-speaking Latinas' understanding of BC prevention interventions while fostering more trust in the patient-provider relationship.

Participants of the SSIs also reported better communication with female physicians over male. Certainly, a preference for a female provider is not unique to Latinas. Previous findings, however, suggest that this preference is particularly strong among Latinas, to the point that some would rather abstain from seeking any type of health care if the provider is not a female (Borrayo et. al., 2001). Efforts should then be made to match Latina participants with Spanish-speaking female health-care providers to ensure their successful enrollment and adherence to BC prevention clinical trials.

Physician referral has been shown to be a significant determinant in decisions to participate in a variety of BC prevention interventions, including the BC Prevention Trial (BCPT) (Yeomans-Kinney et. al, 1998), Tamoxifen for chemoprevention (Taylor & Taguchi, 2005), hormone replacement therapy (McNagney & Jacobsen, 1997; Newton et al., 1998). Yoenams-Kinney and colleagues (1998) found that physician recommendation was the most important factor influencing respondents' decision to participate in clinical trials and that women who were advised by their family physician to participate in the trial were 13 times more likely to participate. Latinas' under-representation in clinical trials might be a reflection of a lack of referral. The social influence that physicians have on Latinas' decision to participate in BC prevention clinical trials was supported by this study's participants. Of the 14 Latinas who participated in the SSI, none had participated in a BC clinical trial, nor had a health-care provider referred them to participate in one. Clearly, some women would not consider participating if their physicians did not recommend this course of action to them. Several reasons could explain this lack of referral to a clinical trial. For one, these women might not be within the "high-risk" population to develop BC and thus, are not eligible to participate in one. Another reason could be that their health-care providers are not appropriately informed about breast cancer clinical trials or are unaware of where to refer the women. An additional viable explanation is that health-care providers do not refer older Latinas to breast health-care services at the same rate that they tend to refer younger and non-Latina Caucasian women. According to the literature, older Latinas are less likely to report a physician referral to BC control activities, (Markides & Black, 1996) suggesting that they are probably also less likely to be referred to BC prevention activities such as those tested in clinical trials. These findings support efforts to increase education of chemoprevention clinical trials to not only Latinas but also to physicians who are well-positioned to make this referral.

Perceptions of Clinical Trials

In general, Latinas' perceptions of clinical trials were negative. Latinas expressed sentiments of feeling like a guinea pig and distrusting the research process. In previous focus group studies, African American participants have reflected on the mistreatment of African Americans in the Tuskegee trial and how this incident shaped their perceptions of clinical trials (Freimuth et al., 2001) and biomedical research (Bates & Harris, 2004). Awareness of the historical mistreatment of African Americans in clinical trials evoked feelings of distrust and suspicion among participants of those studies. In this study a participant cited the Tuskegee study as an influence on her perceptions of clinical trials, "I have a friend that went through some medical research . . . but me, myself, I've always been skeptical about it because of the Tuskegee incident." Clearly, the impact of negative historical events on perceptions of clinical trials is lasting. To allay Latinas' fears regarding their possible mistreatment in a clinical trial explanation of the possible risks of participation should allow for questioning and processing of these fears during the informed consent process.

Latinas in this study perceived entering a clinical trial as voluntarily entering into an ambiguous and risky situation. Freimuth and his colleagues (2001) provided a similar finding in their focus groups with African Americans stating, "many participants perceived such procedures as extremely high risk due to the inability of participants to know for sure what they were receiving and what negative effects it could have on them" (p. 804). Not knowing the consequences of participating in a clinical trial allows for much ambiguity, which, in turn, evokes a sense of fear. Among 48 women at high-risk for BC who discussed taking Tamoxifen prophylactically with their physician, the primary factor inhibiting them from taking this pharmaceutical was their fear of not knowing the potential negative consequences of participation (Taylor & Tuguchi, 2005).

This feeling of ambiguity that Latinas experienced is likely fostered by their lack of knowledge regarding BC prevention, in particular chemoprevention clinical trials. Individuals cope with ambiguity differently. An individual with a low tolerance for ambiguity (Frenkel-Brunswik, 1948) may experience stress, react impulsively, and avoid ambiguous situations. Alternatively, individuals with a high tolerance for ambiguity perceive this as a challenge and react with excitement to enter the ambiguous situation (Furnham & Ribchester, 1995). Hofstede (1984) demonstrated cultural differences in avoidance of ambiguity in an international study of "uncertainty avoidance" in an organizational context. Compared to individuals living in the United States, participants living in Mexico reported higher uncertainty avoidance. Hofstede explained that cultures with higher uncertainty avoidance structure mechanisms (religion) to defend themselves from this uncertainty. Latinas who endorse the concept of predestination may rely on religion to cope with the uncertainty of BC. The women in this study appear to have a low tolerance for ambiguity associated with their minimal knowledge of BC prevention coupled with their distrust in pharmaceuticals and health-care providers. Increasing knowledge and fostering trust among these individuals likely would decrease this ambiguity.

Systemic Barriers to Participation in Clinical Trials

Once Latinas decide to enroll in a clinical trial, the focus should be on ensuring their actual compliance to both the consumption of the chemoprevention intervention and the related clinical procedures. Compliance is both an attitude and a behavior. As an attitude it entails a willingness to follow health advice; as a behavior it is related to the actual carrying out of specific recommendations. In this study, the majority of the participants indicated that they would be "willing" to adhere to the clinical procedures but a lesser number anticipated being "willing" to comply with the intervention (a "pill"). The literature on medical compliance suggests that even fewer women would actually adhere to taking the intervention and to participating in the required clinical procedures such as annual medical exams (DiMatteo, 1994; Haynes, McKibon, & Kanani, 1996). Even when the specific motivators for Latinas to comply remain to be explored, it is likely that most of them would be similar to those that have been identified in the literature. Overall, women's good communication and satisfaction with their health-care provider have the potential to contribute to their adherence (DiMatteo, 1993). Perhaps additional efforts to increase compliance (e.g. telephone reminders or mailings) could be integrated into the protocol of clinical trials to further enhance compliance.

A more complicated issue to address in the recruitment and retention of Latinas to BC prevention clinical trials is overcoming the influence of pervasive access barriers. Societal and institutional barriers are particularly limiting for medically underserved ethnic minority groups. Among the most salient societal barriers is their position at the bottom of the social strata, because of their low socio-economic status and literacy levels, and for some, also on the basis of their immigrant status (Freeman, 1993). All of these social disadvantages were present for the Latinas in this study. Moreover, they recognized the strong influence that institutional barriers play in their access to health-care services. For example, chemoprevention clinical trials are conducted at institutions (e.g., community and university hospitals, comprehensive cancer centers) where women have to travel to access them. Even if the distance is relatively short, transportation and related costs become an issue for poor individuals who must concentrate on day-to-day survival. In this study, transportation to a clinical trial setting was considered problematic by 50% of the participants, whereas the other 50% appraised it as feasible (but for some these women, it was feasible only with the help of a family member who could transport them to the setting).

It is also worth noting women's perception of the level of difficulty that they would encounter in their attempt to navigate the medical institution's system and procedures. Similar to their views on transportation, 50% of the SSI participants responded that they anticipate it would be difficult for them to find a specific clinic, sign in, and talk to several health-care professionals within an institution. An important factor that makes such tasks problematic is some women's inability to communicate in English. Moreover, their lack of English fluency and low health literacy make it difficult for them to also understand the process of informed consent and the paperwork involved in clinical trials research. However, women concurred that the help of a health navigator or a family member would facilitate their access to medical institutions.

Indisputable was the important influence that health insurance coverage has on Latinas' appraisal of their potential participation in a BC prevention clinical trial. Understandably, a vast majority of participants were unwilling to participate if they had no health insurance or if their source of health insurance would not cover medical costs. A survey conducted by the American Society of Clinical Oncology (ASCO), found that denials of reimbursement for routine patient care costs are among the main obstacles to enrollment in cancer clinical trials (Cancer Leadership Council, 2000). Routine patient care costs include physician charges, hospital charges, and routine tests. Changes in public policy since 2000 have increasingly mandated third-party payers, including Medicare, to cover routine patient care costs associated with clinical trials. Although prevention cancer clinical trials are not automatically covered, if they are certified to meet a set of qualifying criteria, they can be covered (NCI, 2002). Thus, assuming that they were clinical trials' candidates, the only Latinas in our study who could potentially participate in an approved BC prevention clinical trial were the few women who had Medicare, whereas the majority of women in this study would not be able to participate.

Changes in public policy, as well as at the institutional level, need to be made in order to overcome the existent access barriers that medically underserved populations face. Certain changes are clearly more feasible than others, and we are beginning to see some of these implemented. There are institutions that provide services that facilitate access, such as travel reimbursements, health navigators, translation services for non-English speaking individuals, and even funds to cover health-care costs for uninsured participants (Brown et al., 2000; Trinkl, 2001). Unfortunately, many other institutions still do not provide many of these services. Consequently, for medically underserved population such as Latinas, equal access to studies testing state-of-the-art BC prevention interventions continues to be both a goal and a challenge.

Future Directions of Research

Development of a theoretical model explaining Latinas' willingness to participate in chemoprevention clinical trials would provide a clearer understanding of this issue. Further analysis incorporating the KI interviews, focus groups, and SSIs would allow for a comprehensive theoretical model guided by various sources of information and data. Once a theoretical model is developed it should be evaluated quantitatively using a scale developed based on the findings of this study. A large distribution of this scale would allow for validation of this theory using testing methods such as structural equation modeling.

This study provided much insight into Latinas' decision to participate in chemoprevention clinical trials. To increase recruitment and retention of Latinas into BC prevention and control activities, awareness of BC must increase. Education efforts to inform health-care providers, policy makers, and other influential leaders of the current clinical trials in the community should begin to increase awareness of BC prevention in these communities. As suggested by the CRM, surveys of the impact of under-representation of Latinas in BC prevention activities should be assessed and results should be used to demonstrate the need for initiatives. In addition, media material should be circulated throughout the community to heighten awareness of this issue and encourage community action. After these measures have been done, a re-evaluation of the awareness of BC prevention and control activities should be taken according to CRM. Re-assessment would assess change in the community as well as demonstrate how to utilize the CRM in community programs.

Finally, the aim of this study was to assess the cultural factors that influence a woman's decision to participate in BC clinical trials. Considering that this study only included Latinas, it is difficult to assess how factors unique to Latino culture influence participation compared to women from other ethnic groups. Without having comparison groups, it difficult to determine how socio-economic factors affect this decision, as opposed to sociocultural factors. However, the scope of this study was to assess Latinas' awareness and perceptions of clinical trials. Future comparative studies should include women from other ethnic groups to assess whether cultural differences, levels of acculturation, and socio-economic status influence participation in clinical trials.

Strengths and Limitations of the Study

Guided by the CR model, the purpose of this study was to understand the barriers to Latinas' participation in BC prevention and control activities such as clinical trials. The CRM was chosen as the guiding theoretical framework for this study because of its previous applications in working with ethnic minority communities (e.g. Jumper-Thurman & Plested, 2000). It was perceived as a culturally sensitive tool to assess Latinas' awareness of BC prevention and control efforts. Originally, the CRM was designed to be used by community members and leaders to address a problem that the community perceives as problematic. In this study the CRM was used to assess an issue, Latinas' under representation in BC prevention and control activities, which we as researchers identified as a problem. A limitation of using the CRM in this study is that it may neglect a variety of factors that contribute to Latinas' under representation in clinical trials that extend beyond the six dimensions assessed during key informant interviews. Factors not assessed by the CRM may include the influence of being from a lower socio-economic background, being female, or being a minority. Unfortunately, the scope of this project did not account for many societal and systematic factors that contribute to this issue. However, it is likely that these factors also contribute and perpetuate Latinas' under representation in prevention and control activities.

In this study the CRM was used to assess awareness of BC prevention and control activities within a particular community and also in comparison to the other communities involved in the study. The findings of the key informant interviews may be interpreted that one community has less or more deficits that the other based on their level of awareness as assessed by the CRM. In turn, these findings may be perceived as derogatory or blaming a community for the cultural or psychosocial factors that may influence one's decision to participate in BC prevention or control activities. While this is a limitation of the CRM, the intent of this study was neither to portray these communities as having deficiencies nor to minimize the influence of societal and systemic factors on the community's ability to address this issue. The CRM has received criticism in the past suggesting that it may threaten the cultural integrity of the communities (Jumper-Thurman et. al., in press). However, the developers of the CRM have repeatedly stated the intention of the model is to embrace the cultural identity of a particular community. Furthermore, the CRM discourages challenging the cultural values of norms of communities and suggests that if this occurs, the recommendations of the model will likely prove unsuccessful in promoting change. In this study, the CRM was used to inform the additional stages of the study (e.g. focus group and semi-structured interviews) and implications offered in this study are not intended to challenge the cultural integrity of the communities involved.

This study provided insight into what factors medically underserved Latinas consider influential in their potential enrollment and adherence to BC prevention and control activities. The use of qualitative techniques ensured proper assessment of this issue. Face-to-face interviews provided flexibility to further explain clinical trials to participants and ensure our understanding of their responses. The format of the focus groups allowed us to witness the influence of peers on decision-making. Often, a woman would begin her statements with one opinion, but after conversing with peers her opinion would change. Using a qualitative approach enhances our understanding of quantitative findings. These methods provide an assessment of how findings might be applied and received among community members. The focus groups provided insight as to how Latinas interpret information they receive from health-care providers and how it influences their decision to participate in BC prevention activities.

This study relied heavily on the generosity of community leaders and members throughout Colorado. Initial contacts with community leaders established relationships that allowed entry into the community. Building from the trust community leaders already established in the community, we were able to recruit and work with community members to address a sensitive topic. This study clearly demonstrated the reciprocal relationship between community members and researchers. Each interview and focus group was not only an opportunity to collect data, but it was an opportunity to heighten community awareness regarding BC and the need to prevent and control BC to decrease mortality from this disease. The effectiveness of this methodology could be used to inform future studies and as a potential method to introduce prevention efforts in the community. Involving community members in the research process bridged research and community to begin to address the issue of BC in these communities. Women in this volunteered not only their time, but also often their homes and transportation for their peers in the group. In doing this participants not only contribute to research but also experience how they can actively participate in the community to address problems or issues.

Using key informant interviews the CRM assesses a community's readiness to address a particular problem or issue. Beebe and colleagues (2001) criticized the use of key informants charging that their views may represent only the vocal majority as opposed to the community at large. They further argued that key informants might use their responses to meet a particular political objective. As with all research, the participants selected may confound the results. However, in this study, we selected key informants who represented several different aspects of the Latino communities throughout Colorado. Building upon previous collaborations established in each community, we went to great lengths to select key informants who work with Latinas on a variety of levels and who would provide different perspectives on the issue. We interviewed a wide range of representatives in the community from the health department as well as workers who work for nonprofit organizations and independent folk healers. By interviewing leaders who work with community members at a variety of levels, we attempted to gain different perspectives that would represent different factions in the community.

Beebe and colleagues (2001) also challenged that the KI interviews are time consuming and an inefficient means of assessing community readiness. Considering the sensitivity of the BC among Latinas and the unfamiliarity of BC clinical trials, we propose instead that these qualitative methods were the best means of assessing knowledge and perceptions of BC prevention and control in these communities. In addition, we perceived the KI interviews were instrumental for establishing rapport. Several variables related to how this study was conducted place some limitations in the generalizability of its findings. First, a small sample of four focus groups and 14 SSIs residing in one state of the United States is unlikely to be a representative sample of the population Latinas in the nation. A number of participants specified that they or their parents were born in Mexico on their demographic questionnaires. Therefore, findings from this study may be more specific to women of Mexican-descent as opposed to Latinas in general. However, since the demographic questionnaire was not designed for participants to specify their country of origin, we are unable to describe the results of this study in reference to women of Mexican-descent.

Second, because the aim of the study was exploratory, in-depth personal interviews with the participants were deemed appropriate. However, the nature of such interviews produces large quantities of qualitative data that is hard to manage with a larger sample. Nevertheless, the study provides information on what factors some medically underserved Latinas perceive as influential in their potential enrollment and adherence to BC prevention clinical trials. The information obtained can guide the development of larger scale studies that can provide findings that are more generalizable.

The only inclusion criteria for participants in this study were being a Latina and being 50 years old or older. Although we inquired about some potential BC risk factors, such as age and personal or family history of cancer, we did not use these or any other information to select participants at high BC risk (that could be candidates for BC prevention clinical trials). Knowing that they were at high BC risk might have influenced differently Latinas' perceptions about their enrollment and participation in BC prevention clinical trials. Likewise, including Latinas already participating in a clinical trial would have afforded information based not just on perceptions but also on actual experiences. Nevertheless, the marked absence of medically underserved Latinas in clinical trials makes any investigation with them difficult. As we become more successful enrolling Latinas in clinical trials, research with this population will be more feasible and imperative. For now, the challenge is to increase the number of Latina participants in BC prevention clinical trials in order to decrease disparities in clinical studies participation, but more importantly to decrease disparities in BC mortality rates.

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APPENDIX A

REVISED READINESS SCALE

KEY INFORMANT INTERVIEW

ENGLISH

Ethnic Minority Women's Participation in Breast Cancer Clinical Trials

Part I (Key Informants)

Key Informant Community Readiness Interview

Hello, my name is _______________, and I'm a research associate at the Tri-Ethnic Center at Colorado State University. We are conducting a State study, related to breast cancer prevention.

For Phone Interviews:

A. (For the first contact from ________, You were contacted by ______________ about our study and the _______ program and she/he indicated that you might be willing to participate in the interview component of the study).

Would you be willing to be interviewed? Yes or No

B. If this is a cold call: Your community was selected randomly to participate in this survey. I'm contacting key people and organizations in (name of community) that have been identified as being knowledgeable and having opinions or perceptions about breast cancer among older women in your community. You were identified as such a person. The purpose of our study is to learn how urban/rural communities are dealing with this issue and ultimately to provide communities with prevention strategies would work to reduce breast cancer rates. We'll be interviewing people by phone or in person. Each interview should last about a half-hour and of course, the entire process, including individual names and the name of your community will be kept confidential.

Would you be willing to be interviewed? Yes or No

If YES:

While your willingness to be interviewed indicates your consent to participate in the study, I would like to reiterate that this interview is part of a research project being conducted through Colorado State University. There is no personal risk, nor is there any direct benefit to you. Data gathered from this interview will be used to create media material and intervention programs that will encourage participation in breast cancer clinical trials in communities such as yours. This interview is voluntary, meaning that you are free to stop at any time during the interview. Should you have any questions upon finishing the interview, please feel free to contact Dr. Evelinn Borrayo in the CSU Psychology Department at (970) 491- 7324.

If NO, or at the end of the interview:

Would you be willing to give us the names of any other people who you think would be good for such an interview such as leaders in public health, the medical profession, alternative medicine, clergy or religious community, social services, elder leaders or community members at large?

Introduction to the interview:

Before I begin, I want to let you know that I will be typing your responses as you give them. Also, the following questions need to be asked in a designated order and I have to ask you all the questions. If you believe that you have already provided the answer to a question, just let me know that, or you may expand on that answer.

Definition: The focus of this study is to learn more about any existing breast cancer prevention efforts in your community, which could include mammography screening, clinical breast exams, or treatments through clinical trials. Clinical trials are studies in which doctors experiment with a pill that could prevent breast cancer. This means that women who participate in clinical trials are given a pill that may keep them from developing breast cancer. So clinical trials, mammography screenings and doctor examinations can all be considered breast cancer prevention efforts.

A and B: PREVENTION PROGRAMMING AND COMMUNITY KNOWLEDGE ABOUT PREVENTION

1. **What efforts addressing breast cancer prevention are available in your community?**
2. **Are the people in the community aware of these prevention efforts? Please explain.**
3. **How long have these efforts been going on in your community?**
4. **What are the benefits of the prevention efforts?**
5. **What are the weaknesses of the prevention efforts?**
6. **How much of a concern is breast cancer in your community?**
7. **How much do the leaders, groups or committees in your community know about these efforts?**
8. **Would there be any segments of the community for which these services would not be available? Prompt: for example due to age, religion, ethnicity, gender or socioeconomic status.**

9. Is there a need to expand these prevention services? If no, why not?

10. Are there plans to expand or develop other efforts? If yes, please explain.

C. LEADERSHIP

***The following questions look at the leadership in your community.* ("Leadership" may include anyone in the community who is appointed or elected to a leadership position or is influential in community affairs.) For example: an individual, an elder, a woman, an agency director...**

11. Who, in your opinion, are the leaders, either formal or informal positions in your Community?

Prompt: people whose opinion is respected and/or are influential and who may be contacted informally when issues arise. (No names are needed, just title)

12. Does the leadership see prevention of breast cancer as an issue? Please explain.

13. Are the "leaders" in your community involved in prevention efforts? Please list.

14. Would the leadership support additional prevention efforts? Please explain.

D. COMMUNITY CLIMATE

15. Would the community support prevention efforts? If yes, how?

16. What are the primary obstacles to prevention efforts in your community?

17. Based on the answers that you have provided so far, what do you think is the overall feeling among community members regarding prevention of breast cancer?

E. KNOWLEDGE ABOUT THE PROBLEM

18. What type of information is available about breast cancer in your community?

19. What does the community know about prevention and treatment of breast cancer? Is there overall knowledge about signs and symptoms of breast cancer?

(Let the person know that there are 10 more questions)

20. How do people obtain this information in your community?

F. RESOURCES FOR PREVENTION EFFORTS

21. Who provides resources or services for people with breast cancer?

22. **What is the community's attitude about supporting prevention efforts, such as providing transportation, volunteering their time, providing money or space?**

23. **Do people in your community know what it takes to run these programs or activities?**

24. Are you aware of any proposals or grants that have recently been submitted for funding that address the issue of breast cancer prevention in your community? If yes, how many?

25. **What is the level of expertise and training among those working toward prevention of breast cancer?**

26. **Are you aware if there are any efforts being made to evaluate the prevention efforts or policies that are in place?**

27. **Are the evaluation results being used to make changes in programs, activities, or policies or to start new ones?**
    If yes, how?

29. What ways could be used to engage a woman in breast cancer prevention clinical trials?
    (If needed prompt, clinical trials are studies to test if pills can prevent breast cancer).

The following questions are optional, but help us know the types of people we have interviewed. Would you be willing to answer questions such as profession, ethnicity, age? *If "Yes"*:

What is your work title?

What is your ethnicity:
Anglo
Hispanic
American Indian
African American
Asian American
Other

What is your age range: 19-24
25-34
35-44
45-54
55-64
65 and above

Do you live in (name community)?
If not the community we have selected, ask what community?

Do you work in (name community)?
If not the community we have selected, ask what community?

How long have you lived in your community?

APPENDIX B

COMMUNITY READINESS MODEL

SCORING INSTRUCTIONS

SCORING INSTRUCTIONS

1) Move through the interviews one at a time, scoring each interview individually. Read through each interview before you begin to score to get a general feeling and impression from the interview.

2) Begin picking out statements and references that refer to specific dimensions, and then create a score for each of the six dimensions according to the anchored grading scales. Each interview will encompass six different dimensions scores. Interviews are scored by dimensions and not by individual questions.

3) Under the section titled INDIVIDUAL SCORE, you are to fill in your scores for each dimension of each of the interviews.

   Please note: There may be more then four key informant interviews in a community. If this is the case simply add #5 and #6, handwritten to this form.

4) The section under the subheading COMBINED SCORE represents the section where you and one other scorer that scored this same community will come together and agree on the scores for each interview on each of the dimensions. It is important that there be consensus on the scores by both scorers. Remember different people can have slightly different impressions and it is important to explain how you arrived at your decision. Enter your agreed upon score on one of the scoring sheets for each dimension and each interview.

5) After both scorers have agreed upon the scores in the above section, the mean will be calculated for the CALCULATED SCORE. For some (actually many) this can be confusing so let me give you an example. Let's say that under the FINAL SCORE section, myself and the other scorer have under Dimension A the following:

Dimension A:	#1	#2	#3	#4
	3.5	5.0	4.25	4.75

I would then add the scores **across** for all interviews under Dimension A and divide by four (calculate the mean). So, I would get a calculated score for Dimension A of 4.37. This will then be entered under Dimension A, CALCULATED SCORE, and so forth by Dimension.

6) For the AVERAGE at the bottom of the page, below Dimension F, you will take the Calculated Score for each Dimension, add them together and divide by six (the mean for all of the dimensions combined). For example, if we had:

Dimension A:	3.28	
Dimension B:	5.67	
Dimension C:	2.54	
Dimension D:	3.29	
Dimension E:	6.43	
Dimension F:	4.07	
	25.28	25.28/6 = 4.21

A score of 4.21 would be entered under AVERAGE.

7) For STAGE, you will enter the stage that is represented by your final average. In the above example, the Calculated Average represents the 4th stage or Preplanning.

   Please Note: The scores correspond with the numbered stage, so a score between a 1.0 and a 1.99 would be the first stage, a score of 2.0 to 2.99 would be the second and so forth.

8) Finally, under comments, write any impressions about this community, any unique outcomes, any qualifying statements that you wish to make regarding the score of the community.

APPENDIX C

COMMUNITY READINESS MODEL

SCORING SHEET

COMMUNITY READINESS SCORING

Staff: ____________________
Date: ____________________

INDIVIDUAL SCORE

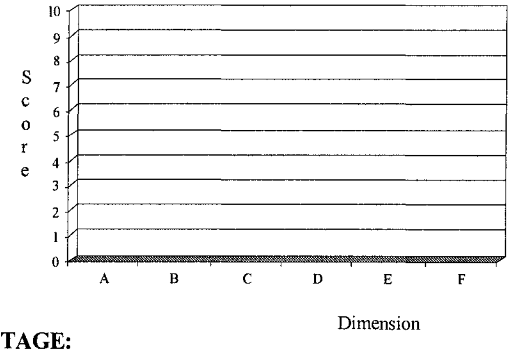
INTERVIEWS:	#1	#2	#3	#4
Dimension A:				
Dimension B:				
Dimension C:				
Dimension D:				
Dimension E:				
Dimension F:				

COMBINED SCORE

INTERVIEWS:	#1	#2	#3	#4
Dimension A:				
Dimension B:				
Dimension C:				
Dimension D:				
Dimension E:				
Dimension F:				

CALCULATED SCORE

Dimension A:
Dimension B:
Dimension C:
Dimension D:
Dimension E:
Dimension F:



AVERAGE: ______ **STAGE:** ______

- **COMMENTS about Calculated Score (if any):**

APPENDIX D

INFORMED CONSENT FOR FOCUS GROUP IN ENGLISH

COLORADO STATE UNIVERSITY
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT
INFORMED CONSENT TO PARTICIPATE IN A FOCUS GROUP

TITLE OF PROJECT: Latinas' Participation in Breast Cancer Clinical Trials

NAME OF PRINCIPAL INVESTIGATOR: Evelinn A. Borrayo, Ph.D.

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS/PROBLEMS: Evelinn A. Borrayo, Ph.D. (970) 491-7324

SPONSOR OF PROJECT: Susan G. Komen Breast Cancer Foundation

PURPOSE OF THE RESEARCH: In this project we want to know what Latinas think about clinical trials. Clinical trials are also known as clinical studies. In a clinical trial, doctors experiment with a pill that could prevent breast cancer. That is, women who participate in clinical trials are given pills that may keep them from developing breast cancer. Usually, women who are at the highest risk of developing breast cancer are allowed to participate in this type of clinical trial.

We are interested in knowing what barriers may prevent Latinas from participating in clinical trials. We will discuss several things, including: "cultural beliefs, acceptance of prevention, barriers to treatments, and appropriate ways to encourage Latinas to participate in clinical trials." The questions that we will ask you will allow us to develop new ways to help Latinas participate in clinical trials. In addition, the information will be shared with other professionals interested in Latinas' health. We will share information through presentations and publications in conferences and professional journals.

PROCEDURES/METHODS TO BE USED: We are conducting a focus group so that we may talk with eight to ten Latinas in four communities. The focus group interview will last approximately 60 minutes. During the interview we will ask you questions around the topic of Latinas' participation in breast cancer clinical trials (see purpose of the research above).

Notes will be taken on the comments made by all group participants. The discussion will be audio-taped. Tapes will help us ensure that none of the information we receive from you is lost. However, we are being cautious so that no one else besides the interviewers can identify who participated. For example, no names will be used when the tapes and the notes are written in a summary. We will destroy the tapes at the end of the study. Other group members will also be asked to respect confidentiality.

To thank you for your time and help, you will be given $10.00 in cash and a small gift.

RISKS INHERENT IN THE PROCEDURES: The focus group could lead to sharing private information. For this reason, we ask that you avoid mentioning names of people outside of the group. We ask you to maintain the confidentiality of all participants. You will not be asked about your personal experiences.

You can tell the interviewer at any time that you do not want to talk any more about the topic. You can also leave the group at no costs to you. You will still be given the $10.00 cash and small gift. Thus, there is no risk to you. If talking about breast cancer makes you feel uncomfortable, we can arrange for you to talk with a counselor. We can also help you access other resources. It is not possible to identify all potential risks in research studies, but the researcher(s) have been cautious to minimize any known and potential, but unknown, risks.

Page 1 of 2

Participant initials _______ Date _______

BENEFITS: Your responses will help us to understand the barriers that keep Latinas from participating in clinical trials. The information you share will help us know the attitude people in your community have about breast cancer and about women who participate in clinical trials. You can also tell us what things are accepted in you culture to help Latinas participate in clinical trials. Once we understand the suggestions we receive from the group, we can help communities like yours. We want to help Latinas so that they can participate in clinical trials. If Latinas take prevention pills that would keep them from developing breast cancer, they could probably also prevent dying from this disease. For all these reasons, your help in getting this information out is very important and appreciated.

CONFIDENTIALITY: As we explained, we will not put your name on the summary of the discussion. When the study is finished, the tapes will be destroyed. The interviewers will be the only people who know the name of each person in the group, and they will not use your name when reporting the study findings.

LIABILITY: The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury. Questions about study participants' rights may be directed to Celia S. Walker at (970) 491-1563.

PARTICIPATION: Your participation in this research is voluntary. You may take away your consent and stop participating at any time. You will not lose any of the benefits offered if you leave. You may also refuse to answer any questions. If the interview raises any concerns and you would like to talk to a counselor, we can help you find a counselor. Your signature indicates that you have read this information and willingly sign this consent form. Your signature also indicates that you have received, on the date signed, a copy of this form containing _2_ pages.

____
Participant name (printed)

__________________________________ __________________
Participant signature Date

__________________________________ __________________
Witness to signature (project staff) Date

Page _2_ of _2_ Participant initials _______ Date _______

APPENDIX E

INFORMED CONSENT FOR FOCUS GROUP IN SPANISH

COLORADO STATE UNIVERSITY
INFORAMACION PARA CONSENTIR PARTICIPAR EN UN PROYECTO DE INVESTIGACION
INFORAMACION PARA CONSENTIR PARTICIPAR EN UN GRUPO DE ENFOQUE

TITULO DEL PROYECTO: Participación de Mujeres Minoritarias en Estudios Clínicos del Cancer del Seno

NOMBRE DEL INVESTIGADOR PRINCIPAL: Evelinn A. Borrayo, Ph.D.

NOMBRE DE LA PERSONA A CONTACTAR Y TELEFONO PARA PREGUNTAS/PROBLEMAS: Evelinn A. Borrayo, Ph.D., (970) 491-7324

PATROCINADOR DEL PROYECTO: Susan G. Komen Breast Cancer Foundation

PROPOSITO DEL PROYECTO: En este proyecto queremos saber que piensan las Latinas acerca de los estudios clínicos. Los estudios clínicos se les conoce en Inglés como "clínica triaos." En un estudio clínico, los doctores experimentan con una píldora que puede que prevenga el cáncer del seno. Esto se refiere a que a las mujeres que participan en estudios clinicote les dan pildoras que las podria librar de desarrollar el cáncer del seno. Usualmente, las mujeres que están a mas alto riesgo de desarrollar el cáncer del seno se les permite participar en este tipo de estudio clínico. El projecto en el que usted esta participando NO ES un estudio clínico. En lugar de serlo, este projecto quiere saber que piensa usted sobre los estudios clínicos.

Nosotros estamos interesadas en conocer que barreras previenen a las Latinas de que participen en estudios clínicos. Discutiremos varias cosas, incluyendo: "creencias culturales, aceptación de la prevención, barreras para los tratamientos, y apropiadas maneras de motivar a las Latinas a que participen en estudios clínicos. Además, la información será compartida con otros profesionales interesados en la salud de las Latinas. Vamos a compartir la información a través de presentaciones y publicaciones en conferencias y revistas profesionales.

PROCEDIMIENTOS/METODOS A USAR: Estamos conduciendo una entrevista de grupo conocida como "grupo de enfoque" para que podamos hablar con ocho a diez Latinas en cuatro comunidades. Antes de la entrevista le pediremos que conteste una encuesta de salud corta que toma en contestar aproximadamente de 5-10 minutos. Porfavor no escriba su nombre en la encuesta. La entrevista en el grupo de enfoque durara aproximadamente 60 minutos. Durante la entrevista le vamos a hacer varias preguntas alrededor del tema de la participacion de las Latinas en estudios clínicos del cáncer del seno (vea el proposito de la investigacion arriba).

Se tomarán notas sobre los comentarios que hagan las participantes del grupo. La discusión será audio-grabada. Las cintas de grabación nos ayudaran a asegurarnos que ninguna de la información que recibimos de usted no se pierda. Sinembargo, hemos sido cautelosas de que nadie mas aparte de la entrevistadora pueda identifacar quien participo. Por ejemplo, ningun nombre será usado cuando las cintas y las notas sean escritas en un resumén. Vamos a destruir las cintas al final del estudio. A otras miembras del group tambien se les va a pedir que respenten la confidencialidad de las demas. Para agradecerle por su tiempo y ayuda, le daremo $10.00 en cash y un pequeño regalo ya sea que continue o no en el estudio.

RIESGOS INHERENTES EN LOS PROCEDIMIENTOS: El grupo de enfoque podria llevar a compartir información que es privada. Por esta razon, le pedimos que evite mencionar los nombres de personas fuera de este grupo. Le pedimos que mantenga la confidencialidad de todas las participantes. No se le pedira que hable de experiencias personales.

Puede decirle a la entrevistadora en cualquier momento que no quiere hablar mas sobre el tema. Tambien puede dejar el grupo sin ningun costo para usted. Por eso, no hay reisgo alguno para usted. Si el hablar del cáncer del seno le hiciera sentirse incomoda, podems arreglar para que hable con una consejera sin ningun costo. Tambien podemos ayudarle a que tenga acceso a otros recursos. No es posible identificar todos los riesgos potencial en estudios de investigación, pero las investigadora(s) han sido cautelosas en minimizar cualquier riesgo identificado y p otencial, sin identificar.

Page 1 of 2 Participant initials _______ Date _______

BENEFICIOS: Los beneficios que obtendra al participar en este estudio pueden ser que piense mas seriamente acerca de su salud. Al oir los comentarios de otras mujeres como usted, puede que aprenda a reconocer mas claramente cuales son los factores culturales y sociales que le impidan que cuide de su salud. Por ejemplo, puede que aprenda sobre metodos de control y prevencion del cáncer del seno que le eran previamente desconocidos o que penso le eran inaccesibles. Además, sus respuestas nos ayudaran a ayudarla. Al aprender de usted que barreras evitan que las Latinas participen en estudios clínicos, nosotros podemos proveerle sugerencias al sistema de salud para facilitar su participacion. La información que comparta con nosotros nos ayudara a enteder mejor las actitudes que personas en su comunidad tienen sobre el cáncer del seno y sobre las mujeres que participan en estudios clínicos. Tambien puede decirnos que cosas son aceptadas en su cultura para ayudar a las Latinas a participar en estudios clínicos. Media vez comprendamos las sugerencias que recibamos del grupo, podremos ayudar a comunidades como la suya. Queremos ayudar a las Latinas para que ellas puedan participar en estudios clínicos pare ver si al tomar "pildoras de prevencion" las pueda librar de desarrollar el cáncer del seno. Por todas estas razones, su ayuda para diseminar esta información es muy importante y apreciada.

CONFIDENCIALIDAD: Como hemos explicado, no pondremos su nombre en el resumen de la discusión. Cuando el estudio finalize, las cintas seran destruidas. Las entrevistadoras seran las unicas personas que sabran el nombre de cada persona en el grupo, y ellas no usaran nombres cuando reporte los resultados de el estudio.

RESPONSABILIDAD: El Acta Guvernamental de Inmunidades de Colorado determina y limita a la Universidad del Estado de Colorado cualquier responsabilidad por cualquier daño que suceda por este estudio. Reclamos en contra de la Universidad deben de someterse dentro de 180 dias desde el daño. Preguntas acerca de los derechos de los participantes de este estudio deben de dirigirse a Celia S. Walker al (970) 491-1563.

PARTICIPACION: Su paricipación en este estudio es voluntaria. Puede retirar su consentimiento y parar su participación en cualquier momento. No perdera ninguno de los beneficios ofrecidos si usted se retira. Tambien puede reusas a contestar cualquier pregunta. Si la entrevista le causa cualquier preocupacion y usted quisiese hablar con una consejera, podemos ayudarla a encontrar una consejera. Su firma indica que usted a leido esta información y esta dispuesta a firmar esta forma de concentimiento. Su firma tambien indica que ha recibido, en la fecha que se firmo, una copia de esta forma conteniendo_2_pagínas.

____
Nombre de la Participante (en letra de molde)

____________________________ ________________
Firma de la Participante Fecha

____________________________ ________________
Firma de la Testigo (personal del estudio) Fecha

Participant initials _______ Date _______

APPENDIX F

INFORMED CONSENT FOR SEMI-STRUCTURED INTERVIEWS

ENGLISH

COLORADO STATE UNIVERSITY
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT
INFORMED CONSENT TO PARTICIPATE IN AN ETHNOGRAPHIC SEMI-STRUCTURED ONE-ON-ONE INTERVIEW

TITLE OF PROJECT: Latinas' Participation in Breast Cancer Clinical Trials

NAME OF PRINCIPAL INVESTIGATOR: Evelinn A. Borrayo, Ph.D.

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS/PROBLEMS: Evelinn A. Borrayo, Ph.D. (970) 491-7324

SPONSOR OF PROJECT: Susan G. Komen Breast Cancer Foundation

PURPOSE OF THE RESEARCH: In this project we want to know what Latinas think about clinical trials. Clinical trials are also known as clinical studies. In a clinical trial, doctors experiment with a pill that could prevent breast cancer. That is, women who participate in clinical trials are given pills that may keep them from developing breast cancer. Usually, women who are at the highest risk of developing breast cancer are allowed to participate in this type of clinical trial.

We are interested in knowing what barriers may prevent Latinas from participating in clinical trials. We will discuss several things, including: "cultural beliefs, acceptance of prevention, barriers to treatments, and appropriate ways to encourage Latinas to participate in clinical trials." The questions that we will ask you will allow us to develop new ways to help Latinas participate in clinical trials. In addition, the information will be shared with other professionals interested in Latinas' health. We will share information through presentations and publications in conferences and professional journals.

PROCEDURES/METHODS TO BE USED: We are conducting a personal interview so that we may talk with six Latinas in four communities. The interview will last approximately 20-40 minutes. During the interview we will ask you questions around the topic of Latinas' participation in breast cancer clinical trials (see purpose of the research above).

Notes will be taken during our conversation and it will be also audiotaped. Tapes will help us ensure that none of the information we receive from you is lost. However, we are being cautious so that no one else besides the interviewer can identify you. For example, your name will not be used when the tapes and the notes are written in a summary. We will destroy the tapes at the end of the study.

To thank you for your time and help, you will give you or mail to you (if phone interview) $20.00 in cash or a gift certificate equivalent to $20.00.

RISKS INHERENT IN THE PROCEDURES: You will not be asked about your personal experiences. You can tell the interviewer at any time that you do not want to talk any more about the topic. You will still be given the $20.00 cash or a gift certificate equivalent to $20.00. Thus, there is no risk to you. If talking about breast cancer makes you feel uncomfortable, we can arrange for you to talk with a counselor. We can also help you access other resources. It is not possible to identify all potential risks in research studies, but the researcher(s) have been cautious to minimize any known and potential, but unknown, risks.

Page 1 of 2

Participant initials _______ Date _______

BENEFITS: Your responses will help us to understand the barriers that keep Latinas from participating in clinical trials. The information you share will help us know the attitude people in your community have about breast cancer and about women who participate in clinical trials. You can also tell us what things are accepted in you culture to help Latinas participate in clinical trials. Once we understand the suggestions we receive from the group, we can help communities like yours. We want to help Latinas so that they can participate in clinical trials. If Latinas take prevention pills that would keep them from developing breast cancer, they could probably also prevent dying from this disease. For all these reasons, your help in getting this information out is very important and appreciated.

CONFIDENTIALITY: As we explained, we will not put your name on the summary of our conversation. When the study is finished, the tapes will be destroyed. The interviewers will be the only people who know the name of each person in the study, and they will not use your name when reporting the study findings.

LIABILITY: The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury. Questions about study participants' rights may be directed to Celia S. Walker at (970) 491-1563.

PARTICIPATION: Your participation in this research is voluntary. You may take away your consent and stop participating at any time. You will not lose any of the benefits offered if you leave. You may also refuse to answer any questions. If the interview raises any concerns and you would like to talk to a counselor, we can help you find a counselor. Your signature [participation] indicates that you have read [heard] this information and willingly sign this consent form [participate in this study]. Your signature also indicates that you have received, on the date signed, a copy of this form containing _2_ pages. [If you participate, we will mail to you a copy of this form containing _2_ pages].

____
Participant name (printed)

______________________________ ________________
Participant signature Date

______________________________ ________________
Witness to signature (project staff) Date

Page 2 of 2 Participant initials ______ Date ______

APPENDIX G

INFORMED CONSENT FOR

SEMI-STRUCTURED INTERVIEWS

SPANISH

COLORADO STATE UNIVERSITY
INFORAMACION PARA CONSENTIR PARTICIPAR EN UN PROYECTO DE INVESTIGACION
INFORAMACION PARA CONSENTIR PARTICIPAR EN UN ENTREVISTA SEMI-ESTRUCTURADA

TITULO DEL PROYECTO: La Participacion de Latinas en Estudios Clinicos del Cancer del Seno

NOMBRE DEL INVESTIGADOR PRINCIPAL: Evelinn A. Borrayo, Ph.D.

NOMBRE DE LA PERSONA A CONTACTAR Y TELEFONO PARA PREGUNTAS/PROBLEMAS: Evelinn A. Borrayo, Ph.D., (970) 491-7324

PATROCINADOR DEL PROYECTO: Susan G. Komen Breast Cancer Foundation

PROPOSITO DEL PROYECTO: En este proyecto queremos saber que piensan las Latinas acerca de los estudios clínicos. Los estudios clínicos se les conoce en Inglés como "clinical triaos." En un estudio clínico, los doctores experimentan con una píldora que puede que prevenga el cáncer del seno. Esto se refiere a que a las mujeres que participan en estudios clinicote les dan pildoras que las podria librar de desarrollar el cáncer del seno. Usualmente, las mujeres que estan a mas alto riesgo de desarrollar el cáncer del seno se les permite participar en este tipo de estudio clínico.

Nosotros estamos interesadas en conocer que barreras previenen a las Latinas de que participen en estudios clínicos. Discutiremos varias cosas, incluyendo: "creencias culturales, aceptación de la prevención, barreras para los tratamientos, y apropiadas maneras de motivar a las Latinas a que participen en estudios clínicos. Además, la información será compartida con otros profesionales interesados en la salud de las Latinas. Vamos a compartir la información a través de presentaciones y publicaciones en conferencias y revistas profesionales.

PROCEDIMIENTOS/METODOS A USAR: Estamos conduciendo una entrevista personal para que podamos hablar con seis Latinas en cuatro comunidades. La entrevista en el grupo de enfoque durara aproximadamente de 20-40 minutos. Durante la entrevista le vamos a hacer varias preguntas alrededor del tema de la participacion de las Latinas en estudios clínicos del cáncer del seno (vea el proposito de la investigacion arriba).

Se tomarán notas sobre nuestra conversación y será audio-grabada. Las cintas de grabación nos ayudaran a asegurarnos que ninguna de la información que recibimos de usted no se pierda. Sinembargo, hemos sido cautelosas de que nadie mas aparte de la entrevistadora pueda identifacar quien participo. Por ejemplo, ningun nombre será usado cuando las cintas y las notas sean escritas en un resumén. Vamos a destruir las cintas al final del estudio.

Para agradecerle por su tiempo y ayuda, le daremos un regalo por el valor de $25.00.

RIESGOS INHERENTES EN LOS PROCEDIMIENTOS: No se le pedira que hable de experiencias personales. Puede decirle a la entrevistadora en cualquier momento que no quiere hablar mas sobre el tema. Tambien puede dejar la entrevista sin ningun costo para usted. Se le dara aun asi un regalo por el valor de $25.00. Por eso, no hay reisgo alguno para usted. Si el hablar del cáncer del seno le hiciera sentirse incomoda, podems arreglar para que hable con una consejera. Tambien podemos ayudarle a que tenga acceso a otros recursos. No es posible identificar todos los riesgos potencial en estudios de investigación, pero las investigadora(s) han sido cautelosas en minimizar cualquier riesgo identificado y potencial, sin identificar.

Page 1 of 2 Participant initials _______ Date _______

BENEFICIOS: Sus respuestas nos pueden ayudar a entender que barreras evitan que las Latinas participen en estudios clínicos. La información que comparta con nosotros nos ayudara a enteder mejor las actitudes que personas en su comunidad tienen sobre el cáncer del seno y sobre las mujeres que participan en estudios clínicos. Media vez comprendamos las sugerencias que recibamos del grupo, podremos aydar a comunidades como la suya. Queremos ayudear a las Latinas para que ellas puedan participar en estudios clínicos. Si las Latinas toman pildoras de prevencion que las librara de desarrollar el cáncer del seno, ellas podrian tambien prevenir morir de esta enfermedad. Por todas estas razones, su ayuda para diseminar esta ayuda es muy importante y apreciada.

CONFIDENCIALIDAD: Como hemos explicado, no pondremos su nombre en el resumen de la conversación. Cuando el estudio finalize, las cintas seran destruidas. Las entrevistadoras seran las unicas personas que sabran el nombre de cada persona en el estudio, y ellas no usaran nombres cuando reporte los resultados de el estudio.

RESPONSABILIDAD: El Acta Guvernamental de Inmunidades de Colorado determina y limita a la Universidad del Estado de Colorado cualquier responsabilidad por cualquier daño que suceda por este estudio. Reclamos en contra de la Universidad deben de someterse dentro de 180 dias desde el daño. Preguntas acerca de los derechos de los participantes de este estudio deben de dirigirse a Celia S. Walker al (970) 491-1563.

PARTICIPACION: Su paricipación en este estudio es voluntaria. Puede retirar su consentimiento y parar su participación en cualquier momento. No perdera ninguno de los beneficios ofrecidos si usted se retira. Tambien puede reusas a contestar cualquier pregunta. Si la entrevista le causa cualquier preocupacion y usted quisiese hablar con una consejera, podemos ayudarla a encontrar una consejera. Su firma [participación] indica que usted a leido [oido] esta información y esta dispuesta a firmar [participar] esta forma de concentimiento. Su firma tambien indica que ha recibido, en la fecha que se firmo, [si participa, le enviaremos] una copia de esta forma conteniendo_2_pagínas.

____
Nombre de la Participante (en letra de molde)

______________________________ __________________
Firma de la Participante Fecha

______________________________ __________________
Firma de la Testigo (personal del estudio) Fecha

Participant initials _______ Date _______

APPENDIX H

DEMOGRAPHIC QUESTIONNAIRE

ENGLISH

Colorado State University Research on Women's Health

The following information helps us to analyze the research and is totally confidential. Thank you.

SECTION I

Please answer all the questions. Answer based on what you really believe and do, not what you think you should do or what a doctor or nurse would want you to do. Thank you for your time.

Please circle one answer:

1. Have you ever been diagnosed as having any type of cancer ? . . . . Yes No
   1a. If you circled yes, what type of cancer ? ____

2. Has any blood relative of yours ever had breast cancer ? . . . . Yes No
   2a. If you circled yes, what relative? ____

3. Has a doctor or nurse taught you how to examine your breasts?. . . . . Yes No

4. Have you examined your breasts in the past month? . . . . Yes No

5. How many times have you examined your breasts in the past year? .0 1-2 3-5 6-9 10-12

6. When was your last mammogram. . . . .

Last year	2 years Ago	3 years Ago	More than 3 years ago	Never had one

7. When was your last Pap Smear. . . . .

Last year	2 years Ago	3 years Ago	More than 3 years ago	Never had one

8. Has a doctor recommended for you to have a mammogram every year? Yes No
9. Has a doctor or nurse educated you about breast cancer clinical trials? Yes No
10. Has a doctor or nurse referred you to participate in breast cancer clinical trials? Yes No
11. Have you ever or are you currently participating in a breast cancer treatment clinical trial? Yes No
12. Have you ever or are you currently participating in a breast cancer prevention clinical trial? Yes No

SECTION II

1. Your age?_______[Years]

2. Your current marital status? [Circle one]

Single [never married] Married Divorced Separated Co-habitating [living with a partner] Widowed

3. Where did you do most of your schooling? Latin America ____ or USA ____

4. Place an 'X' in the box that best described the highest level of education you completed:

Grade School								**High School**				**College**				**Post**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**	**4**	**Graduate**

5. Are you now employed? ___ Yes ___ No Retired? ___ Yes ___ No What is/was your occupation?

6. Do you have: Medicare? ___ Yes ___No Medicaid?___Yes ___No Private insurance? ___ Yes ___No

7. Circle the range that best describes the total annual income from all sources for yourself.

Less than $17,000 $17,001-$23,000 $23,001-$28,000 $28,001-$34,000 $34,001-$40,000

$40,001-$46,000 $46,001-$52,000 $52,001-$57,000 More than $57,001

SECTION III

Please answer the following questions . Circle only one answer.

1. Do you speak----->

Only Spanish
Spanish better than English
Both Spanish and English equally well
English better than Spanish
Only English

2. Do you read---->

Only Spanish
Spanish better than English
Both Spanish and English equally well
English better than Spanish
Only English

3. Was your early life [childhood and teenage years] spent in---->

Only in Latin-America
Mostly in Latin-America
Equally in Latin-America and the USA
Mostly in the USA
Only in USA

4. Is your current circle of friends---->

Almost all Hispanics/ Latinos
Mainly Hispanics/ Latinos
Equally Hispanics & Non-Hispanics from the U.S.A.
Mainly Non-Hispanics from the U.S.A.
Almost all from USA

5. In relation to having an Hispanic/Latino background, do you feel---->

Very Proud
Proud
Somewhat Proud
Little Pride
No Pride

6. How long have you lived in the United States? ___ All my life ___ years

7. What is your country of birth?____

8. How would you describe yourself? Predominantly:
___White Hispanic ___ African-Caribbean Hispanic ____other

9. Place an 'X' in the box that answers the following questions:

	Latin-America	U.S.A.	Other
Where were you born?			
Where was your mother born?			
Where was your mother's father born?			
Where was your mother's mother born?			
Where was your father born?			
Where was your father's father born?			
Where was your father's mother born?			

Thank you for your time in helping us understand how women think about breast cancer and health!

Date ____/____/____

Location: ____________________________

APPENDIX I

DEMOGRAPHIC QUESTIONNAIRE

SPANISH

Investigacion sobre la Salud de la Mujer de la Universidad del Estado de Colorado

La siguiente información ayuda a analizar esta investigación y es totalmente confidencial.

SECCION I

Encierre su respuesta en un círculo

1. ¿Ha sido usted alguna vez diagnosticada con algún tipo de cáncer? .... SI NO
   1a. Si responde SI, ¿qué tipo(s) de cáncer?________________________________

2. ¿Ha sido alguna parienta suya diagnosticada con cáncer del seno?..............................SI NO
   2a. Si responde Si, ¿qué parentesco tiene con usted?

3. ¿Le ha enseñado el doctor o una enfermera como examinarse sus senos?..................SI NO

4. ¿Se examinó usted los senos el mes pasado?..SI NO

5. ¿Cuántas veces se examinó usted los senos el año pasado? 1-2 3-5 6-9 10-12

6. ¿Cuando fué su último mamograma?.......Hace 1año Hace 2 años Hace 3 años Más de 3 años Nunca uno

7 ¿Cuando fué su último Papanicolau?.........Hace 1año Hace 2 años Hace 3 años Más de 3 años Nunca uno

8.. ¿Le ha recomendado el doctor a usted que se haga tomar un mamograma cada año? SI NO

9. ¿La ha educado el doctor o enfermera sobre los estudios clinicos del cancer del seno? SI NO

10. ¿Ha o esta participando en algun estudio clinico para tratamiento del cancer del seno? SI NO

11. ¿Ha o esta participando en algun estudio clinico para prevencion del cancer del seno? SI NO

SECCION II

1. ¿Cuántos años tiene? ____________________

2. ¿Cuál es su actual estado civil? (por favor encierre su respuesta en un círculo).

Soltera (nunca casada) Casada Divorciada Separada Co-habitante (vive con pareja) Viuda

3. Donde curso usted la mayor parte de su educacion? Latino America____ o U.S.A. _____

4. Por favor ponga una 'X' en el cuadro que mejor describa el nivel más alto de educación completada:

	Primaria								Secundaria				Técnico/Vocacional o Universidad				Post-grado
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	4+
Usted																	

5. Está usted actualmente trabajando?___Sí___No Retirada?___Sí ___No ¿Cual es/fue su ocupación?_______

6. Tiene usted: Medicare?___Sí ___No___ Medicaid?___Sí ___No ¿Seguro privad?__ _Sí ___No

7. Círcule su ingreso total por año:

Menos de $17,000 $17,001-$23,000 $23,001-$28,000 $28,001-$34,000

$34,001-$40,000 $40,001-$46,000 $46,001-$52,000 $52,001-$57,000 Mas de $57,001

SECCION III

Por favor conteste las siguientes preguntas. Circule solamente una respuesta.

1. Usted habla----->

Sólo español	Español mejor que inglés	Español e inglés igualmente bien	Inglés mejor que español	Sólo inglés

2. Usted lee---->

Sólo español	Español mejor que inglés	Español e inglés igualmente bien	Inglés mejor que español	Sólo inglés

3. Pasó su edad temprana[niñes y adolescencia] en--->

Sólo en México	La mayor parte en Latino America	Igualmente en Latino America y en U.S.A.	Principalmente en USA	Sólo en U.S.A.

4. Actualmente su círculo de amigos es ---->

Casi todos son Hispanos/ Latinos	La mayoría son Hispanos/ Latinos	Igualmente Hispanos y anglos de U.S.A.	La mayoría son anglos de U.S.A.	Casi todos anglos de U.S.A

5. Tener origen hispano o latino hace que usted se sienta ---->

Muy orgullosa	Orgullosa	Algo orgullosa	Poco orgullosa	Nada orgullosa

6. ¿Cuántos años lleva Ud. de vivir en Los Estados Unidos? __Toda la vida _____años

7. ¿Cuál es su pais de nacimiento?_______________________

8. Como se describiria Usted a si misma? Predominantemente

___Hispana Blanca ___Hispana Africana Caribeña ____otro

9. Marque con una 'X' el cuadro que conteste las siguientes preguntas:

	Latino America	U.S.A.	Otro
Dónde nació usted?			
Dónde nació su madre?			
Dónde nació su abuelo de parte de su madre?			
Dónde nació su abuela de parte de su madre?			
Dónde nació su padre?			
Dónde nació su abuelo de parte de su padre?			
Dónde nació su abuela de parte de su padre?			

Gracias por ayudarnos a comprender qué piensan las mujeres acerca de la salud del seno! ________

fecha ___/___/_____ **Local:**

APPENDIX J

QUESTIONS AND PROBES FOR FOCUS GROUPS

ENGLISH

Questions and Probes for Focus Groups

Ice-breaker: Mrs. __________, do you know or have you heard that a women you know have or had breast cancer? And who is that?

As we can see, all of us know of or have heard about a woman who had breast cancer (briefly cite examples given by the group).

Questions and Probes:

1. **How common do you think is for Latinas to get breast cancer?**

   (Probe: What puts a Latina woman at "risk" of developing breast cancer?)

   A.) How likely do you think you are to get breast cancer?

   (Probe: What would put you at "risk" of developing breast cancer?)

2. **How do you think these women or any woman can "prevent" getting breast cancer?**

   (Probe: can you "prevent" an illness that you don't feel or think that is not going to happen to you?)

3. **If you heard that a group of doctors created a pill that could keep you from developing breast cancer, would you take it?**

   (Probe: What if that doctors thought that this pill could prevent BC but were testing it with some women to see if it really worked? Would you be willing to be part of such experiment/tryout?)

   (Probe: What if you had indeed developed BC, would you be willing to take a pill that they were testing to see if could cure your cancer? Would you be willing to be part of such experiment/tryout?)

   What are your perceptions of taking a pill…fears, reservations?

   (Probe: Do you think that you could develop cancer from taking this pill?

4. **Are you aware of any doctors trying such a pill in your community? Or in major hospitals in cities like Denver?**

   (Probe: Have you heard the term "clinical trials" or "clinical studies" that are doing this?)

   Assuming very few know or have heard of clinical trials:

(Probe: What types of BC prevention services are you aware exist in your community? Probe specifically for BSE, CBE, and mammography)

5. **Have you heard of any breast cancer education activities advertised through your church (give name of the church______)?**

(Probe: What types of BC prevention services are you aware exist in your community? Probe specifically for BSE, CBE, and mammography)

(Probe: How else have you seen information delivered to you through the church or church-affiliated institutions and clinics (e.g. Clinica Tepeyac, promotoras)?

6. **Would you be more open to information on breast cancer and prevention activities if this information came from the church? Or if it supported the delivery of such information in the church setting?**

(Probe: Would you feel more confident about the credibility of the information? Would you be more willing to follow health recommendations if you felt that the church approved of activities such as mammograms, where you have to have your breast exposed?)

(Probe: What if the church went as far as supporting the participation of women in experimental studies such as clinical trials to test prevention drugs? Do you think the church would do that? At least encourage women to find out if they are at risk of developing breast cancer and follow-up to see if are eligible for a clinical trial)

7. **How can the information be best delivered to you about breast cancer prevention activities that will encourage you to participate?**

(Probe: Is the church one of the best community places to have health information delivered to Hispanic/Latina women? Why?

(Probe: Any suggestions on how the information can be effectively delivered to you and other women in your community?

(Probe: What things would make it easier for you to participate? What things at the personal and family level as well as at the community level would make it easier?)

(Probe: What would you need to know about studies that are testing pills that could very well work to prevent breast cancer in order to participate in them?

(Probe: Would you encourage another women to participate in such studies?)

APPENDIX K

QUESTIONS AND PROBES FOR SEMI-STRUCTURED INTERVIEWS

ENGLISH

Semi-Structured Interview Questions[a]

- *Following informed consent, explain that you have to ask all questions in this interview even when it may be based on assumptions about what women would do or not do.*

- *Go back to briefly explaining what "clinical trials" are:*

"**Breast Cancer Clinical Trial**s are studies conducted by a group of scientists and doctors. They are usually experimenting to see if a particular medicine can prevent or cure breast cancer. Currently, they are conducting a clinical trial to see if the drugs Tamoxifen and Raloxifene can prevent breast cancer in women who are a high risk to develop this cancer."

1. Would you participate in a clinical trial where you are asked to take an experimental pill?

Yes:

No:

If no: A) Would you take it if your doctor said you were at "high risk" of developing BC? (*If participant asks, explain "risk factors"...age, weight, heredity, etc.*)

B) Would you take it if it was already "approved" rather than "experimental"?

Yes:

No:

2. Do you believe that this pill developed by scientists and doctors can an INDEED keep you (or women at "high risk") from developing BC? (*Probe:* that it really works to prevent that you will develop BC?)

Yes:

No:

If no: Do you believe that if you are going to come down with this illness, you will regardless of what you take or do? (*Probe about "God's will" or "one's destiny"*)

Yes:

No:

---

[a] *Regardless of "yes" or "no" answers, proceed with all of the questions: 1- 8.*

3. Would you have any concerns about what this "pill" might do to your body?

If not mentioned probe for all of the following:

3.1 Do you think that the "pill" might actually cause BC to develop in your body?

3.2 Are you afraid of any other physical harm that might be caused by this "pill"?

3.3 What side effects do you think such a "pill" could cause?

➢ *Give women a 3 minute educational talk about STAR (Study of Tamoxifen and Raloxifene), including information on:*

A. Which women qualify (explain "risk factors" if not previously explained).

B. Potential benefits (give simple statistics such as: approximately 50% of the women in Tamoxifen reduced their risk of BC and it is expected that this percentage of women who benefit might be higher for Raloxifene; Other benefits: reduces Osteoporosis, etc).

C. Potential side effects (give simple statistics on serious side effect such as: about 2-3 women out of 1,000 who took Tamoxifen developed "endometrial cancer" or other side effects such as stroke, heart attack, clogging of the veins, increased cholesterol, etc. Minor side effects such as: cataracts, hot flashes, vaginal discharge, leg cramps, etc.

Assuming that you decided to participate,

3.4 What side effects would you BE willing to take if you were at high risk for developing BC, but taking this "pill" could lower your chances significantly?

3.5 What side effects would you NOT BE willing to take if you were at high risk for developing BC, even when taking this "pill" could lower your chances significantly?

(If needed, debrief women about the pros and cons. For example, it is much easier to find and treat endometrial cancer if a woman has regular Pap Smears. In comparison, BC is much harder to detect at a very early stage because sometimes mammograms fail to detect lumps, while rarely does a Pap Smear fails (because it's a sample of cells). Probe:

3.6 After knowing this, would you be more willing to take this risk and participate to potentially prevent breast cancer?

- *Probe women for family and cultural values*:

4. In spite of the potential side effects of this pill, would you feel motivated to participate in such a study if…

   4.1. You felt that if a pill proved to be effective in preventing breast cancer you could benefit and be there for your children instead of developing this illness?

   4.2. You felt that by participating in this study you could potentially benefit future generations of women in your family?

   4.3. You felt that by participating in this study you could potentially benefit other women in your community?

- *Give women a 3 minute educational talk about the STAR trial, including information on:*

  D. *In the STAR clinical trial some women will receive a pill containing either Tamoxifen or Raloxifene. The pill is to be taken for 5 years "free of charge" (it would cost $100/month if a woman had to purchase it).*

  E. *There are required pre-entry exams and regular medical exams once women are participants in the study. These exams include yearly physical and Pap Smear exams, mammograms, blood tests and breast exams. These exams must be performed at least for 7 years even thought the pills are taken only for 5 years.*

  F. *For women who cannot afford or have no insurance to pay for these exams, there are funds to cover them free of charge for the entire 7 years.*

5. Knowing this and supposing that you decided to participate, do you think that you could and would be able to: [b]

   5.1 Commit yourself for 5 years to taking this pill regularly (*Note: find out how often they have to take it (e.g., once a month, a week, a day or more*)?

---

[b] <u>Note</u>*: probe also for how obstacles could be facilitated for them:*
So what would make it easier for you to…

5.2 What about having to have an annual physical exam, Pap Smear, mammogram, blood tests, and regular visits to your physician for 7 years, do you think you can commit to this?

How easy or difficult would it be to comply with all of these exams? (*Probe for: remembering to take the pill, disliking blood test, feeling embarrassed about mammograms and Pap Smears etc.*).

How do you anticipate these commitments would interfere with other responsibilities that you might have? (*Probe for: child care (grandchildren care), household duties, church duties, etc.*).

5.3 If you or your insurance (including Medicare) would have to pay for some of these exams (*not the pill because its free*), would you still participate in the study?

5.4 Assuming that all of the exams and the pill would be free of charge to you, would you be concerned about other financial problems associated with your participation such as lost wages, given that you have to take some time away from work?

- *Give women a 1-minute educational talk about seeing STAR health care professionals:*

    G. *Because all the procedures involved in the study, your doctor might have to refer you to a group of doctors and health professionals such as nurses who might be more specialized in administering this breast cancer prevention medicine. In other words, at least for this study, you will have to go to some else that is not your regular doctor.*

Assuming that you decided to participate,

6. Do you think that you could and would:[c]....

6.1 Trust the new doctor and health professionals who are very knowledgeable about the prevention pill but who you don't know? (*Note: find out if they have to see one or several docs*)?

6.2 (*Note: this question is <u>only</u> applicable for the Spanish interview*). What about having a doctor and other health professionals who although are friendly do not speak Spanish, how motivated would you feel to participate?

---

[c] *Note: probe also for how obstacles could be facilitated for them:*
So what would make it easier for you to...

Would having translators be enough for you? (*Probe for:* do you prefer to bring a family member or friend to translate for you?).

If NO to previous question: Would you participate only if you could communicate with you doctor directly in Spanish?

6.3 Would you prefer to see a male or a female doctor at least while you participate in this study?

6.4 Would you prefer that the doctor who you might see for this study be Latino/a (Mexicano/a) or it doesn't matter?

- *Give women a 1-minute educational talk about travel involved in participating in STAR ...*

H. *Participating in this study will also imply that you have to travel for doctor's appointments and to have the exams done (Note: find out how often and if they can get the pill from their own doctor or at a community hospital).*

Assuming that you decided to participate,

7 Do you think that you would be able to:[d] ....

7.1. Travel some distance, let's say to the local hospital (*Note: give name of corresponding city and hospital...depending on city of interview)? (Probe: for problems finding transportation, driving long distances, etc.*).

7.2. What about having to be at an unfamiliar and large medical setting where you have to find the specific clinic, sign yourself in, and talk to several professionals, how able do you think you would be to do all this?

Are you afraid that it might be too complicated and confusing? (*Probe for:* do you think that large medical settings might intimidate you?).

---

[d] *Note: probe also for how obstacles could be facilitated for them:*
So what would make it easier for you to...

If YES to previous question: Would it be easier for you to have someone meet at the hospital entrance and stay with you throughout your visit to the hospital guiding you on where to go?

- *Give women a 1-minute educational talk about paperwork involved in participating in STAR:*

  I. *Participating in this study will also require you to read, fill-out, or sign some paperwork. For example, you will be given information about the pill, its benefits and potential risks. The doctors will then ask you to sign a form indicating that you understand all that is involved.*

Assuming that you decided to participate,

8 Do you think that you would be able to:[e] ....

8.1 Read the medical information that they give you, assuming that it is similar to other information that you have received at a hospital or medical settings (e.g., information on how to take medication and its possible side effects)

8.2 What about having to fill out forms that ask you personal information such as you age, weight, medical history or how the medication is working for you, do you think you would not mind giving this information or would not have any problems providing it?

How easy or difficult would it be for you to read these forms? (*Probe for: low reading levels, understanding medical terms, hesitation to give out personal information*).

8.3 (*Note: this question is only applicable for the Spanish interview*). What about having a to read this forms in English rather than Spanish, how motivated would you feel to participate?

Would having translators be enough for you? (*Probe for:* do you prefer to have a family member or friend to translate for you? Would this preference be because the information is personal?).

If NO to previous question: Would you participate only if the information and paperwork is in Spanish?

We are done with the structured part of the interview.

---

[e] *Note: probe also for how obstacles could be facilitated for them:*
So what would make it easier for you to...

Are there any other comments you would like to make regarding what would make it difficult for you to participate or motivate you to participate in a breast cancer prevention study?

(Probe: Maybe there is something we haven't cover that you think is important but we haven't asked you, would you like to tell us some more?)