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Abstract

Clinical trials (CT) in breast cancer have been crucial for new treatment discoveries. While participation in cancer CT is low, minorities are particularly underrepresented.This study aimed toidentify factors influencing the participation in CTs based on the experiences of Latina breast cancer survivors in Puerto Rico (PR), especially their CT knowledge, motivations, and concerns.Method:Focus groups (FG) were conducted by two social workers and the University of Puerto Rico/MD Anderson Community Health Educator. Participants were stratified into two subgroups: a) women with CT experience and b) those without CT experience. Seven FG were completed among breast cancer survivors (n=34) at two hospitals from the PR metropolitan area. Results: Our findings showed that participants expressed a basic knowledge and understanding of clinical trials. Motivations to participate included a desire to help others, non-monetary incentives to participation, self-benefits, readiness to participate based on the phases of illness, and enhanced relationships with the clinical trial recruitment team. Regardless of their previous experience with CTs, participants expressed concerns about participation including limited of knowledge about trial procedures and results, and lack of transportation, childcare, and support from family. Recommendations: The barriers and motivations identified for CT participation are modifiable and best targeted using a multidisciplinary approach.Social workers could play a potential role in participant recruitment and retention by clarifying research protocols to potential participants, as well as conducting CT. Our findings can help enhance capacity and training efforts for health professionals involved in CT recruitment and retention in culturally-relevant ways.

Keywords

Breast Cancer Survivor, Clinical Trials, Latinas, Hispanic, Puerto Rico

Cover Page Footnote

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ABSTRACT

Clinical trials (CT) in breast cancer have been crucial for new treatment discoveries. While participation in cancer CT is low, minorities are particularly underrepresented. This study aimed to identify factors influencing the participation in CTs based on the experiences of Latina breast cancer survivors in Puerto Rico (PR), especially their CT knowledge, motivations, and concerns. **Method:** Focus groups (FG) were conducted by two social workers and the University of Puerto Rico/MD Anderson Community Health Educator. Participants were stratified into two subgroups: a) women with CT experience and b) those without CT experience. Seven FG were completed among breast cancer survivors (n=34) at two hospitals located in Caguas and San Juan, PR. **Results:** Our findings showed that participants expressed a basic knowledge and understanding of clinical trials. Motivations to participate included a desire to help others, non-monetary incentives to participation, self-benefits, readiness to participate based on the phases of illness, and enhanced relationships with the clinical trial recruitment team. Regardless of their previous experience with CTs, participants expressed concerns about participation including limited of knowledge about trial procedures and results, and lack of transportation, childcare, and support from family. **Recommendations:** The barriers and motivations identified for CT participation are modifiable and best targeted using a multidisciplinary approach. Social workers could play a potential role in participant recruitment and retention by clarifying research protocols to potential participants, as well as conducting CT. Our findings can help enhance capacity and training efforts for health professionals involved in CT recruitment and retention in culturally-relevant ways.

Keywords: Breast Cancer Survivor, Clinical Trials, Latinas, Hispanic, Puerto Rico

INTRODUCTION

Clinical trials research in cancer is essential for the development of effective prevention, diagnostic, and treatment methods. Ethnic and racial minorities and underserved populations are particularly underrepresented in clinical trials in the United States (US) (Advani et al., 2003; Brown, & Topcu, 2003; Ford et al., 2013; Moreno-John et al., 2004; Murthy, Krumholz, & Gross, 2004; Powell, Fleming, Walker-McGill, & Lenoir, 2008; Yancey, Ortega, & Kumanyika, 2006). It is estimated that less than 5% of cancer patients participate in clinical trials, and that racial and ethnic minorities are disproportionately underrepresented compared to non-Hispanic Whites (Fracasso et al., 2013). Only 2.0–4.0% of clinical trial participants self-identify as Latino (Kwiatkowski, Coe, Bailar, & Swanson, 2013; Parra, Karnad, & Thompson, 2014). This underrepresentation of Latino populations in clinical trials hampers the generalizability of trial results, such as new treatments or interventions that may be relevant to this population and contributes to inequitable distribution of benefits and risks of trial participation among these populations.

Researchers have explored factors influencing Latino participation in trials (Arevalo et al., 2016; Calderón et al., 2006; Ellington, Wahab, Martin, Field, Mooney, 2006; Ford et al., 2013; Nodora, O'Day, Yrun, & García, 2010). Results have suggested that factors associated with their participation include knowledge, awareness, age, comorbidities, socioeconomic status, fears, research mistrust, and logistic barriers, such as transportation and time constraints (Arevalo et al., 2016; London et al., 2015). Studies exploring clinical trial participation in Puerto Rico (PR) are scarce. This is despite the burden of breast cancer in PR, as well as, the controversial history of clinical trials among Puerto Rican women (Vargas, 2017).

Breast cancer is the leading incidence and mortality cancer among Puerto Rican women. The number of Puerto Ricans living with breast cancer in 2010 was estimated to be 13,736 women (Centeno-Girona et al., 2013); thus, it is important to understand patients' knowledge, barriers and facilitators that might help or interfere with participation of Puerto Rican women in breast cancer clinical trials. An enhanced understanding of these factors is necessary to design strategies that will aid in increasing recruitment and retention of participants in future clinical trials. Moreover, it is also necessary to explore whether or not these factors differ among women with and without clinical trial experience because it could aid in identifying opportunities to increase recruitment and retention of these two populations. The general purpose of this qualitative study was to identify the knowledge, motivations, and concerns influencing CT participation of Latinas in PR, including those with and without prior clinical trial participation experience. The specific aims of the study were: a) To identify factors (individual, cultural, social, and economic) influencing clinical trial participation and recruitment among breast cancer women survivors in PR; b). To explain issues surrounding willingness or unwillingness to participate in Cancer clinical trials; c) To describe the most common concerns and questions asked about an ongoing cancer clinical trial; and d) To explore clinical trial satisfaction, and willingness or unwillingness for future participation among breast cancer women survivors with clinical trial participation experience.

METHODS

Study Population

An interdisciplinary research team consisting of epidemiologists, social workers, and a community health educator (CHE) recruited participants from two hospitals located in Caguas and

San Juan, PR. Previous research collaborations existed between our research team and hospital institutions because these institutions provide health services to women with breast cancer diagnosis. Individuals were eligible to participate if they were: 1) Spanish speakers; 2) women; 3) 21 years of age and older, and 4) had been previously diagnosed with breast cancer. Participants were identified by the hospitals. Those that agree to participate were subsequently referred to the research team. Research assistants contacted women that agree to participate and confirmed the women's participation in this study by phone.

Study Design & Procedures

Focus groups (FG) were conducted in Spanish by two social workers and the University of Puerto Rico/MD Anderson Community Health Educator (CHE), all of whom were trained in qualitative methods. Two groups of breast cancer survivors were included in the FG: (1) women who had previously participated in a clinical trial and, 2) women who had not participated. Study participants reviewed and signed an informed consent and completed a brief survey including questions regarding their sociodemographic, cancer clinical history, and their previous experience with clinical trials, when applicable. Each FG had approximately five participants in each group. Four (4) FGs were conducted with participants who had participated in clinical trials, and three (3) FGs with participants without clinical trial participation experience. All FGs were audio recorded, lasting approximately 90 minutes. During the FG conversations, participants were asked to share their experiences and perceptions of clinical trials using a semi-structured interview guide addressing as summarized in Table 1. Upon completion, each participant received an incentive of $20.00 for their time and transportation costs. The Institutional Review Board of the University of PR, Medical Sciences Campus reviewed and approved the study protocol.

Table 1: Questions of the FGs, and topics*

Aims:

Topics	Questions addressing aim
1. Knowledge, attitudes, and beliefs towards clinical trials	• What do you know about clinical trials? • Have you ever been invited to participate in a breast cancer clinical trial or other type of clinical trial? • Would anyone like to share their experience from trials you have participated in? (WE) • If you were invited to participate in a clinical trial, what reasons would motivate you to participate? • If you are invited to participate in a clinical trial again, what reasons would motivate you to participate? (WE) • What opinion do you have in general about people that participate in clinical trials?
2. Motivation towards participating in clinical trials	• (An example of a clinical trial is presented to the participants of FGs). As a result of the previously described research protocol, what questions do you have about this clinical trial? • If we ask you to participate in this clinical trial, what reasons would you have to participate in this clinical trial? • What reasons do you think could influence your decision to participate in this clinical trial?
3. Barriers and facilitators in clinical trials	• What are the things that would make difficult your participation in a clinical trial? • What are the things that would facilitate your participation in a clinical trial? • Which reasons do you understand will influence your decision to participate in a clinical trial? • Why do you think that clinical trials are important for you and your family? • If you have children, what reasons would you have to register them in a clinical trial? • What kind of research related with cancer do you think should be conducted in PR?
4. Preferences for obtaining information about clinical trials	• Have you ever seen or listened any social media or promotion of a specific clinical trial? (Explore details) • Let's assume that we want to develop educational materials to increase the knowledge and recruitment of breast cancer survivors in clinical trial, like the example mentioned before, what information do you think is necessary to include in the informational material to help people decide to participate?

* WE refers to women with clinical trial experience.

Analysis

Triangulation technique, peer debriefing, and negative case analysis were applied for credibility as recommended in the literature (Barush, Gringeri, & George, 2011). After each FG section, a peer debriefing short meeting was implemented to discuss systematically the FG's

experience and explore researchers' perspectives and thoughts. A research assistant transcribed all of the Spanish audio recordings_of FG conversations *ad* verbatim, and another staff member revised the transcripts for accuracy. After all the data was transcribed, the research team conducted a process of triangulation of peer's analysis (Strauss, 2003). This type of triangulation involved five researchers from different disciplines, who were trained in coding and analyzing FGs, and were non-blinded to the purpose of the study. They were asked to code the first two transcripts independently, identifying major themes according to the aim of the study. Also, coders were encouraged to identify emergent new themes. This allowed the team to confirm findings across researchers without prior discussion (Carter et al., 2014; Denzin, 1978; UNAIDS, 2010). Then, the team came together to determine similarities and differences in the coding process and define themes combining the multiple discussions (Barush, Gringeri & George, 2011). Coders are described as interdisciplinary researchers that were directly involved in the data collection process as well other research assistants not involved. A preliminary data codebook was developed for this initial phase of the analysis. Three specific themes were identified that contribute to understand patients' knowledge, barriers and facilitators that might help or interfere with participation of Puerto Rican women in breast cancer clinical trials. Subsequent weekly research team meetings were conducted to apply this triangulation technique with all the transcripts. If negative case analysis emerged, it was integrated into the discussion to critically question the pattern of responses identified among other participants. Once the group reached consensus, the thematic data analysis was entered into the *Nvivo* software version 11 to begin linking codes and associate quotations for all transcripts. Similarities and differences were intended to be identified between groups with previous clinical trial experiences and without clinical trial experiences. This paper organized findings into the three major themes: 1) knowledge about clinical trials; 2) motivations to participate; and 3) concerns to participate in a trial (See table 2).

Table 2: Themes and definitions as part of the analysis

Themes	**Definitions**
Knowledge about clinical trials	The information that participants had about clinical trials (ex. definitions, descriptions about clinical trial processes, etc.).
Motivations to participate	The elements that promote or facilitate the participation of women's breast cancer survivors in clinical trials. In our study, it included the reasons Latinas provided for participation in future clinical trials. It includes the following 5 subcategories: *a) help to others, b) incentives, c) self-benefits, d) phases of illness: diagnosis, treatment, and remission, and e) patient and clinical trial research team's relationship.*
Concerns to participate	Issues, general concerns, or barriers to participate in clinical trials. It includes the following 5 subcategories: *a) Implications of the experimental intervention, b) Lack of access to results, c) Lack of knowledge of the clinical trial protocol and adverse effects, and d) Historical memory of clinical trial experiences.*

RESULTS

Demographics

A total of seven FGs (n=34) were conducted. Four of them were conducted with participants with clinical trial experience and three FGs with participants without clinical trial experience. Across all the seven groups, more than the half (61.7%) of the women were married or cohabitating; 64.7% had some years of college or a college degree; and 63.6% had an annual household income below $34,999. More than the half of the women (64.7%) had private health insurance (See table 3).

Breast Cancer Treatment Experiences

A vast majority (82.4%) of the women reported that they had had difficulty with medical insurance to receive services related to their breast cancer treatment and 57.6% were currently in breast cancer treatment at the time of study. More than the half of the women (61.7%) used their personal car as transportation method for appointments (See table 3).

Clinical Trial Experiences

A total of 41.2% of all of the participants in the FGs had heard about clinical trials before participating in our study, 32.4% were invited to participate in clinical trials, and more than the half of the women (63.6%) were willing to participle in clinical trials in the future (see table 3).

Table 3: Participant sociodemographic information

Socio demographic information (n=34)	n (%)
Marital Status	
Married living together	21 (61.7)
Divorced/separated	8 (23.5)
Single/never married	2 (3.8)
Widow	3 (8.8)
Education	
Less than high school	5 (14.7)
High school	7 (20.6)
Some years of college or college degree	22 (64.7)
Employment	
Unemployed	7 (20.6)
Full-time job	6 (17.7)
Part-time job	2 (5.9)
*Other	19 (55.9)
Total	**34 (100.0)**
Household income	
Less than $15,000	10 (30.3)
$15,000-$34,999	11 (33.3)
$35,000-$49,999	5 (15.2)
More than $50,000	6 (18.2)
Blank	1 (3.0)
Total	**33 (100.0)**
Medical insurance	
No insurance	1 (2.9)
Private	22 (64.7)
Mi Salud/Government Insurance	11 (32.4)
Total	**34 (100.0)**
Difficulty with medical insurance to receive services related to Breast Cancer treatment	
Yes	28 (82.4)
No	6 (17.6)
Total	**34 (100.0)**
Currently in Breast CA treatment	
Yes	19 (57.6)
Heard about clinical trial?	
Yes	14 (41.2)
No	19 (55.9)
Invited to participate in clinical trial?	
Yes	11 (32.4)
No	22 (64.7)
Don't remember	1 (2.9)
Total	**34 (100.0)**
Future willingness to participate in clinical trial?	
Yes	21 (63.6)
No	3 (9.1)
Don't know	9 (27.3)
Total	**33 (100.0)**

Results of Analysis

The quotations obtained during the FG are presented below according to the three main themes used for analysis: 1) knowledge about clinical trials; 2) motivation to participate; and 3) concern to participate. Each quotation is identified by the number of the FG.

1. Knowledge about clinical trials

In general, participants expressed that clinical trials are scientific processes in which new treatments are developed for different illnesses. They contribute to advance the medicine and to identify the causes of cancer. A participant with prior clinical trial experience indicated:

> *I do not know if I am correct, but [clinical trials] their purpose is to improve the quality of life of a patient with cancer. Other [purpose is] research for the future. Other, it is for…something related with these research studies, with these studies is that have something in their hands to develop it. I mean, like the most important purpose for me is advance a cure for cancer and advance cancer research (FG #4).*

Some participants also understood how the scientific method is applied to achieve the goal of the clinical trials. A participant without clinical trial experience expressed:

> *I believe that a clinical trial can be detached from a hypothesis. Because the trial comes from a hypothesis, you seek to prove it…And depending on the results, new discoveries can be obtained that benefit us all. Like all of the advantages that we are now enjoying with the prescribed drugs, as these investigations also come from clinical trials. FG #8*

2. Motivation to participate

Next, we present our findings about elements that participants indicated that would promote or facilitate their participation in a breast cancer trial in five sub-categories: a) *help to others, b) incentives, c) self-benefits,* d) *phases of illness: diagnosis, treatment and remission, and e) patient and clinical trial research team's relationship.*

a. Help to others. Participants said that they would take part in clinical trials, if doing so could help others, including their families. Because of their journey with breast cancer, both groups understand the difficulties that can be experienced and they expressed it as a motivation to take part in clinical trials. Regarding possible benefits, they expressed that if they could help prevent cancer and find better treatments with their participation, they would do it. Other participants expressed their gratitude towards the women that had been part of previous clinical trials, and recognized their duty in the development of the treatments they currently receive. Two participants in the FG with CT experience expressed the following:

> *In my case, I would be motivated by the same, the possibility of helping and contributing to other patients who are disoriented. You know, for example, right now I have an aunt that just had a biopsy and we are waiting for the results. I would like to learn a little more, so I could help her and my family, and anyone who needs help. FG #3*

> *In my case, I thank all the people who served and participated in clinical research. For example, with Tamoxifen, the pill that we take in our treatments. If those women had not participated, I would not have been beneficiated. And that's how it goes with every*

> *medicine that is on the market right now. So, I'm very grateful of these studies and to be able to participate. FG #4*

Participants without clinical trial experience indicated:

> *Well, it's hard... When you have the condition, you say: "let's go, let's do it." Honestly, if you ask me now, I'd tell you: "Yes, I would participate in a research study." Before having cancer, I would had told you that I would not participate; I will not be a guinea pig. But since you go through the experience, it touches you closely and it hurts. You want to help. You want to help other people to prevent the disease. Actually, the word is, prevention... helping other people. I would accept it right now. If you asked me 7 months ago, no. FG #2*

b. Incentives. Incentives means something concrete or accommodations patients can receive to motivate them to participate in clinical trials. Participants in general expressed having access to their results during their participation to be a motivation. Neither group discussed the need to obtain money as a priority for their participation. Other issues, such as flexibility for scheduling clinical trial procedures, and access to results and health services, were also important and perceived as incentives for participation. Other factors to be considered to accommodate their participation were: employment status, geographical location, transportation, and child care. A participant with clinical trial experience indicated:

> *In my experience, because I had lost a lot of work days, I could not participate of the study. So they went to my house on a Saturday, my free day…also the schedules; why can't clinical studies be conducted at nights or weekends? …I told her: "I really can't miss work." And she went to my house…I think it's very difficult to leave your work area for a study, and then go back to work if you have the time. It would have been easier for me if the study had been at night or on a Saturday…There are many people who do not work, but if you are a person who does, you have some responsibilities there, and in addition, you have to go to three appointments a month…The solution is "I won't do it". FG #4*

Another participant without clinical trial experience said:

> *Even during the time that the group is being monitored in the trials, the research team should also be orienting them about how the study is going, how are the findings; because that motivates the person to also continue her to participate... Because I see it as you're trying to help me, and I'm not just another number. …you are helping me to improve and to overcome my situation, and I contribute as well. FG #2*

c. Self-benefits. Self-benefits mean something concrete patients could receive to help improve their own health. Some participants with clinical trial experience expressed an interest in knowing the results of their tests so that they could use them for their treatments, considering this as a self-benefit. There was also an expectation of a reduction or elimination of treatment costs and privilege-related priority at treatment appointments. Two participants with clinical trial experience

expressed the importance of knowing the causes, treatments, and alternatives as a motivation to consider their participation:

> *Yes, because that is important. Because you want to help to improve the situation and promote the disclosure of the results for better treatments. But also, you would like to see how it can help you too. FG #6*

> *…I would participate in the study in the group of chemotherapy alone, if they offered me an incentive that guarantees me that I will not have to wait that long for treatment. And that because I'm part of this study, I have the benefit of having the first turn. FG #6*

d. Phases of illness: Diagnosis, Treatment, and Remission. Participants with clinical trial experience expressed concern regarding the stage of cancer in which some of them were contacted to participate in clinical trial. They expressed, that if the reach out process was made at times when they had overcome their negative emotions about their diagnosis, there was a higher possibility that they would participate.

> I would participate because I believe that when you already pass to that other stage, like the one that I am at now, where you already saw what happened. Before you were the protagonist, but now you are not, you become part of the show and you can analyze things without being touched in a personal way. And there you have the disposition and the knowledge of what touched you personally, and now you can sit in the other's seat…And if you're going to invite me to a study that I can contribute something that is needed, I want to be part of that because I have a lot to talk about. FG #6

e. Patient and clinical trial research team's relationship. Participants in both groups valued the communication between the clinical trial research team and themselves. Women with experience in clinical trials, expressed their satisfaction with the process by the amount and quality of the contact kept by the team. Participants with no experience, manifested that if the conversations with the team were constant, they would consider participation. Participants with clinical trial experience reported that a close relationship between patients and research team was a very important element to decide to participate in clinical trial.

> *…it should be done in a way that shows the humanized treatment given to the patients. They even went to my home on New Year's Eve and took pictures of the family sharing with the patient…Even the psychologists went, and I saw that the doctors were also involved…it was very nice. FG #5*

Also, participants of FGs without clinical trial experience focused on having a good relationship and constant conversation with the team. As part of these conversations, they expressed their interest to receive information about the progress of the study:

> *That the professionals in charge of the trial keep participants informed the whole time, not only in the beginning, but "during the process"...I am a risk taker… I am adventurous... I*

> *like to investigate things... I would even dare to participate, if I have these data, updated with a reasonable frequency. FG #8*

3. Concerns to participate

Women in both subgroups expressed that there was some fear to be exposed to a new drug with unknown effectiveness. Also, concerns about socioeconomic issues such as transportation costs, lack of childcare (especially those taking care of grandchildren), lack of family support, and time invested from work to participate in clinical trials (daily activities requirements from clinical trials) were verbalized.

a. Implications of the clinical trial on their health. Most of the participants found it difficult to decide joining a clinical trial because of the lack of information about the implications of the clinical trial on their own health. Some expressed their concerns about co-morbidities, the interaction of the clinical trial drug with their previous medications, and the capacity to be managed as part of the clinical trial protocol. Two participants with clinical trial experience said:

> *"The same, the side effects, which I believe are worse than the remedy". FG #3.*

> *But I would be questioning: "What is this for?"; the pros and cons. Right now, I have to ask about my medications, because I am allergic to aspirin and penicillin, and I developed that after I had surgery. Now, wherever I go, I have to say it. FG #5*

b. Lack of access to results. Concerns about the use of data collected in clinical trials and not having information about the research results during and after the clinical trial is completed, were frequently manifested as a main reason for not participating by groups with clinical trial and without clinical trial experience. Some of the women expressed their interest to have access to the clinical trial tests (i.e. genetic tests) that are very expensive, but are required by their doctors for their cancer treatment's strategy. A participant with experience said:

> *...I would think about it and maybe would not participate. Because you give and do not receive. Also, you will not have access to the genetic studies that could help in the future to solve any health situation. If I'm not going to benefit, then I don't understand, because I believe that one has the right to receive everything that is yours. FG #4*

Participant without experience:

> *The deductible only was more than a thousand dollars. The deductible! If we talk about the cost, it is very high. I pay a 25%. If I'm aware that the study was already done by blood samples, why I cannot have access to the results? Do you understand?... It must be part of the same treatment of that patient, and not see it merely as a statistical result. It should be as a sign of commitment to that patient, who is also undergoing through medical improvement. FG #2*

c. Lack of knowledge of the clinical trial protocol and adverse effects. Participants manifested some concerns about the testing group that they would be assigned to in the clinical

trial. They would not like to be exposed to some unnecessary or repeated treatment, and there could be some hesitation to participate if they could not choose. The lack of knowledge about the processes of the clinical trial, could be determinant to resign participation. A participant without clinical trial experience expressed:

> *I would not participate, because if I will not benefit... You will not know; they will not tell you in which group you will be... And the selection of the group is randomized.... because that's the purpose of the study, this ... it's a difficult question. FG #2*

d. Historical memory of clinical trial experiences. Even though participants without clinical trial experience recognize that the participation of other women has been crucial for the development of new treatments, there was a fear to be treated as guinea pigs, this is in reference to the birth control pill trial carried out in PR in the 1950s (De Malavé, 2005) and other historical trials implemented among Puerto Rican women.

> *P03: In the past it was said that we were treated like... like I am. What was it like...?*
> *P02: Like Guinea Pigs?*
> *P03: That! (Laughs) Guinea Pigs, because they were always experimenting with us. (P02 & P03) FG #1*

Also, some women with clinical trial experience expressed their concerns about the interests that are behind the development of clinical trial. There was some recurrent fear of becoming *guinea pigs*, and that they could be used for the economical and scientific advantage of the research team, instead of for their health.

> *I am also worried, that sometimes…the primary interest is to obtain information from patients already involved in this situation. But what kind of risks can one have as a patient when undergoing this type of clinical trial? It favors, of course, the group that is doing the research. We could be like guinea pigs, because the primary interest is: "Let's see how we get information, an injection, something that provides what we want to find, the last Coca-Cola in the desert." Even though the people who are participating in the studies are already patients and their lives are compromised. FG #5*

DISCUSSION

This qualitative study assessed knowledge, barriers and facilitating factors to increase clinical trial participation among Puerto Rican breast cancer survivors. The most common motivations for participants reported were: a) help to others, b) incentives for getting access to results, flexibility for scheduling clinical trials procedures, and health services, c) self-benefits, d) consideration of the phases of the illness: diagnosis, treatment and remission, and e) strong patient and clinical trial research team relationship. On the other hand, concerns about participating in clinical trials discussed included: a) lack of access to results of clinical tests conducted during clinical trial, b) lack of knowledge of the clinical trial protocol and possible adverse effects, c) historical fears based on memory of clinical trial experiences in PR, and d) the notion of being *guinea pigs*. As revealed by both subgroups of participants, their motivations were not directly

related with economic benefits or incentives, but might be possibly driven by altruism, which is different from the literature as discussed by Townsend and Cox (2013). The precarious status of the health system in PR and lack of access to treatments for most of the chronic conditions could explain the patients' motivations. Clinical trials could mean a possible window for these patients to get access to health services and innovative treatments. This finding is consistent with recent research that concluded that low participation of Latinos in clinical trials is not due to lack of interest, but lack of awareness about clinical trials (Arevalo et al., 2016; Lucero, Siddhartha, & Ginossar, 2017).

A crucial element for this investigation was to understand the motivations and concerns that could increase future participation in breast cancer clinical trials of Latina women in the context of PR. When analyzing the data, the greatest motivation that the participants expressed was to help others, especially other women diagnosed with breast cancer. They often verbalized the importance of giving other women hope of a good quality of life or to promote prevention to people that have not been diagnosed. This was also represented in terms of their families and the possible future health benefits they could obtain through their participation. In contrast with another qualitative study about motivations to participate (e.g. Townsend, & Cox, 2013), our study participants showed more interest in helping their families and other generations, than in getting benefits for themselves. Other recent research studies exploring Latina participation in clinical trials agrees with the altruism perspective (London et al., 2015). Possible explanations for the altruistic motivation to participate in clinical trials observed in our study may be based on that the participants were all women, and in the Latino culture matriarchal characteristics include nurturing and taking care of others.

According to the patriarchal discourse imposed in the Latino culture, women are adjudicated responsibilities in the private sphere or domestic/family space (Rivera-Díaz, Varas-Díaz, Coriano-Ortiz, Padilla, Reyes-Estrada, & Serrano, 2015). They are socialized and taught that they are responsible for being the caregivers, assuming this role throughout the process of socialization at every stage of their lives. This is also evidenced in the health services scenario, including issues regarding family approval for treatment, motherhood responsibilities versus their health, among other concerns. A recent research study by Lucero, Siddhartha & Ginossar (2017) sustains the idea that involving family members in the clinical trial educational process may help participants make better decisions. In terms of clinical trial recruitment, this is an interesting finding to consider implementing in order to increase and obtain an effective participation of Latinas. Incentives for these women do not mean monetary benefits (London et al., 2015). Having access to some services and flexibilities such as flexible time, child care, transportation, and clinical interventions at home, unless medical or hospital intervention is required, are more effective participation incentives for this population. Also, considerations for providing socio-emotional support to participants depending the stage of their cancer diagnosis at the time of recruitment and research team's sense of empathy are highlighted. Those factors could play a decisive role for their willingness to participate in a clinical trial.

Also, there is a reality to consider regarding the difficulty in obtaining access to health services in the public health system in PR (Gobierno de Puerto Rico, 2005; Muñoz Sosa, Rivera Díaz, & Correa Luna, 2018; Rivera Díaz, 2015). It is possible that breast cancer survivors would accept to participate due to their capacity to obtain specialized health services such as laboratories, and specialized evaluations (82.4% of the participants reported difficulties in obtain health services), that otherwise they would not have access to. Not having access to laboratory test results

that are part of the clinical trial could be consideration for not participating. Our findings showed that education and continuous information about the purpose of the trial and its implications is needed to motivate participation. Participants expressed that it would be very difficult for them to accept participating in a clinical trial if they were not provided with a complete overview of the study.

When addressing important factors that determine retention in clinical trials, women from both subgroups expressed the need for open and constant communication with the clinical trial research team. They would like to be informed on how the research is going, how it will benefit to them, and how the objectives will be fulfilled. Physicians and the clinical trial research team should be open to interdisciplinary work to help attain the goals of the study. The inclusion of different professions, such as social workers, would help on the ongoing process of communication and motivation to participate in the trial, by advocating for the patient's rights in future research. The social work profession has the responsibility to advocate for right to health for all individuals, in order to promote an illness-free environment and contribute to the eradication of social determinants that impact health. Also, social workers in clinical settings could play a potential role for providing specific benefits information and to clarify research protocols to patients, facilitate access to clinical trials, conduct clinical trials as researchers as well as defend the right of patients for health information and access to new treatments through educational intervention models.

Some limitations need to be considered in this study. For future studies, inclusion criteria should consider the stage of diagnosis of those participants without clinical trial experience. Participants with a more recent diagnosis were more emotionally vulnerable during the FG than those on remission or those who had finished their treatment. Also, most of the FG (6 out of 7) were carried out in one site (hospital), this could have an effect in the variability of the experiences reports as women coming from different regions of the country, and with different socioeconomic and health insurance coverage backgrounds, may have had different experiences. Despite these limitations, our study provides important qualitative data to pursue future studies which promote retention and recruitment strategies for clinical trials in the Island. A promising endeavor given that most of the participants (63%) reported willingness to participate in a future trials, and that most of the barriers discussed by the participants, are manageable and best targeted using a multidisciplinary approach.

CONCLUSION

Based on the findings, we recommend the following ten (10) considerations to recruit and effectively retain Puerto Rican women in clinical trials: 1) Consider the personal and work-related circumstances of the women (Ex. Productive life, job's limitations, child care); 2) Identify benefits and incentives, in addition to monetary incentives, that could help in recruitment and retention, such as access to medical examinations, medical care, and clinical lab results; 3) Involve the families in the process of recruitment, education, implementation, and culmination of clinical trials, as it might increase the family's support for the patient in the trial; 4) Consider the stage of the cancer when recruiting participants and identify culturally-sensitive ways to work with them; 5) Educate survivors about the differences between standard of care for their cancer and the implications of clinical trial procedures; 6) Develop creative strategies to explain the implications of the clinical trial protocols to participants such as radio, non-medical journal announcements (magazines) with clinical trial information, educational videos in medical offices, among others ;

7) Clarify and provide information about protocols in case of adverse situations or emergencies; 8) Promote interdisciplinary work. (i.e. the social worker's role in trial); 9) Develop protocols that require the disclosure of study results to participants as part of the IRB protocol. This should include publication of results in general and popular magazines using a friendly and accessible language; and 10) Encourage the dissemination of the study results through popular access platforms. To achieve this, as social scientists, we need to restore the confidence and eradicate the misperceptions about clinical trials and the "guinea pig" reference from our popular memory. Building a trustworthy relationship between research/recruitment team and patients will enhance trust and participation of Latinas in breast cancer clinical trials. Therefore, it will contribute to the development of effective prevention, diagnostic, and new treatment interventions, methods, and strategies that may be culturally relevant and appropriate to this population.

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