Focus on You: Cancer clinical trials perspectives

Brandi N. Robinson\textsuperscript{a,b}, Antoinette F. Newman\textsuperscript{a,b}, Sherrie F. Wallington\textsuperscript{c}, and Sandra M. Swain\textsuperscript{b,d,*}

\textsuperscript{a}MedStar Health Research Institute, 6526 Belcrest Road, Suite 700, Hyattsville, MD 20782, USA
\textsuperscript{b}Washington Cancer Institute at MedStar Washington Hospital Center, 110 Irving Street, NW, Washington, DC 20010, USA
\textsuperscript{c}Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, 3300 Whitehaven St., NW Suite 4100, Washington, DC 20007, USA
\textsuperscript{d}Georgetown University Medical Center, 4000 Reservoir Road NW, 120 Building D, Washington DC 20057, USA

Abstract

\textbf{Background}—Clinical trials test new ways to prevent, detect, diagnose, or treat diseases. Researchers have found that minority patients are willing to participate in clinical trials, yet these patients have barriers which hinder their access to trials.

\textbf{Methods}—To explore African American women's participation in breast cancer clinical trials, eight focus groups were conducted with breast cancer patients, family members/care givers, religious leaders, and healthcare providers to gather information on the perspectives and opinions on the topic. The focus group conversations were transcribed, and transcripts were imported into QSR International's NVivo 10 software. The transcripts were organized into folders based on four categories. The content analysis performed was based on recordings and notes.

\textbf{Results}—The following themes were generated as a result of conducting these focus groups and gathering information on the perspectives and opinions about participating in clinical trials, based on the groups who participated: Promoting participation in research; Personal experience with cancer; Support and support services; Awareness, knowledge, and experience with clinical trials; Providers' roles in clinical trials.

\textbf{Conclusion}—The data collected in this study present several actionable themes that, if addressed by individual researchers and the medical community at large, could increase participation in clinical trials by African American patients. They also provide a deeper and more nuanced understanding of the factors influencing African American patients' decisions around participating in clinical trials.

This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

\textsuperscript{*}Corresponding author. Georgetown University Medical Center, 4000 Reservoir Road NW, 120 Building D, Washington DC 20057, USA. Sandra.Swain@georgetown.edu (S.M. Swain).

Conflict of Interest

All authors declare that they have no conflict of interest.
Keywords
Focus groups; Clinical trials; African americans; Cancer disparities; Breast cancer

1. Introduction

Disparities impact African American women across the breast cancer spectrum with respect to access and utilization of screening and preventive services, clinical care subsequent to breast cancer diagnosis, and long-term follow-up care and clinical management for Black breast cancer survivors [1]. Racial differences in breast cancer survival can be explained by poorer health of Black patients at diagnosis, more advanced disease at time of diagnosis, more severe biological features of the disease, and more co-morbid conditions [2,3]. The data collected by Silber et al. to determine if racial disparities in breast cancer survival were attributable primarily to differences in presentation characteristics at diagnosis or subsequent treatment provide evidence that Black patients diagnosed with breast cancer had previously received less adequate primary care compared to White counterparts. Also, Blacks were diagnosed with more advanced disease and with larger tumors [4].

Clinical trials test new ways to prevent, detect, diagnose, or treat diseases. Individuals who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts [5]. Advances in breast cancer prevention, diagnosis, and treatment are the direct result of patient involvement in therapeutic and non-therapeutic clinical trials. The success of these trials depends on enrolling the statistically required number of participants and keeping them in the study until completion. Despite increases in the numbers of new clinical research initiatives and trials open to accrual, only 2–3% of women with breast cancer ever enroll in a clinical trial [6]. Poor recruitment to clinical trials leads to delays in study completion and slows down the approval of more effective cancer treatments for patients with all stages of cancer [7].

Increasing Black patients' participation in cancer clinical trials is particularly important because of their lower survival rate. Critical to the conduct of any clinical trial is identifying the right group of people to include in the study. Most clinical trials conducted in the U.S. suffer from a pronounced lack of diversity. And, too often, there is a lack of appreciation of cultural and genetic factors particular to African American and other ethnic communities. This diversity gap can lead to sub-optimal development of new medicines and can further exacerbate minority health disparities. While African Americans represent 12% of the total U.S. population, they comprise just 5% of clinical trial participants [8].

Researchers have found that minority patients are willing to participate in clinical trials, but that these patients have barriers which hinder their access [9]. Therefore, further exploration of the potential barriers and motivating factors in regard to participation in clinical trials is essential to increasing participation and retention rates, and ultimately, to reducing disparities in quality healthcare and treatment options.
The purpose of our focus group study was to explore African American patients’ participation in breast cancer clinical trials. To accomplish this, we conducted formative data-focused groups to investigate different thoughts, attitudes, and beliefs associated with cancer clinical trials from various viewpoints.

2. Methods

Study design

We conducted eight focus groups in 2014 and 2015, made up of Black patients with breast cancer, patient family members/caregivers, religious leaders, and healthcare providers from Washington Cancer Institute (WCI) (52 participants = 12 patients, 21 faith-based leaders, 11 healthcare providers, 8 family caregivers).

Eligibility

Participants who met the following eligibility criteria were appropriate to take part in the study:

- **Patient**: Self-identified Black or African American (to include African, Caribbean, West Indian ancestry, or any other persons self-identifying as Black); 2) aged 18 years or older with breast cancer diagnosis, receiving treatment at WCI; 3) ability to communicate verbally in English, male or female, ability to comply with all study procedures.

- **Family member/caregiver**: A family member, spouse, significant other, or caregiver to a patient diagnosed with breast cancer who is receiving treatment at WCI.

- **Provider**: Healthcare provider practicing at WCI.

- **Religious leader**: Religious leader (to include pastor, health ministry member, deacon, or any other position closely involved with parishioners) at a church in the District of Columbia Metropolitan Area.

Recruitment

Fifty nine percent of participants screened for eligibility participated in the focus groups. Patients were recruited through medical/oncology clinics and from staff referrals. Recruiters met with patients before or after the oncologist saw them for an appointment. They introduced and explained Focus on You, confirmed eligibility, invited participation, conducted the informed consent process, and obtained written informed consent from those who wished to participate. Patients were assured that consenting to this study would not imply that they were consenting to a therapeutic clinical trial. Family members/caregivers were approached as they accompanied their loved ones to their appointments. Religious leaders were referred by patients and WCI staff, and were approached about participating in person, via email, or by telephone. Providers were approached about participating on site at WCI and via email communication.
**Focus group implementation**

Prior to conducting the focus groups, WCI staff (the project leader and research assistant) were trained in focus group methods and facilitation. The training was coordinated by an experienced facilitator who conducts qualitative training with academicians and community members. The patient and provider focus groups occurred on site at WCI, while the religious leader focus groups occurred at the respective churches. A trained moderator facilitated each focus group. Focus groups were recorded and a note-taker was present to capture handwritten notes. A moderator who was not employed by the Washington Cancer Institute conducted both provider focus groups to avoid any conflict of interests and to allow providers to feel comfortable participating. These focus groups took place at WCI.

The interview guides for each focus group cohort used by the WCI team were developed during the initial training session. The guides consisted of prompts/questions to solicit responses from the groups. An introduction and overview script was developed to assist the facilitator and moderator in properly introducing the focus group and cover the purpose, logistics, goals, and ground rules.

The moderator asked participants a series of questions/probes using a semi-structured interview guide [10]. The guides were tailored to each focus group category (See Table 1). Sample questions included:

- **Patients:** “*What is a clinical trial or clinical research?*” and “*Do you think it is important to include Blacks in clinical trials or clinical research?*”

- **Providers:** “*How often do you talk to your patients about clinical trials or clinical research?*” and “*Do you think your attitudes/beliefs about clinical trials play a role in your patients’ decision to participate in research?*”

- **Family members/caregivers:** “*In your opinion, what do you think are some of the advantages and disadvantages of clinical research?*” and “*If your family member was asked to participate in a clinical trial trying to find new and better treatment for breast cancer, would you encourage them participate?*”

- **Religious leaders:** “*Do you think you and/or other leaders in the church have an impact on your members’ healthcare choices and decisions, including participating in clinical research?*” and “*What do you think can be done to encourage more Blacks to participate in clinical research?*”

All focus groups were audio recorded with a digital recorder and a note-taker was present. The number of participants in each focus group ranged from 3 to 12 (Table 1). Each focus group lasted between 60 and 80 min. Refreshments and parking vouchers were provided. All participants, with the exception of physicians, received a $25.00 gift card for their participation. The study was approved by the Georgetown University MedStar Health Research Institute Institutional Review Board. The demographic characteristics of the patient participants are displayed in Table 2.
Data analysis

An outside research firm was hired to analyze the focus group data. A conventional qualitative content analysis approach [11] was used to inductively analyze and identify the categories/themes that emerged from the focus groups. This is a bottom-up approach that builds upon the data as opposed to a deductive coding scheme that is established in advance of the analysis. The focus group conversations were transcribed, and the transcripts were imported into QSR International’s NVivo 10 software. The transcripts were organized into folders based on four categories. Using a line-by-line open coding technique [12], each sentence of the focus group conversations was reviewed. The relevant text was coded with one or more codes as necessary. Key concepts, thoughts, ideas, and events were coded using participants’ words to establish the codes. Codes were added or modified as necessary as new meanings emerged [13]. To assess coding consistency, codes and their assignment to text were checked and rechecked. Using a constant comparison method [12], codes were compared and queried in NVivo to determine overall reoccurring themes and subthemes that emerged from all of the groups. Representative quotes were selected to support the themes and subthemes. To ensure trustworthiness of the data, confirmability was performed by two doctoral-level researchers, who audited the data and ensured internal consistency of the codes, themes, and subthemes [14].

3. Results

Five main themes and 24 subthemes (Table 3) emerged from the data. These themes include: promoting participation in research; personal experiences with cancer; support and support services; awareness, knowledge, and experience with clinical trials; and providers’ roles in clinical trials.

4. Discussion

The aim of our study was to gather information on the perspectives and opinions about participating in clinical trials by different cohorts of stakeholders such as breast cancer patients, their family members/caregivers, religious leaders, and healthcare providers. The objective was for the information we received from the focus groups to help us improve our approach to clinical trial enrollment among African American patients at MedStar Washington Hospital Center, Washington Cancer Institute.

The history of medical research and experimentation and the African American community is complicated and fraught with both neglect and abuse [15]. With this historical background, it is not surprising that exploration into the willingness of African Americans to participate in medical research is both plentiful and unclear in its findings. In past studies, research indicates that African Americans are significantly less willing to participate in medical research than other populations [16–19]. On the other hand, despite underrepresentation in clinical trials, recent studies suggest that African Americans, more than any other racial and ethnic group, have interest in participating in research.” [20–25] Our study's findings are significant in the ability to shed some light on these conflicting findings.
An awareness of the complicated history is evident in some of the answers, particularly to theoretical participation. For example, “I’m glad the question was asked because it shows, I hope, a genuine interest in including a demographic that’s typically excluded in a lot of settings” suggests awareness of exclusion from studies, while “They gonna have separate units. You just watch. They gonna have separate units” suggests concern about how African Americans are typically included. Similarly, participants discussed concerns about how they are perceived by the medical community: “I think we tend to think that the medical professional, in general, think that we’re expendable, so they’re willing to use us as quote unquote the guinea pig for somethin’ better.” There is also an awareness of the disparities in how cancer impacts African Americans: “… yeah, I think on paper we do need to be involved because so many diseases hit African Americans so much harder.” In discussing how to encourage participation, trust is a major theme that came up in multiple ways. Trust in one’s provider (“Anything my doctor would ask me to do, I would try”), and needing medical providers to prove themselves—and by extension the trial—trustworthy (“It’s really on the medical professionals, too. They have to build a level of trust that when they recommend something that you trust their judgment and say, okay, you haven’t steered me wrong yet”), emerged as essential. This fits with the literature, which suggests that successful recruitment of minority participants to clinical trials needs to begin with efforts to develop trusting relationships between the minority community and the research institution.” [26].

This study sought to illuminate the decision-making process by asking Black cancer patients both about their feelings about theoretical participation (“Do you think it is important to include Blacks in clinical trials or clinical research?”) and their personal barriers to, and likelihood to participate in, clinical trials. Furthermore, it explored their knowledge and experiences with trials and the conversations they had with their providers. By asking their influencers—family members and caregivers, religious leaders, and providers—the study also looked at the larger context for that decision-making.

Supporting informed decision-making can be one way of establishing trust and respect in a relationship, and there was a lot of interest in being informed, feeling that education and support were important, as compared to pressure or persuasion. For example, “I think, well, the first thing is to want—participate is to understand what kind of research [it] is, what it means.” This is important even with the awareness of how very much information is involved with cancer treatment (“It’s a lotta stuff, the detail”). Both patients and their caregivers highlighted word of mouth as a way to establish comfort with a specific trial (“Okay, if like my friend, for instance, she is participatin’ in the research. If she knew someone, maybe she could tell them about the trial that she’s going through right now”). Participants with family members or friends who had had positive experiences with trials seemed to carry that positive impression (“I had a brother that went through clinical trial at Johns Hopkins. For him, it turned out to be very successful”).

The strategy of working with religious leaders to establish trust was also explored. One-on-one conversations (“I think that I probably have a minimal impact congregation-wide. There are members who approach me about their health challenge and how it’s gonna be treated. They are often open to any input that I might have. Yes, I would say for those persons yes
there’s great influence; unconditional support regardless of whether the decision is to participate or not (“More often than not, I think most persons end up doing what they have thought to do and then I lend my support if they go a different way than I would suggest, because that’s my role is to support them in whatever decision they make”); and literature in its appropriate location in the community such as on bulletin boards (“We have an administrative desk in our church. They put a lot of literature and things out on that desk”) were important points that were brought up.

Once trust is established, another area of concern is that of practical commitment to participate. How much time would be involved? Will being assigned to the control still be a good option for the patient (“If you got [randomized to] either one and that would be good for you. If we can say things like that, you’re gonna get a lot more buy-in from patients”)? This in particular echoes, and deepens our understanding of, other research suggesting that the presence of a no-treatment control or placebo control is inversely correlated with participation [27].

For providers, there was a strong desire for more support. They felt they needed to have more information about studies before they could promote participation in them (“I think that if I believe the trial, I think it’s much easier to pass along the passion or the interest that I have. If I believe and if I fully understand the trial. Rather than if it’s something that I don’t think that it’s a good idea, probably if it’s a not a good idea I will not even remember”). They indicated they needed more time with patients to cover their health appointment needs and the study recruitment communication needs (“The major barrier, I guess time is also because the visits are very quick”), and/or more staff to address the study recruitment needs (“You need more hands, and this is a time in health care that there are no more hands”).

All of these practical and actionable points provide both depth and instruction to the clinical research community in how to engage African American communities with regard to recruitment and retention. They also build upon the research study where we developed a culturally targeted video designed to impact six specific attitudes of African American cancer patients toward therapeutic trials and measured intent to enroll [28].

4.1. Strengths and limitations

A major strength of this study is that it incorporated not only patients, but also key stakeholders who have the ability to influence patients’ decisions to participate in clinical research and shape how physicians and researchers approach patients. It is important to gain insight from family members/caregivers, providers, and religious leaders because in our experience at WCI and as studies have shown, these have been some of the main dissenters and skeptics of therapeutic trials. In a study conducted by Brown et al. [29], participants described pressures from family members and feeling overwhelmed as reasons for declining clinical trial participation. Of 14 participants who discussed the trial decision with a family member, either during or after the visit, eight stated that family members directly encouraged them to decline participation; three stated that such advice was indirect. Reasons for this included feeling that the trial was too dangerous and they did not want their family member to be a research “guinea pig.”
Some study limitations should also be considered. Our sample consisted of patients, family/caregivers, providers, and religious leaders only affiliated with WCI, so the results cannot be generalized to those outside of this community. Also, all of our patient participants were female, as there were no eligible African American men with breast cancer available at the time of the study. Furthermore, religious leaders were not required to personally have or know anyone with breast cancer, which could have limited their ability to fully sympathize and understand the journey that breast cancer patients embark upon from diagnosis to treatment.

5. Conclusion

Our study aimed to explore African American participation in breast cancer clinical trials, particularly with an eye toward facilitating such participation. Through positive experiences in building trust, word of mouth, increased support of informed decision-making, and supporting providers to initiate conversations about trials, there is the potential to increase participation in clinical trials. The data collected give a deeper and more nuanced understanding to the sometimes conflicting information collected on this complex topic.

Acknowledgments

The authors thank all study participants. This study was supported by the Breast Cancer Research Foundation (BCRF). The content is solely the responsibility of the authors and does not necessarily represent the official views of BCRF. Informed consent was obtained for all participants who took part in the study.

References

1. Ooi SL, Martinez ME, Li CI. Disparities in breast Cancer characteristics and outcomes by race/ethnicity. Breast Cancer Res. Treat. 2011; 127(3):729–738. http://dx.doi.org/10.1007/s10549-010-1191-6. [PubMed: 21076864]
2. Mandelblatt JS, Sheppard VB, Neugut AI. Black-White differences in breast Cancer outcomes among older medicare beneficiaries: does systemic treatment matter? JAMA. 2013; 310(4):376–377. http://dx.doi.org/10.1001/jama.2013.8273. [PubMed: 23917286]
3. Curtis E, Quale C, Haggstrom D, Smith Bindman R. Racial and ethnic differences in breast cancer survival. Cancer. 2008; 12(1):171–180. http://dx.doi.org/10.1002/cncr.23131.
4. Silber JH, Rosenbaum PR, Clark AS, Giantonio BJ, Ross RN, et al. Characteristics associated with differences in survival among black and white women with breast cancer. JAMA. 2013; 310(4):389–397. http://dx.doi.org/10.1001/jama.2013.8272. [PubMed: 23917289]
5. Cancer Clinical Trials Facts & Figures February. National Cancer Society. 2013. Available at: http://www.cancer.gov/cancertopics/factsheet/clinicaltrials/clinical-trials
6. Swain-Cabriales S, Bourdeanu L, Niland J, Stiller T, Somlo G. Enrollment onto breast cancer therapeutic clinical trials: a tertiary cancer center experience. Appl. Nurs. Res. 2013; 26(3):133–135. http://dx.doi.org/10.1016/j.apnr.2013.01.003. [PubMed: 23490340]
7. Wright JR, Whelan TJ, Schiff S, Dubois S, Crooks D, et al. Why cancer patients enter randomized clinical trials: exploring the factors that influence their decision. J. Clin. Oncol. 2004; 22(21):4312–4318. http://dx.doi.org/10.1200/JCO.2004.01.187. [PubMed: 15514372]
8. Lechleiter, J. [Accessed on March 9 2016] Closing the Diversity Gap in Clinical Trials. Available at., Forbes US Edition, 2014 http://www.forbes.com/sites/johnlechleiter/2014/04/09/closing-the-diversity-gap-in-clinical-trials/?utm_campaign=forbestwitters&u&utm_source=twitter&utm_medium=social#6b6c7d7b3c91
9. Linden HM, Reisch LM, Hart A Jr, Harrington MA, Nakano C, et al. Attitudes toward participation in breast cancer randomized clinical trials in the African American community: a focus group study.
10. Morgan, DL. Focus group interviewing. In: Gubrium, JF., Holstein, JA., editors. Handbook of Interviewing Research: Context & Method. Sage; Thousand Oaks, CA: 2002. p. 141-159. http://dx.doi.org/10.1097/01.NCC.0000281732.02738.31. [PubMed: 17666974]

11. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual. Health Res. 2005; 15(9):1277–1288. [PubMed: 16204405]

12. Glaser, BG., Strauss, AL. The Discovery of Grounded Theory: Strategies for Qualitative Research. Aldine Publishing Company; Chicago, IL: 1967.

13. Schilling J. On the pragmatics of qualitative assessment: designing the process for content analysis. Eur. J. Psychol. Assess. 2006; 22(1):28–37. http://dx.doi.org/10.1027/1015-5759.22.1.28.

14. Lincoln, YS., Guba, EG. Naturalistic Inquiry. Sage Publications; Beverly Hills, CA: 1985.

15. Washington, H. Medical Apartheid: the Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present. Doubleday; New York, NY: 2006.

16. Corbie-Smith G, Thomas SB, St George DMM. Distrust, race, and research. Archives Intern. Med. 2002; 162(21):2458–2463. http://dx.doi.org/10.1001/archinte.162.21.2458.

17. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. JAMA. 2004; 291(22):2720–2726. http://dx.doi.org/10.1001/jama.291.22.2720. [PubMed: 15187053]

18. Braunstein JB, Sherber NS, Schulman SP, Ding EL, Powe NR. Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. Medicine. 2008; 87(1):1–9. http://dx.doi.org/10.1097/MD.0b013e3181625d78. [PubMed: 18204365]

19. Buchbinder SP, Metcch B, Holte SE, Scheer S, Coletti A, et al. Determinants of enrollment in a preventive HIV vaccine trial: hypothetical versus actual willingness and barriers to participation. J. Aquir Immune Defic. Syndr. 2004; 36(1):604–612.

20. Cottler LB, McCloskey DJ, Aguilar-Gaxiola S, et al. Community needs, concerns, and perceptions about health research: findings from the clinical and translational science award sentinel network. Am. J. Public Health. 2013; 103(9):1685–1692. http://dx.doi.org/10.2105/AJPH.2012.300941. [PubMed: 23409875]

21. Wendler D, Kington R, Madans J, et al. Are racial and ethnic minorities less willing to participate in health research? PLoS Med. 2006; 3:201–210. http://dx.doi.org/10.1371/journal.pmed.0030019.

22. Byrd GS, Edwards CL, Kelkar VA, et al. Recruiting intergenerational African American males for biomedical research studies: a major research challenge. J. Natl. Med. Assoc. 2011; 103:480–487. http://dx.doi.org/10.1016/S0027-9684(15)30361-8. [PubMed: 21830630]

23. Durant RW, Davis RB, Marcantonio E, Freeman MB, Landon BE. Willingness to participate in clinical trials among elderly whites and African Americans previously exposed to clinical research. J. Cult. Divers. 2011; 18(1):8–19. [PubMed: 21526582]

24. Powell-Young YM, Spruill II. Views of Black nurses toward genetic research and testing. J. Nurs. Scholarsh. 2013; 45:151–159. http://dx.doi.org/10.1111/jnu.12015. [PubMed: 23470244]

25. Research!America. New Poll Shows Minority Populations Support Clinical Trials to Improve Health of Others but Participation Remains Low Among African-americans. Hispanics and Asians. Accessed January 15, 2014 at www.researchamerica.org/release_31july13_clinicaltrialspoll

26. Vickers SM, Fouad MN. An overview of EMPaCT and fundamental issues Affecting minority participation in Cancer clinical trials: enhancing minority participation in clinical trials (EMPaCT): laying the groundwork for improving minority clinical trial accrual. Cancer. 2014; 120(7):1087–1090. http://dx.doi.org/10.1002/cncr.28569. [PubMed: 24643645]

27. Mills EJ, Seely D, Rachlis B, Griffith L, Wu P, et al. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. Lancet Oncol. 2006; 7(2):141–148. http://dx.doi.org/10.1016/S1470-2245(06)70576-9. [PubMed: 16455478]

28. Banda D, Wang H, Libin A, Swain S. A pilot study of a culturally targeted video intervention to increase participation of African American patients in Cancer clinical trials. Oncol. 2012; 17(5):708–714. http://dx.doi.org/10.1634/theoncologist.2011-0454.

29. Brown RF, Cadet DL, Houlihan RH, Thomson MD, Pratt EC, et al. Perceptions of participation in a phase I, II, or III clinical trial among African American patients with cancer: what do refusers
say? J. Oncol. Pract. 2013; 9(6):287–293. http://dx.doi.org/10.1200/JOP.2013.001039. [PubMed: 24130251]
Table 1

Categories of participants.

| Group               | Description                                      | Number of participants in each focus group |
|---------------------|--------------------------------------------------|--------------------------------------------|
| Faith Group         | Participants were faith-based leaders            | FG 1 n = 9, FG 2 n = 12                    |
| Family and Caregivers| Participants were either family members of or caregivers of breast cancer patients | FG 1 n = 3, FG 2 n = 5                     |
| Patients            | Participants were undergoing treatment for breast cancer | FG 1 n = 6, FG 2 n = 6                     |
| Providers           | Participants were healthcare providers at WCI     | FG 1 n = 7, FG 2 n = 4                     |

*a Focus group 1 is FG 1, focus group 2 is FG 2.*
Table 2
Demographic characteristics of breast cancer patient participants.

| Demographic                        | n (%) |
|------------------------------------|-------|
| **n = 12**                         |       |
| Age (years): median[range]         | 65 [41–77] |
| Marital status                     |       |
| Never married                      | 3 (25) |
| Married                            | 3 (25) |
| Widowed                            | 2 (17) |
| Separated/divorced                 | 4 (33) |
| Number of children                 |       |
| None                               | 2 (17) |
| 1 or more                          | 10 (83) |
| Education                          |       |
| High School                        | 5 (42) |
| Some college or technical school   | 2 (16) |
| College graduate                   | 5 (42) |
| Religion faith                     |       |
| Baptist                            | 7 (58) |
| Catholic                           | 1 (8.3) |
| Lutheran                           | 1 (8.3) |
| Pentecostal                        | 1 (8.3) |
| Presbyterian                       | 1 (8.3) |
| No affiliation (none)              | 1 (8.3) |
| Household income US$               |       |
| <40000                             | 6 (50) |
| ≥40000                             | 6 (50) |
| Type of insurance                  |       |
| Medicaid                           | 4 (33.3) |
| Medicare                           | 4 (33.3) |
| Private                            | 4 (33.3) |
| Family history of any cancer       |       |
| Yes                                | 10 (83) |
| No                                 | 2 (17) |
| Stage of cancer                    |       |
| I                                  | 6 (50) |
| II                                 | 3 (25) |
| III                                | 1 (8)  |
| IV                                 | 2 (17) |
Table 3
Themes and subthemes.

| Themes/subthemes                        | Description                                                                                                                                                                                                 | Examples of responses                                                                                          |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| Theme: Promoting participation in research | Participants discussed African Americans’ participation in clinical research and how to promote their participation in research. Several topics were addressed by participants, including: the importance of including African Americans in research, ways to encourage African Americans to participate, participants' willingness to participate or encourage others to participate, family and friends' roles and opinions about clinical trials, church leaders' involvement in clinical trial participation, and using the church to educate and facilitate access to participants. | a. “I think it is important to include African Americans in the research as well as many other things and not just African Americans, but seniors.”  

b. “I think given the African American disposition as well as even unique particularities, it would behoove us to participate so that we might even understand how particular procedures might impact us juxtaposed to other populations.”  

c. “… Black people get cancer, too, so yeah. Everything’s not gonna work like what works for Caucasians, or Asians, or Latinos. That don’t mean it’s gonna necessarily work for African-American(s).”  

d. “I’m glad the question was asked because it shows, I hope, a genuine interest in including a demographic that’s typically excluded in a lot of settings.”  

e. “They gonna have separate units. You just watch. They gonna have separate units.”  

f. “… Yeah, I think on paper we do need to be involved because so many diseases hit African Americans so much harder.”  

Subtheme: Importance of including African Americans in research  

a. Participants felt it was important when collecting research and data to include all races, socio-economic groups, genders, and ages.  

b. A number of participants expressed that including African Americans in clinical research can help to identify how different procedures affect African Americans versus other [racial] groups.  

c. Some participants mentioned that Blacks are treated differently than Whites when it comes to clinical research.  

d. Another participant shared that she thought there would be separate units for Blacks versus Whites in the future (*units refer to departments where hospital rooms are housed).  

e. Some participants shared that including African Americans in clinical research is important because African Americans are heavily impacted by diseases.  

Subtheme: Ways to encourage African Americans to participate in clinical research  

a. Participants shared a number of different ideas for encouraging African Americans to participate in clinical research. One idea was to have them talk to other participants about their experience.  

b. Participants discussed having physicians talk to their patients and educate them as a way to encourage African Americans to participate.  

c. Some participants mentioned using flyers and literature to inform and recruit participants. They mentioned leaving the flyers in social workers’ offices,  

a. “… If possible, speak with patients about their experience and whether or not they think it’s worth it, whether or not they feel they made a mistake and wish they could do it over.”  

b. “Okay, if like my friend, for instance, she is participatin’ in the research. If she knew someone, maybe she could tell them about the trial that she’s going through right now.”  

b. “I think also it would be important to key in on the physicians. I know the different institutes or hospitals have their medical staff and especially if they’re connected with the research oriented institution or university institution, let them know to talk to their patients, and especially in this...
### Themes/subthemes

| Description | Examples of responses |
|-------------|-----------------------|
| waiting rooms, elevators, hospitals, and churches. | 
| Some participants thought that the church providing flyers, different types of information, or even a schedule of different events related to clinical research could help increase clinical trial participation. | “I guess if I was looking for something I know there might be things visibly displayed on boards, like bulletin boards or something, some upcoming events having clinical research, like a flier like that.” |
| In addition, participants discussed the availability of information. | “… Putting flyers in the social worker’s office” would be a way to encourage participation. |
| Subtheme: Willingness to participate or encourage others to participate | 
| Participants were asked if they were willing to encourage others to participate in clinical research. A number of them responded that they would encourage others and that they themselves would consider participating in clinical research. | “If it was going to find more ways to treat cancer or to come up with new medicine or new techniques or better techniques, I would encourage them.” |
| Some participants expressed that they would need to trust the doctor in order to encourage others to participate or participate themselves. | “If it was me, I would participate because I would want to stay here longer. Anything my doctor would ask me to do, I would try …” “It’s really on the medical professionals, too. They have to build a level of trust that when they recommend something, that you trust their judgment and say, okay, you haven’t steered me wrong yet.” |
| Patient understanding of the clinical trial along with any potential side effects was mentioned as an important idea in participants’ decision to either participate or encourage others to participate. | “Who is doing the research? What’s entailed? I don’t know if I would get into the specifics of what drugs, but I guess I’d try to get an understanding of their understanding of what they’re being asked to participate in.” |
| Some participants mentioned that it is important that clinical research accounts for their other comorbid health conditions. | “I think, well, the first thing is to want—participate is to understand what kind of the research is, what it means.” |
| Participants discussed trying to understand and digest all of the information they are provided about the clinical trial. | “Then I have to incorporate my other health issues. Okay, I have ulcerative colitis. How is that gonna deal with my ulcerative colitis?” “… The treatment which we’re talkin’ about to help someone else, might counteract with something else that I’m taking. I don’t wanna make matters worse tryin’ to make matters better.” |
| | “They keep on, you know? It’s a lotta stuff, the detail.” |
| | “They give you the information, because even then she would say, There’s certain things that you can’t have. You couldn’t have been on this or certain amount of time you couldn’t have been on that.” |
| Themes/subthemes | Description | Examples of responses |
|-----------------|-------------|-----------------------|
| **Subtheme: Family and friends' roles and opinions about clinical trials** | Most of the participants indicated that family members and/or friends' opinions were important to them in considering their participation in a clinical trial. | “I think yes. My opinion will help her. If I wanted her to try it out or something she would. She would go with it. I feel like that.” “… [t]hen she’ll just come to me and ask my opinion about it. If I'm not too iffy about it or I don’t feel comfortable with it then she starts to get second thoughts.” |
| **Subtheme: Church leaders' involvement in clinical trial participation** | Participants discussed their thoughts on the role that church leaders play in promoting African American participation in clinical trials. | “I can say that the leadership has had some influence on the way—on my healthcare and the way that I approach it.” |
| | Church leaders shared that they can encourage individual church members who ask for their input regarding their health, but do not necessarily influence the entire congregation. | “I think that I probably have a minimal impact congregation-wide. There are members who approach me about their health challenge and how it's gonna be treated. They are often open to any input that I might have. Yes, I would say for those persons yes there's great influence.” |
| | Church leaders shared that it is their role to support the choices made by congregation members. | “More often than not, I think most persons end up doing what they have thought to do and then I lend my support if they go a different way than I would suggest, because that's my role is to support them in whatever decision they make.” |
| | A couple of participants spoke about the importance of keeping the congregation and church leadership aware of what was going on with respect to illnesses. | “It is important that you keep your congregation or your leaders involved into what's going on with you and your family. Because if you don't tell us, we don't know.” |
| | Another participant shared that she believed the church leadership would pray for a congregation member if that member approached him or her regarding a health-related condition. | “I think if one of the members should come to our leader with something like that and ask him or the congregation to pray for them, it would be well welcomed.” |
| **Subtheme: Using the church to educate and facilitate access to participants** | Participants shared that they thought using the church to increase efforts in educating patients and recruiting participants for clinical research was a good idea. | “The church as an institution has access to large numbers of people. I think that's a forum for getting sort of the message out.” “I think it's imperative almost to encourage not only that [they] want to participate, but just to become more educated and informed about the many ways in which a person can find, address in a holistic way.” |
| **Theme: Personal experiences with cancer** | During the focus group sessions, participants shared their personal experiences with cancer. | “—When they first discovered the mass and I was at the —I was just getting’ a mammogram.” “When I initially was told, it was like I instantly cried. I prayed on it. When I went to the doctor, and the first thing I said is, “so what's next?” Because it's already been out there. I have breast cancer. [That's] not something that oh, we...” |
Subtheme: Thoughts of suicide

a. Some participants shared that their experience with cancer left them with thoughts of suicide.

b. Another participant shared thoughts about the power of prayer from a group.

Subtheme: Importance of faith and God

a. Many participants talked about the importance of faith and God when going through the cancer experience. They shared that they relinquished their fate and put their lives in God's hands.

b. Another participant shared thoughts about the power of prayer from a group.

Subtheme: Not discuss cancer

a. Some participants mentioned the stigma around talking about cancer. They noted that African Americans in particular do not want to discuss their experiences with cancer.

Subtheme: Family members with cancer

a. Many participants discussed living through the cancer experience with their family members.

b. Another participant noted that cancer runs in her family. She experienced several family members going through cancer treatment.

Examples of responses:

made a mistake. No, it’s there.” “Cuz I've been through it, myself. I had the high dose of it and it made me not walk. It threw me off my legs, and I’ve been in and out the hospital, which you all know.”

“Every day I was cryin’, say like, “Oh Lord, why me? Why me, Lord?” All the time. I just wanted to give up and all these bad thoughts just gonn’ through my mind. I felt like I wanted to commit suicide, you know? I just wanted to jump off—”

“[I] got to the point where I realized I did not—I mean I hate to say it out loud cuz it sounds horrible, but I had got to the point where I didn't wanna live anymore.”

“Because I feel that you put it in God's hands and let it go. Let Him take care of it.”

“I was on death bed, but the medicine that they gave me and stuff, and people like y'all that helped me through it, and my family helped me through it and prayed for me.”

“I have a very strong support group of people that I know that's prayin' for me.”

“I think a lot of folks are still scared to talk about it. It's just kinda like, Yeah, I had it. I'm cured. I don't wanna talk about it anymore.” “Even though the church is full of cancer survivors, nobody's talkin' about it.”

“We just get that way, 'cause when I'm dealing with my brother and with his bone cancer and my niece and my sister and all the different cancers, but we don't talk about it too much. People gotta hide it. Back in the days, we didn't know anything about cancer. It was a sore, they wouldn't say anything.”

“What I went through with my mom for 14 weeks, waking up 3:00 in the morning. She screaming, yelling hard. She falls out the bed. I put her [bathroom] in her bedroom. She couldn't make it there. She fall. My buddy who lived with us, we be waking up, picking her up. I kept thinking about the medicine. Something wasn't interacting. Both of us are diabetic. She taking chemo, too.”

“... Half of my family has cancer. It runs in the family, from generation on to now. I had a cousin that was eight years old that had brain cancer. I watched, from growin' up, how my family got sick and what they went through and stuff like that. Back then, they didn't have the medicine like they have now. I had [an] aunt, a favorite aunt that had breast cancer. She was in her 70s, I think, 74 years old and they took one breast. She got real sick. She went through all these tests and stuff. She couldn't take it, the medicine and stuff.”
| Themes/subthemes | Description | Examples of responses |
|------------------|-------------|----------------------|
| **Theme: Support and support services** | Participants discussed their sources of support, including family support, support from friends, support services, and support from the church. | |
| **Subtheme: Family support** | a. When going through cancer, support from a family is important. | a. In April I found out my husband had cancer. That wasn’t a [good feeling], but I had support from my sisters.” |
| | b. Another participant talked about how her family helped support her through research. | b. “Both my daughters, when they found out that I had breast cancer, they went online and searched. They told me, they say, ‘Mom, hey, it’s your body. You need to learn what’s goin’ through your body and about your body, because that’s your body. We can’t tell you what to do, but we’re here for you to support you.’ They’ve been there.” |
| **Subtheme: Support from friends** | a. Many participants mentioned the importance of support from friends. | a. “Also, I have a very good support system. I have a friend who had stage four cancer. She had the surgery, and that was about ten years ago. Then two years ago it returned, the tumors and all that. She was very supportive, and we talk all the time.” |
| | b. Another participant emphasized the importance of not going through cancer alone. | b. “It was, like you said, the family, the friends, the support group means a lot when you’re goin’ through this. When you’re goin’ through it, it means so much. I tell anybody, you just cannot do this by yourself.” |
| **Subtheme: Support services** | a. Participants discussed the importance of taking part in support services such as sessions on how to care for your skin, wig options, or home remedies. | a. “I remember one woman introducing some type of program to help hydrate the skin for a nominal fee, extremely nominal, and then there was another option regarding limited wig options.” |
| | b. Other participants talked about sessions involving scarf tying and nail painting. | b. “There was a scarf tying. They also had nail painting for when your nails become dark because of chemo.” |
| **Subtheme: Support from the church** | a. Participants shared that the church and church members provide support for patients going through cancer and clinical research. | a. “That’s part of our responsibility to be of great support to them in our faith and being into supporting our members through any situation, especially when they’re going through cancer, how they’re feeling. When they’re just going through, we fix meals for ‘em or different things to take them to their appointments and stuff like that. I think we do play a major role when someone is going through a time with cancer.” |
| | b. Another participant echoed the importance of supporting congregation members. | b. “I think it’s important for the community to rally around those who are given a diagnosis wanting not only medical advice, but spiritual direction in the process.” |

**Theme: Awareness, knowledge, and experience with clinical trials**

Awareness of, knowledge, and experience with clinical trials varied across participants. Participants discussed topics including: caregiver awareness, knowledge about clinical trials, and experience with clinical trials.

**Subtheme: Caregiver awareness**

a. Family members and caregiver participants shared that they are aware of clinical research because they have seen it

b. “Yeah, I’ve seen in the paper or on the train that have billboards, some talking about clinical research going on.”
Themes/subthemes | Description | Examples of responses
--- | --- | ---
advertised in various places such as television, billboards, pamphlets, and the newspaper. | b. | “I don’t come over here too often, but when I do I may have seen a poster or something talking about it maybe once or twice. It’s not every time I come I see something.”
“As far as for the research I come up here almost three times a week with my mom. I’m always peeking at one of the pamphlets or something and just reading it. Maybe I’m passing time or whatever, but I’ll read it.”
c. | “She never told me nothing about the research, but I know she here all the time. She’s going through something with that. I don’t know. I guess she okay with it. I don’t know. I'm not sure.”
“I know she’s always into something here. It might have been something that she might have spoken about. Off the top of my head I can’t be too sure.”

Subtheme: Knowledge about clinical trials | a. Participants shared what they knew about clinical research and trials and their thoughts about them. Some participants mentioned that clinical research helps not only the people participating in the trials but others as well. | a. | “A lot of times these things, although we’re looking for something to help ourselves, it’s not just for us. It’s for those that’s coming after us because if it works, then it can be distributed to the other patients.”
“I thought, well, this may help someone else, and it’s helped me when I researched the treatment that I wanted to be involved with.”
b. Some participants indicated that African Americans think that White people receive better quality healthcare and treatments. | b. | “I think—most African American people have a tendency to think that—especially the White race, Caucasians—that they are always given better healthcare, better quality healthcare.”
“That’s how I felt when I came here, and I don’t see that many White people sittin’ upstairs. Askin’, well, where are they goin’? They’re gettin’ better treatment than I am?”
c. A few participants mentioned that they thought clinical research involved being a guinea pig. | c. | “My family member was not on board with participating in the study, primarily for the reason that we mentioned earlier in the discussion. They felt like they were being a guinea pig.”
“I think we tend to think that the medical professional, in general, think that we’re expendable, so they’re willing to use us as quote on quote the guinea pig for somethin’ better.”
d. Many participants shared that there is a mistrust regarding clinical research and trials in the African American community based on history and abuse that occurred. | d. | “I would probably have to think of the distrust that folk in African American community have when you have studies such as the Tuskegee syphilis process that went on for generations, for decades.”
“[e]ven when you talk of whether the procedure is ethical or whether the organization or governmental agency is reputable, history might not always be favorable to both, as it relates to Blacks.”

Subtheme: Experience with clinical research | a. Most participants have family members or friends who are participating or have participated in clinical research. | a. | “I had a brother that went through clinical trial at John[s] Hopkins. For him, it turned out to be very successful.”
**Theme: Providers’ roles in clinical trials**

Providers play an important role in encouraging participation in clinical research. In this section, participants described their thoughts about clinical trials, knowledge about available trials, barriers to clinical trial participation, communication with patients about clinical trials, research coordinators’ roles in supporting physicians, and ways to approach patients about clinical trials.

| Subtheme: Thoughts about clinical trials | | |
| --- | --- | |
| **a.** Provider participants shared that if they believe in the trial and understand the aims of the trial, it is easier to discuss with patients. | **a.** “I think that if I believe the trial, I think it’s much easier to pass along the passion or the interest that I have. If I believe and if I fully understand the trial. Rather than if it’s something that I don’t think that it’s a good idea, probably if it’s a not a good idea I will not even remember.” | |
| **b.** Another provider participant offered that it is also easier to get patient buy-in when the provider believes in the trial. | **b.** “We think it’s a very good trial. We think both arms are okay. If you got either one and that would be good for you. If we can say things like that, you’re gonna get a lot more buy-in from patients.” | |
| **c.** Although some may feel the protocol designs are very rigid, the providers noted that the rigidity is there to protect patients because the trial may not work. | **c.** “Some of the rigidity is to protect the patients. Cuz they don’t know if it’s gonna work or not.” | |
| **d.** As one participant shared, sometimes a patient may want to participate but the protocols exclude them. | “I agree with them being rigid because it gives you an algorithm that it has to be safe for the patient.” | |
| **e.** Patients participating in clinical trials sometimes have other medical issues. Several provider participants shared that having clinical trials specifically designed to handle these co-morbidities would be best. | “To gather appropriate data, more rigid protocols are necessary. I think they are rigid and I think that’s good because otherwise, you can’t systematically evaluate the data.” | |
| **d.** “It’s not that they just don’t wanna do it; we can’t get ‘em on it.” | “It's not that they just don't wanna do it; we can't get 'em on it.” | |
| **e.** “Number one, we have a large HIV population, so we don’t see enough trials enrolling for HIV.” | “[t]he HIV Consortium has trials that they use for patients with HIV and things like that. I don't think there should be a looser inclusion criteria, but maybe trials specifically designed for those groups.” | |

| Subtheme: Knowledge about available trials | | |
| --- | --- | |
| **a.** In order to talk with patients about trials, the providers noted the need to know what trials are available. Most provider participants mentioned that they attend weekly meetings to learn about what trials are available. | **a.** “Every Tuesday … It’s just we meet with the research… nurses, the teams, and go through what trials are sort of in the queue to open …” “We have weekly research meetings and we talk about our open trials.” | |
| **b.** In addition to talking about which trials are available or are about to open, the providers also shared that they talk about | **b.** “Tuesdays is our research meeting where we go through all our protocols and prospective outpatients and accruals.” | |
| Themes/subthemes | Description                                                                                                                                                                                                 | Examples of responses |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Subtheme: Barriers to clinical trial participation | a. Provider participants discussed some of the barriers they face when approaching patients about clinical trials and research. A barrier mentioned by most of the providers was eligibility. | a. “… Because I'm thinking about trials outside of the surgical realm, and so the major barrier is the eligibility.”  
   “… Just making sure that they're eligible for the trials.”  
   b. “You need more hands, and this is a time in health care that there are no more hands.”  
   “But you need the ancillary support in order to get all that set up because we have nothing right now to help us.”  
   c. “The major barrier, I guess time is also because the visits are very quick. We don't necessarily have the time to delve into all of the particulars about the study, but we try to at least introduce the concept and tell ‘em that someone will be approaching them about these things and try to make them feel like they're a partner in the care and that this is something they have to give.”  
   d. “Well, part of it too is again goes back to the patient's time, but then to also allow them to speak to the research person. That you don't want the visit to seem rushed, but if you have already talked about what you're talking about; they've already taken off work or they've arranged for their visit, their transportation to get here. You don’t want ‘em to have to come back for another visit to speak, but yet you don't want it to be a rushed visit with research.” |
| Subtheme: Communication with patient about clinical trials | a. When communicating or explaining clinical trials to patients, most s providers shared that they try to avoid using the term “trial” and use “study” or “research study” instead. | a. “I always say study instead of trial. I try to say study with my own patients.”  
   b. “Those seem to be the easiest ones [to discuss].” |
| Subtheme: Research coordinators' roles in supporting physicians | a. The support mechanisms that the providers have to help them approach or talk to patients about clinical research are the research coordinators. A participant noted that the research coordinators have the time to talk with the patients. | a. “I think that's the big one because they can take the time to talk about and make schedules for patients and listen to their complaints.” |
| Subtheme: Ways to approach patients about clinical trials | a. One way to improve the ability to approach patients about clinical trials is to provide reimbursement or incentives for providers who spend time with those patients discussing the trials or enrolling them in the study. Currently, counseling a patient about trial participation is not reimbursable time. | a. “I mean counseling someone for a trial it's not like a reimbursable event.”  
   b. “… Can't it be transforming our views, like the number of patients that the physician enrolls to a clinical trial per year that would be a type of incentive.”  
   c. “More people to help and not [doing] everything—it has to be a team approach. It has to be. You might have one or two
| Themes/subthemes | Description | Examples of responses |
|------------------|-------------|----------------------|
| b.               | Another participant mentioned an incentive for enrolling patients. | people [being] very good, but if there's no other members, the team will not work.” |
| c.               | Participants shared that having more people to assist is a way to help the providers approach patients. | “I mean there's plenty of studies that show the rate of involvement is much higher when the physician speaks to them first.” |
| d.               | Other participants noted that having the physician involved is a better way to approach patients and leads to higher participation. | |

*Contemp Clin Trials Commun. Author manuscript; available in PMC 2017 July 31.*