"I am not a guinea pig":
Factors Influencing the Participation of Latinas Breast Cancer Survivors in Clinical Trials

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Introduction

- Breast cancer is the leading cause of cancer death among Hispanics women living in the US and PR.
- One of the greatest potentials for reducing cancer mortality in cancer patients is through increasing participation in cancer clinical trials.
- Disproportion of minority participants in clinical trials has been documented.
- As it has been previously argued, without minority participation in studies of diseases that affect them disproportionately, understanding whether clinical findings apply equally or whether there are racial and ethnic differences in response to therapy is limited.

NIH Statement

" … all NIH-funded clinical research will be carried out in a manner sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups and, particularly in NIH-defined Phase III clinical trials, to examine differential effects on such groups."[9]

Study Objective

Identify facilitators and barriers influencing participation in clinical trials to increase participation among breast cancer survivors in Puerto Rico and to enhance U54 and partners recruitment efforts.

Methods

- The methodology used for this study was a focus group approach, a qualitative data collection method that is especially effective for capturing information about different points of views and opinions within the population of interest.

Figure 1. Clinical Trial Focus Group Composition

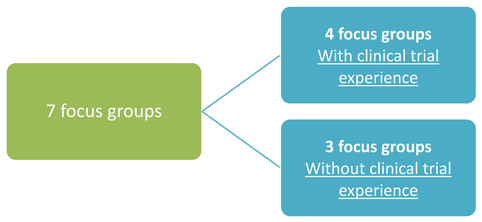

Figure 2. Study Protocol

- Focus Groups guide included:
  1. open-ended questions about breast cancer, clinical trials knowledge attitudes or beliefs
  2. Discussion of a current NIH/NCI protocol
     - facilitators and barriers
     - concerns regarding participation of clinical trials
     - health services received and barriers to access health care.

Analysis

Categories	Definition
Facilitators	Elements that promote or facilitate the participation of women in clinical trials. Reasons why they decided to participate in the future of a clinical trial.
Barriers	Concerns that could serve as barriers related to the clinical trials for future participation by women with or without clinical trials experience.

Results

Table 1. Characteristics of participants.

Variable	Total (%) (n=34)
Participant's characteristics	
Marital status	
Never married	9.0%
Married or living together	59.0%
Divorced, separate, or widowed	32.0%
Educational Level	
≤High School	11.8%
> High School	88.2%
Employment status	
Unemployed	20.0%
Full-time employee	18.0%
Part-time employee	6.0%
Retired	44.0%
Homemakers	12.0%
Income	
<$15,000	31.3%
≥$15,000	68.6%
Health Insurance coverage	
Private	68.0%
Public	29.0%
None	3.0%
Years after diagnosis	
≤5	75.8%
>5	24.2%

Barriers

- Women verbalized concerns about possible ethical issues surrounding research institution and researchers.

"A mí me preocupa también, perdóname, que a veces uno se somete a los estudios, como estudios así, no digo que este sea el caso, pero el interés primordial es obtener información de pacientes ya envueltos en esta situación, pero ¿qué riesgos puede tener uno como paciente al someterse a este tipo de, de ensayo clínico? Favorece, claro, al grupo que está haciendo la investigación. Nosotros en sí, podríamos ser como conejillos de india, porque el interés primordial es el: "Vamos a ver de qué manera conseguimos una información, una inyección, algo que provea que encontramos, vamos, la última coca cola en el desierto. […] …y tú dices: "Bueno, tomo esta decisión por lo que me está diciendo. ¿Será la más correcta? ¿Con qué fines están estas personas envueltas en este tipo de estudio para lograr conseguir lo que quieren a costa de los otros? No sé si me explico."[1]

- Some of the women addressed that the communication between the research team and them, as participants, was not as expected. Also expressed the lack of knowledge about their results tests and the results of the overall research.

"La comunicación, el saber porque ella me indicó al fin, "nos comunicamos contigo", y lo cual no sucedió. Digo, yo tampoco me comuniqué con ellos, y tengo la información allí, (risas), pero tú esperas eso. Y en ese momento, obviamente que sucedió, pues yo estaba en el proceso de pre-operatorio, o sea todo este tipo de… que tú lo menos que piensas es llamarlos a ellos… […] que tu estas pendiente de otras cosas, ya luego tu analizas y tú dices wow, para mí ya va un año, y yo digo ajá y ¿En qué habrá quedado eso?" [1]

Other barriers:

- The majority of the women had concerns regarding the possible implications of the experimentation such as health risks, side effects, cancer or co-morbidities complications, and interactions with other medications.
- Women addressed that emotions surrounding cancer diagnosis period could be conflictive with recruitment period.

Leyend:
[1] women with clinical trial experience ; [2] women without clinical trial experience

Facilitators

- Some women mentioned the diagnosis of breast cancer and breast cancer stage as a facilitator for clinical trials participation. They explained that, through clinical trials participation, they will help others, family and future generations, by preventing or finding the cure for the disease.

"Bueno, es es duro… ya cuando tú tienes la condición… pues, tú como que, dices pues vamos, vamos a tirarnos… ¿Sabes qué?, honestamente, si me preguntan ahora, eh, yo te diría que sí, que participaría en un estudio de investigación, eh, yo antes no teniendo la condición, pues te hubiera dicho que no, no voy a ser conejillo de indias, pero pues, ya que pasas por la experiencia, te toca bien de cerca, te duele, y entonces pues, eh, quieres ayudar. […] porque no es fácil, tienen que otras personas prevenir […] ayudar a otras personas. Es más, yo ahora mismo aceptaría. Si me preguntas 7 meses atrás, no."[2]

- The vast majority of the women agreed that communication with research staff could be a facilitator for participation. Communication should be during all the process and even after the participation.

"Tiene que ver la percepción que uno tiene sobre el proceso. Si es un proceso informado, un proceso en que me dicen a mí: "Mira, tu participación va a ser así, vas a recibir esta ayuda, tiene que ser en tal tiempo, esto va a durar tanto tiempo. Esto tiene sus efectos secundarios pero no van a ser nocivos para tu condición, que no vayan agravar tu condición…" ehhh A lo mejor yo sí me sometería a participar en un ensayo clínico. Porque después que uno esté informado y que uno esté monitoreado, claro que sí. Que los profesionales tengan a uno bien informado todo el tiempo. No es al comienzo […] no, no, no es "during the process". Yo hasta me atrevería hacerlo siempre y cuando yo tenga esos datos, esa información actualizada y todo el tiempo con una frecuencia bien razonable, yo me sometería."[2]

- Women acknowledged the women that had participated in cancer clinical trials.

"En mi caso yo le agradezco a todas las personas que sirvieron verdad de… que participaron en investigaciones. Por ejemplo, con la pastilla que nosotros tomamos; Tamoxifen. Si no unas mujeres en algún momento no hubieran participado, yo no estuviera saliendo beneficiada de eso, y así surge con todos los medicamentos que están en el mercado hoy en día. Así que yo estoy bien agradecida de que se hagan estudios como estos y de poder participar."[1]

Preliminary Recommendations

- Consider the circumstances of the women participating in clinical trials. (Ex. Productive life, work, child care)
- Identify benefits and incentives that could help in the recruitment and retention of participants in clinical trials.
- Development of creative strategies to explain the implications of the clinical trials protocols to participants.
- Develop protocols that require the disclosure of the results as part of IRB.
- Encourage the dissemination of the results through popular access platforms.

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