Mexican-American perspectives on participation in clinical trials: A qualitative study

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ABSTRACT

Clinical trials are essential to advancing knowledge to reduce disease morbidity and mortality; however, ethnic and racial minorities remain under-represented in those studies. We explored knowledge and perceptions of clinical trials among Mexican-Americans in Texas. We conducted focus groups (N = 128) stratified by gender, language preference, and geographical location. This paper presents four emergent, primary themes: 1) knowledge and understanding of clinical trials, 2) fears and concerns about participating, 3) perceived benefits of participating, and 4) incentives to participate. Results suggest that lack of knowledge and understanding of clinical trials leads to misunderstanding about research, including fears and lack of trust. Participants indicated that fears related to perceived experimentation, harm, immigration status, and lack of clinical trial opportunities within their communities were barriers to participation. On the other hand, free healthcare access, helping family members in the future, and monetary incentives could facilitate participation. We also found differences across themes by language, gender, and place of residence. Findings from our study could inform the development of interventions to enhance recruitment of Mexican-American participants into clinical trials.

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1. Introduction

Clinical trials tell researchers whether new therapies help or hurt different population groups [1]. Despite the National Institutes of Health’s efforts to increase the number of women and individuals from different racial and ethnic subgroups in all its funded clinical studies, minorities remain under-represented. It is estimated that only 1% of the 10,000 National Cancer Institute (NCI)–sponsored clinical trials have focused on racial and ethnic minorities [2]. Hispanic accrual rates in nationwide cancer clinical trials are 2–4% [3,4]. Such low rates are especially surprising in Texas, where Hispanics represent about 40% of the population [5] and are expected to be the majority by 2020 [6].

Researchers have explored barriers and facilitators to clinical trial participation among minority groups. Commonly, Hispanics do not participate because they are unaware of trial opportunities, lack transportation, mistrust research and the medical system, and have other family considerations [7]. Focus groups with Mexican-American, Medicaid-eligible patients found that although most believe clinical trials help advance science, they cite a number of participation barriers, including fear of adverse events, mistrust of physicians, fear of experimentation led by inexperienced physicians, language, and lack of time and transportation [8]. A study of immigrant Latinos identified similar barriers including fear of experimentation or harm, lack of transportation, time conflicts, and language. They reported facilitators to participation that included wanting to contribute to a disease cure, helping a close family member with a disease, accessing healthcare, and working with...
staff from their own racial/ethnic group [9].

Few qualitative studies have explored factors that influence Hispanics’ participation in clinical trials [8–10]. Most of these studies have been conducted among Spanish-speaking females [8,9], or have made comparisons between Hispanics and African Americans [9]. However, little is known about how perceptions of clinical trials among Hispanics differ by gender, place of residence in the U.S., or preferred language. To our knowledge, there is only one comparative examination of factors influencing decisions to participate in clinical trials among English and Spanish-speaking individuals; yet, in that study, only four out of thirty English-speaking participants self-identified as Hispanic, so authors could not examine differences between English and Spanish-speaking Hispanics [10].

Our study was part of cancer control research activities conducted by an NCI-funded Community Network Program Center and the Center for Clinical and Translational Science Community Engagement Component. These projects aim to decrease the burden of cancer in Houston, Brownsville, and El Paso, Texas. Self-identified Hispanics largely comprise these three communities. Houston is a large, metropolitan city in southeast Texas, and Brownsville and El Paso are smaller cities that share a border with Mexico. Between 34% [11] and 86% [12] of household residents in these communities report Spanish as the primary language spoken at home. It is estimated that Mexican Americans make up 32% of the foreign-born population in the US [13]. The foreign-born population in Houston, El Paso, and Brownsville are estimated at 25.3%, 25.9% and 24.7%, respectively [5]. However, despite being the largest Hispanic subgroup in the country, our understanding about Mexican American perceptions of clinical trial participation is limited. Thus, in this study, we wanted to better understand the reasons for the low rates of clinical trial participation in these communities, and explore Mexican-Americans’ knowledge and perceptions of clinical trials.

2. Methods

Two bilingual members of the research team conducted focus groups between 2012 and 2013 using a semi-structured interview guide (Table 1). The research team developed the guide in English based on a review of related studies and discussions with the full research team. Bilingual study staff translated the guide into Spanish. Using a convenience sampling method, research staff invited English- or Spanish-speaking Hispanic adults to participate. They recruited participants using flyers and one-on-one contact at community-based organizations and public housing complexes. Focus groups were stratified by gender, preferred spoken language (English or Spanish), and place of residence (Houston, Brownsville, or El Paso). The Institutional Review Board of the University of Texas Health Science Center at Houston approved the study protocol.

2.1. Data collection

Bilingual, trained moderators led the focus groups, accompanied by one note taker at each location. Moderators conducted all focus groups at locations that included community centers and apartment complexes. Participants reviewed and signed an informed consent and, subsequently, completed a brief demographic survey that inquired about participants’ age, marital status, country of origin, years living in the U.S., education, household income, and medical insurance status. Moderators audio-recorded all focus groups; each lasted 60–90 min. As shown in Table 1, at the beginning of all focus groups, moderators assessed participants’ prior knowledge of clinical trials, and then read aloud a brief definition of clinical trials to participants. At the end of each focus group, each participant received a $20 gift card.

2.2. Data analysis

The coding and analysis team were bilingual. The coding team consisted of four research coordinators, and the analysis team included members of the research team who summarized and interpreted the data. We analyzed participant demographic information data using SPSS v. 21 software (IBM-SPSS, Inc.). We transcribed all focus group recordings verbatim, in the language in which they were conducted, and then reviewed them for accuracy. Next, the coding team conducted the data analysis using Atlas.ti, version 7. Three coders read all transcripts, taking notes on major themes and common threads and ideas. Then, they developed an initial draft of the coding scheme, subsequently revised and finalized it based on group consensus.

The coding team used the co-occurrence explorer tool in Atlas.ti to determine how codes were related and then they began linking codes to form a thematic network. The coders discussed the network, that is, all codes nested under larger themes, with the full research team. The research team reviewed all themes and the associated quotations for the codes in that theme. After the discussion, the team revised the network based on findings from this review. The research team used the completed network and accompanying data to guide the development of this manuscript.

We conducted the analyses using the systematic and iterative process described above. While we had not intended to formally analyze group differences, as the analytic process proceeded these differences began to emerge. Thus, we used a thematic analysis technique to compare the emergent themes by gender, language, and place of residence by creating document families in Atlas.ti. Then, a staff member used these families to extract queries of all codes associated with the primary themes and reviewed them to identify similarities and differences across them.

3. Results

3.1. Participant demographics

We conducted 15 focus groups, 8 with females and 7 with males. We held 4 focus groups in Brownsville, 7 in El Paso, and 4 in Houston. We conducted 8 groups in Spanish and 7 in English (Table 2). A total of 128 adults took part in the study, including 54 males and 72 females (see Table 3). The majority of participants were Spanish speakers (63.3%), born in Mexico (60.9%), had earned a high school degree or less (63.4%), had a household income of less than $30,000 (67.2%), and were uninsured (66.4%). About half of the participants were married (47.7%). On average, participants were 40 years old and had lived in the U.S. for 23 years.

3.2. Qualitative themes

Results are organized into four emerging themes: 1) knowledge and understanding of clinical trials, 2) fears and concerns, 3) perceived benefits of participation, and 4) incentives to participate. Findings presented below are given first as similarities across all focus groups and then as differences by gender, language, and place of residence.

3.3. Knowledge and understanding of clinical trials

Overall, participants’ knowledge about clinical trials was limited. They commonly associated clinical trials with various types of research, from therapeutic or drug trials to marketing research
A clinical trial is when you go to the doctor and the doctor sends you to get labs. Those are clinical trials. (El Paso, female, Spanish). Also, some participants thought that clinical trials are conducted at health departments, in laboratories, or in hospitals by lab technicians, radiologists, or doctors. None of the participants said that researchers (medical or non-medical) conducted clinical trials. At the beginning of each focus group, the moderators provided a definition of clinical trials (Table 1), yet
even after hearing this definition, some participants still discussed their experiences when seeking medical care.

Across all groups, participants frequently mentioned the need for more information about clinical trials. Many indicated that having sufficient information about what is involved in the study, the disease being investigated, medications, risks, side effects, and costs related to participation would make them more likely to consider participating. They also believed that having bilingual recruiters and staff could help enrollment efforts and that information provided should use simple terminology in Spanish. One participant said, “… [language] is important … often times we are afraid because we don’t have information … it’s important that they speak Spanish [and] that they don’t use those medical terms.” (El Paso, Male, Spanish). There was consensus across all focus groups that the community needs more information and education about clinical trials and that bilingual communication using appropriate literacy levels could help community involvement. One participant said, “… a lot of people are ignorant about what a clinical trial is. So, yeah, education. Educate us about that topic” (El Paso, Female, English).

3.3. Differences by language

Our results indicated a greater lack of understanding about the meaning of clinical trials and what it entails among mono-lingual Spanish speakers. One participant said, “Being bilingual helps a lot because, you see, many times there are words in English that I don’t even understand. I didn’t go to school to learn English, so if you are bilingual you would know it.” (El Paso, Male, Spanish). English-speaking participants had a slightly better concept of clinical trials, their comments showed fewer misunderstandings, and the conversations quickly moved on to discussions about information they needed to consider for participation.

3.3.2. Differences by geographical location

Participants from Brownsville and El Paso indicated not being aware of research opportunities in their communities and that they had not been approached to participate in clinical trials. A participant in Brownsville said, “There are many projects here, and we don’t know about them because we are not given information about them …” (Female, Spanish). Participants believed that the lack of information, limited understanding of clinical trials, and little exposure to clinical trial opportunities are barriers to participation.

3.3.3. Differences by gender

We found no major differences in knowledge and understanding of clinical trials by gender. Both males and females indicated similar awareness, and both expressed the need for more information. Males were more specific as to what type of information they needed in order to make a decision to participate in a clinical trial. A participant in Brownsville said, “I probably wouldn’t do it because I would feel like I’m a guinea pig, and I’m taking some medicine that I don’t even know.” (El Paso, Male, English). Fears of experimentation were associated with distrust of research, as several participants expressed concerns about being “infected with a disease,” “injected with a virus,” or “diagnosed with something I don’t have.”

Participants in all focus groups also expressed concerns about side effects and medication safety. Many said they would not agree to take new medications due to potential negative side effects. Also, early phase trials were perceived as more risky or dangerous, and some participants indicated that they would rather wait until any medications being tested were safer. One participant stated, “I’m thinking I wouldn’t be a guinea pig for them. I mean, I would rather play it safe. If someday they tell me it is going to help me out and at the end it does not help me, and it just leaves me the same or worse. So why take the risk?” (El Paso, Male, English).

All participants expressed concerns about adverse effects related to their participation. Most said they would not participate in a clinical trial that could potentially harm or cause them pain. Some participants also feared needle sticks and having blood drawn. Participants seemed more receptive to participating in studies of less-invasive procedures or those less likely to cause them bodily harm. Importantly, participants in all focus groups discussed fears related to immigration status. In fact, participants said that fears of being found out and deported might decrease the likelihood of participation among undocumented immigrants.

3.4. Fear and concerns about participating in clinical trials

Many focus group participants expressed fears and concerns about clinical trials. Across all groups, they seemed generally concerned about being “used” in experiments, feeling like a guinea pig. One participant said, “I probably wouldn’t do it because I would feel like I’m a guinea pig, and I’m taking some medicine that I don’t even know.” (Houston, Male, English). Fears of experimentation were associated with distrust of research, as several participants expressed concerns about being “infected with a disease,” “injected with a virus,” or “diagnosed with something I don’t have.”

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3.4.1. Differences by geographical location

Participants from Houston and Brownsville thought that fears about participation in clinical trials were due to lack of awareness and information in their communities. Participants from El Paso expressed concerns about physical harm caused by medications and many expressed hesitancy to take medications as part of their participation.

3.4.2. Differences by gender

Both males and females mentioned concerns about risks and side effects. However, males expressed concerns about the potential of being physically harmed (e.g., developing a tumor or organ damage) more often than fear of pain. One participant indicated that he would rather give blood than take a medication that could cause him harmful side effects. Females, on the other hand, expressed concerns about experiencing pain as a result of their participation more often than concerns about physical harm. For both genders, concerns of physical harm or pain were deterrents of participation.

3.4.3. Differences by language

We found no differences in fears and concerns related to language spoken.

3.5. Perceived benefits of participating in clinical trials

Across all focus groups, participants indicated that they would be willing to participate in clinical trials to help advance science and to benefit society. One participant said, “I think that clinical studies are very good and can help out our friends, family, and people we care about. And, even if we don’t know somebody, we should care about them.” (Houston, Male, English). Participants also mentioned the potential of helping their families and helping future generations as a positive outcome of clinical trial participation. One participant said, “I would let others test me in case they find a cure and my family could benefit from it.” (Brownsville, Female, Spanish).

Others said that improving their own health status would be a compelling reason to participate. An important perceived benefit across groups included hopes of improving their poor health status by getting access to health care or receiving medications. Many participants said they would only consider participating in a trial as a last resort, if they were terminally ill or had a serious condition. Lastly, some thought that people in good health should not take part in therapeutic clinical trials because it could be detrimental to their health, and it would not contribute to science. For example, one participant said, “It’s worth it for those with a health problem, but
otherwise, why would you jeopardize your health?” (Houston, Male, English).

3.5.1. Differences by geographic location

For participants from El Paso, the perception that participation could lead to the discovery of new diseases and treatments and helping to find a cure for diseases were salient themes. In contrast, only one participant from Brownsville said that she would participate to help find a cure, while no participants from Houston brought up this point. Participants in El Paso also expressed a sense of cohesion and a desire to give something back to their community. One participant said, “We, Hispanics, need to get involved to help each other out because we are a minority.” (Male, Spanish).

3.5.2. Differences by gender

Female participants indicated altruistic motives for participating in a clinical trial (e.g., desire to help future generations). Males indicated more frequently that they would participate to benefit their own poor health than a desire to help others. Both males and females expressed a desire to participate in clinical trials to help advance science. However, when verbalizing their willingness to help, females indicated specific examples of how their participation in clinical trials could help advance science, which included discovery of new diseases and development of treatments and medications. Comments made by males were more general. For example, one male said, “Participating more than anything is for a good cause. To help somebody, to save somebody, to improve something.” (Brownsville, Male, Spanish).

3.5.3. Differences by language

Participants in the Spanish-speaking groups mentioned the desire to help future generations more often than English-speakers did. We observed no other differences by language spoken.

3.6. Incentives to participation

Across all groups, incentives ranged from financial incentives to decreasing logistic barriers. Participants believed that monetary incentives, such as gift cards or cash stipends, could encourage participation. Across all groups, participants mentioned having access to medications and the potential to offset costs associated with medical procedures as incentives. Other incentives mentioned were providing transportation to and from the study sites, compensating mileage, and providing refreshments.

Many indicated that they would want to participate in a clinical trial to learn more about their own health status or to find out if they had a disease. Others believed that they would be able to get free check-ups, receive blood work results, or gain access to their medical information by participating in a trial. Because some believed that participation would facilitate medical screenings or tests, participants discussed expectations about finding out test results as incentives to participation. One woman stated, “I think people want to take advantage of the labs since they will not charge you for them.” (Brownsville, Female, Spanish).

3.6.1. Differences by geographic location

Participants from Brownsville believed that the uninsured would benefit from participation by obtaining free access to healthcare. For participants from El Paso, a major incentive to participate was getting free check-ups, access to medications. Some participants from El Paso believed that they had to pay for medications and other health care, and some said that they would not participate in a clinical trial for this reason.

3.6.2. Differences by gender or language

We found no differences in perceived incentives to participation by either language spoken or gender.

4. Discussion

The purpose of the study was to explore knowledge and perceptions about clinical trials among Mexican Americans residing in three cities in Texas. We aimed to identify barriers and facilitators that would help improve their participation in this type of research. By capitalizing on unique data containing perceptions of English- and Spanish-speaking Mexican American adults living in one large metropolitan city and two U.S.-Mexico border cities in Texas, we were able to examine differences by gender, language of preference, and geographical location. To our knowledge, this is the first study that qualitatively examined similarities and differences in knowledge and perceptions of clinical trials among Mexican Americans in Texas.

Our findings are consistent with previous qualitative research exploring barriers and facilitators of clinical trial participation among Hispanics. First, we found limited knowledge and understanding among our focus group participants. Among Spanish speakers, the term estudios clinicos (clinical trials) was confusing and hard to understand. This is consistent with findings from a study of Spanish-speaking Puerto Ricans [14]. Another study found that Hispanic participants were familiar with the term experimental studies and were able to define the term in their own words but that they were less familiar with the term clinical trials [15]. However, it is unclear whether using other terms (e.g., experimental studies) could exacerbate fears of experimentation. Future studies should assess participant’s acceptability and comprehension of alternative Spanish-language terms.

Our findings related to fears and concerns about clinical trial participation are similar to those found in other studies, such as fears of experimentation, concerns about unethical research practices, and fears of potential harm [8,9]. However, we observed that males and females articulated their concerns differently about potential harm and pain related to participation. Females were more concerned about pain than males, while males more often expressed concerns about physical harm than females did. The way participants voiced their fears and concerns about participation might be relevant to researchers who are developing targeted clinical trial educational messages to Mexican-Americans. Future research should examine whether these findings are genuinely gender-based concerns and ways that they could be addressed.

In all three cities, we found that participants’ fears of deportation could be a barrier to their participation. This is of particular importance among immigrant communities, as those included in our study. Mexican Americans are the largest ethnic group of undocumented migrants in the US; of the 10.3 million estimated undocumented migrants, Mexican Americans make up 57%, and 14% of those reside in Texas [13]. Although findings related to fears and concerns about participation in clinical trials are not necessarily unique to Mexican Americans, other groups have also expressed similar concerns [8,9]. Nevertheless, there may be differences in the degree to which these beliefs influence participation particularly when logistic, economic and other concerns such as those related to immigrant status are considered.

Focus group participants expressed receptivity to participate in clinical trials and a desire to help research and science, which is consistent with another study among Mexican Americans [8]. Participants thought that taking part in a clinical trial would give them access to healthcare, a phenomenon known as therapeutic misconception [16], and has been observed and studied in other ethnic populations [17]. We found that major incentives to
participation were monetary stipends and eliminating logistic barriers. Although these incentives are not unique to Mexican-Americans in Texas, we believe that is important to highlight findings that are similar to those of other qualitative studies [18]. We also found that females expressed more altruistic motives for participation such as the desire to help others, whereas males said they would participate in a clinical trial to benefit their own health. We believe that this might be related to gender roles and expectations, whereby Mexican American women are often expected to take the role of caretakers and demonstrate collectivistic characteristics [19]. Future studies should examine whether these findings are truly related to gender roles and expectations. Lastly, our participants expressed an increased need for bilingual staff, use of simple language in written materials, and the use of community channels (e.g., media ads, word-of-mouth) to disseminate information.

By examining our data across geographic regions, we were able to gather information about our participants’ context and social realities. Our findings suggest that participants in the border-town communities, as compared to those in the metropolitan city, may have less exposure to research and clinical trials information and opportunities to participate. This lack of exposure may also contribute to their fears and concerns about participation. A recent review [20] reported that familiarity and interest in research facilitated clinical trial participation. Thus, our findings identify an opportunity to increase familiarity and access to research in these geographic regions. We also found that altruistic motives were more salient in border towns as compared to Houston. We believe that this may be related to social cohesion within those communities and cultural aspects such as the desire to help others within their communities.

Limitations of this study are related to its qualitative nature. One limitation is that we used a convenience sample; hence, our findings are not generalizable to all Mexican-Americans or to a broader Hispanic population. Future studies should explore participants’ perceptions of other Hispanic subgroups. A second limitation is that other factors, such as education, financial status, and other socio-demographics may have influenced participants’ opinions; therefore, findings should not be attributed solely to cultural factors since they may have also been influenced by socio-demographic factors. Our study was not designed to tease apart potential differences and we recommend future research in this area. We acknowledge that some of our participants’ lacked sufficient knowledge of clinical trials and that this may have influenced their perspectives, as well. Approximately 12% of participants indicated having participated in a clinical trial on their demographic surveys. However, this question was asked before participants were provided with a definition of clinical trials and before they discussed it with other focus group participants; thus, we believe that 12% participation might be an overestimation and it may be indicative of their lack of sufficient knowledge about the concept of clinical trials. This was an important finding in our study and has implications for future research and development of educational materials to increase participation. Our last study limitation is that our data did not permit comparisons in responses between those who may and may not have participated in clinical trials because individual survey responses could not be linked to comments made by individuals during the focus group discussions.

A major strength of this study is its use of focus group methodology. It allowed us to garner community perspectives on clinical trial participation among Mexican-Americans, the largest underrepresented minority group in the country. We thereby gained a better understanding of barriers and facilitators to clinical trial participation through comparisons across gender, language, and place of residence. These findings could inform the development of interventions to enhance recruitment of Mexican-American participants into clinical trials.

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