Contemporary Clinical Trials Communications 4 (2016) 170–178

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Focus on You: Cancer clinical trials perspectives

Brandi N. Robinson [a, b], Antoinette F. Newman [a, b], Sherrie F. Wallington [c], Sandra M. Swain [b, d, *]

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

ARTICLE INFO

Article history:
Received 28 April 2016
Received in revised form
23 August 2016
Accepted 11 September 2016
Available online 16 September 2016

Keywords:
Focus groups
Clinical trials
African americans
Cancer disparities
Breast cancer

ABSTRACT

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.
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.
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.
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.

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

* Corresponding author. Georgetown University Medical Center, 4000 Reservoir Road NW, 120 Building D, Washington DC 20057, USA.
E-mail address: Sandra.Swain@georgetown.edu (S.M. Swain).

http://dx.doi.org/10.1016/j.conctc.2016.09.004

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 hand-written 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