Available online at www.sciencedirect.com

ScienceDirect

Contemporary Clinical Trials 27 (2006) 498 – 505

Contemporary Clinical Trials

www.elsevier.com/locate/conclintrial

African Americans and participation in clinical trials: Differences in beliefs and attitudes by gender

R. BeLue [a,*], K.D. Taylor-Richardson [b], J. Lin [c,1], A.T. Rivera [c,1], D. Grandison [c,1]

[a] *The Pennsylvania State University, Department of Health Policy and the Methodology Center, University Park, PA 16802, USA*
[b] *Center for Evaluation and Program Improvement, Vanderbilt University, Nashville, TN 37203, USA*
[c] *Meharry Medical College, Clinical Research Center, 1005 Dr. DB Todd Jr Blvd, Nashville, TN 37208, USA*

Received 29 November 2005; accepted 1 August 2006

Abstract

Objectives: To explore gender differences in perceptions of 1) barriers and motivators to participation in clinical trials and perceived need of clinical trials and 2) perceptions of risks and benefits of participation in clinical trials in African American men and women.
Methods: Focus groups were conducted among African American participants by gender. A total of 67 African American participated in the focus groups. All focus groups were audio-taped and transcribed verbatim. Data analysis was performed by combining the key elements of grounded theory and content analysis with the assistance of the qualitative software ATLAS.ti 5.0.
Results: Different themes emerged for men versus women. The business and economic of research were important to male participants. The researcher–participant relationship emerged as one of the strongest themes related to potential female participation in research.
Discussion: Focus group results indicate that African American men and women present different preferences, beliefs and barriers to participation. Men expressed the desire to know information on funding issues, financial benefit and impact of the research. Women expressed the desire to be treated respectfully and as an individual as opposed to just a study subject. Integrating gender preferences into researcher–participant interactions, advertisement, informed consent delivery and advertisement of research studies may lead to increased participation rates. Discussing and presenting relevant information on clinical research funding mechanisms, and the business of clinical research with potential participants may be helpful in building trust with the researcher and the research team. Creating a process for information exchange and methods to minimize the power imbalance between the researcher and participant may also build trust and help participants feel more comfortable to participate in research.

Keywords: African Americans; Research participation; Barriers; Motivation; Clinical trials; Gender differences

---

[*] Corresponding author. Tel.: +1 814 865 6898; fax: +1 814 863 2905.
E-mail address: rzb10@psu.edu (R. BeLue).
[1] Tel.: +1 615 327 5770.

1551-7144/$ - see front matter © 2006 Elsevier Inc. All rights reserved.
doi:10.1016/j.cct.2006.08.001

1. Introduction

The Randomized Clinical Trial (RCT) is one of the most effective methods for evaluating the efficacy and safety of healthcare interventions [1]. However, low participation rates and under-representation of racial/ethnic and other minorities in clinical trials and in the published literature may be insufficient to accurately assess the safety and efficacy of many new health care treatments among racial/ethnic and other minorities [2–6]. The purpose of the present study was to explore African Americans' attitudes regarding clinical research by gender in order to identify possible strategies to improve participation.

Non-participation of racial/ethnic minorities in clinical research and clinical trials jeopardizes the generalizability of findings, limits ability to do subgroup analysis, denies patients access to state-of-the-art treatment for disease, and raises issues about equity in health [7,8]. Under-representation is especially deleterious for diseases that have disparities in health outcomes by race and ethnicity. The National Institutes of Health Revitalization Act 1993 mandates broader inclusion of minorities in clinical research and clinical trials [9]. Although federal initiatives mandate inclusion of minority groups in research that inclusion has not consistently translated to reporting of results that might guide therapeutic decisions [2,9,10]. Although, more attention has been paid to this problem, there is still a need for significant strides to advance empirical evidence that explains under-representation of racial/ethnic minorities in clinical trials. Recent groundbreaking research led by investigators at the National Institutes of Health (NIH) has shattered the myth that racial/ethnic minorities are generally less willing than non-Hispanic whites to participate in health research [2]. In fact, the authors cited several studies in which minorities agreed to participate at significantly higher rates than non-Hispanic whites suggesting that there are other important issues affecting minority participation in clinical research. One of the limitations cited in the NIH study was not assessing minority groups' attitudes toward health research.

Historically, women have been under-represented in clinical research [11]. Data on under-representation of minorities in clinical research by gender is limited. Some research studies on participation and retention in clinical trials indicate that recruiting sufficient numbers of women, especially minority women, is often challenging [11–18]. For example, a cancer clinical trial found that black women were less likely than white women to participate as a result of "more negative attitudes toward clinical trials" [15]. Under-representation of women in clinical trials has similar implications to low minority participation, including fewer opportunities for the patient to receive state of the art treatments and limited ability to generalize and develop treatments for women. Studies that explore how both gender and race/ethnicity influence participation are clearly needed.

Motivators to encourage research participation for minorities are not well investigated. More research is needed regarding procedures and methods that can be employed that may encourage racial/ethnic minority group participation. Strategies to increase participation have included culturally and contextually sensitive strategies to overcome barriers to minority participation [19]. Building trust during the research process, explaining clearly the participation criteria, risks and benefits of participation, and including African Americans in the study design from project inception to data analysis and presentation, have been found to be critical components in obtaining African American participation in planning research studies [19,20]. Careful attention also needs to be given to study design inclusion and exclusion criteria. Many minorities are excluded from study participation on the basis of poor health status and presence of comorbid illness [21]. Given the evidence that both racial/ethnic minorities and women, especially minority women are often difficult to recruit into clinical trials, it is possible that recruitment strategies need to be tailored by race and gender, not just one or the other.

2. Study design and methods

2.1. Study design

A qualitative focus group study of African Americans was conducted to explore gender differences in perceptions of 1) barriers and motivators to participation in clinical trials and perceived need of clinical trials, and 2) perceptions of risks and benefits of African American participation in clinical trials.

Focus group methodology has proven to be effective in uncovering beliefs, perceptions, opinions and attitudes about health services, prevention, and treatments in minorities [22–26]. We employed this methodology to assess beliefs and perceptions of male and female African Americans regarding participation in clinical trials.