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Reported Benefits of Participation in a Research Study

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Abstract

Racial and ethnic minorities are significantly underrepresented in clinical research trials. Several socio-cultural and systemic barriers, ranging from discrimination by the health care system, medical mistrust, to low physician referral rates and lack of knowledge of research studies have been identified as impacting participation. One hundred and fifteen participants were culturally matched and were interviewed followed by up to an additional four interviews over a 12 month period. Responses were analyzed to understand the perceived benefits to participating in a prospective, randomized, longitudinal clinical research trial about screening colonoscopy. Over two-thirds (64.4%) of participants reported “knowledge, awareness, and/or information about colonoscopy and general health” as being the greatest benefit they received. Desire to undergo the screening and the pride of completing the study was ranked second and third, respectively. Understanding the reasons that participants choose to participate in research studies will ultimately assist researchers close the gap in minority representation, allowing for greater generalizability of research findings.

Keywords

Minority groups; Clinical trials; randomized; Participation; Colonoscopy

Introduction

According to 2000 census data, the United States (US) was home to approximately 281,421,906 [1] uniquely diverse individuals. Racial/ethnic minorities comprised 31% of the total US population and that percentage continues to grow [1]. This diversity is what in essence makes this country a multicultural mosaic. East Harlem (EH), the study site, located in New York City (NYC), provides an example of a metropolitan area highlighting the

changing face of the US According to the New York City Department of Health and Mental Hygiene (DOHMH), 108,100 people resided in EH in 2000 [2]. Racial/ethnic minorities comprised 93% of the total population [2]. In comparison to NYC residents overall, EH residents face many barriers to healthcare access, such as high poverty (40% of its residents live below the poverty level) and uninsured rates (30%) [2]. According to a report by the *Institute of Medicine*, disparities within healthcare are defined as racial, ethnic, and/or socioeconomic differences in the quality of healthcare, and frequently associated with negative health outcomes [3]. Many of these existing healthcare disparities, as well as certain health behaviors stem from events, both historic and social, as well as economic inequalities deeply rooted within minority communities. As a result of these lingering and silent events, illness and diseases which don't necessarily have to be fatal often are, tearing families as well as communities apart.

There are numerous preventable diseases that affect ethnic minorities in a disproportionate way; colorectal cancer (CRC) is a prime example of such an illness. While CRC is the second leading cause of cancer-related deaths in the US, routine screening can save lives [4]. It is estimated that 51,370 CRC deaths were expected to occur in 2010 [4]. According to the US Multi-Society Task Force (USMSTF) guidelines, there are a variety of options for CRC screening, beginning at the age of 50 [5]. However, colonoscopy is considered the gold standard of CRC screening since it allows for the removal of cancerous and pre-cancerous polyps, thereby preventing CRC [6–8]. When pre-cancerous polyps are removed early, it results in a significant decrease in the likelihood that a patient will develop CRC. Furthermore, according to the National Polyp Study (1993), which compared patients completing a colonoscopy in which one or more polyps were removed, showed the use of colonoscopy reduced the incidence of CRC by 76–90% [9]. A study conducted by Jones and colleagues concluded that only 61% of US adults 50 years report having had any type CRC screening recently [10]. However, many individuals, particularly minorities, remain non-adherent to colonoscopy (the gold standard); only four out of 10 EH resident over the age of 50 have had a screening colonoscopy within the last 10 years [2]. This finding needs to be viewed in light of the fact that for African Americans (in the present study African Americans includes Black Americans), the overall incidence of CRC is approximately 22% higher compared to their Caucasian counterparts. Taking these differences into consideration the American College of Gastroenterologist (ACG) put forth recommendations specific for African Americans to be screened starting at the age of 45 using colonoscopy as the preferred method of screening [11, 12].

According to the *National Institutes of Health* (NIH) minorities are also continuously underrepresented in research [13]. When comparing non-Hispanic Blacks with non-Hispanic Whites, lower participation rates in clinical trials have been seen [13]. Several barriers have been put forth affecting the recruitment and retention of minority populations in research. Socio-cultural barriers to minority participation in research include past or present discrimination within the health care system, mistrust, suspicion and thoughts of exploitation, ill treatment, fears or concerns about safety, and study requirements [14]. Lack of knowledge or awareness about research, low rates of physician referral, time or interference with work, family, or personal responsibilities, and transportation are additional

barriers which contribute to the lack of participation and sample retention [15]. Furthermore, many studies suggest that the Tuskegee Syphilis Study, being one example of an unethical study which was conducted on almost 400 African American men from 1932 to 1972, left a profound level of fear and distrust towards research within the African American community particularly among the older generation [16–18]. Therefore, in order to obtain an appropriate representation of ethnic minorities in research, the use of standard recruitment methodology may not always be sufficient.

Gilliss et al. [19] identified many strategies that can increase recruitment rates across racial backgrounds. The authors found that the most successful strategy for recruiting African Americans, in comparison to non-Hispanic European Americans and Mexicans/Central Americans, was face-to-face recruitment. The Midlife Women's Health Study, a 5-year longitudinal study conducted by Kennedy et al. [20] looked at the menopausal transition of women of all races. The investigators used specific strategies to recruit African American and Mexican/Central American women, including culturally matched recruiters [20]. When recruiting African American women into the study, face-to-face recruitment was found to be the most effective, resulting in 79% enrollment. Similarly, matching participants and recruiters according to age, gender, and particularly race, resulted in an effective recruitment approach in studies conducted by Gavalier et al. and Blumenthal et al. [21, 22]. Several studies also indicate that culturally matching participants with recruiters plays an important role in increasing research participation [14, 19]. In 1999, Moorman et al. [23] undertook the Carolina Breast Cancer Study, a comprehensive case–control study calculating rates of contact (defined as the ability to reach and inform a participant about the study) and cooperation (defined as the ability to reach, inform and enroll participant in the study), which examined age, race of participant, and race of interviewer. Cooperation rates among African American women increased when the interviewer was also African American. A 15% increase in participation among young African American controls was noticed as well as a 6% increase in young African American cases. Furthermore, there was a 15% increase in participation among older African American cases and a 14% increase in older African American controls. Even though the interviewer's first contact with the participant was over the phone, the participants' decision of whether or not to participate in the study was presumed to be based on the perceived race of the interviewer based on language patterns and accent. These studies demonstrate the positive impact that the culturally matching of recruiters has had on recruiting African Americans and increased participation, possibly relaying a message of the importance of the study to women of their same race and may also play an important part in overcoming fear or mistrust [23].

Truly understanding the need to increase minority participation in health research is essential for identifying, addressing, and overcoming existing health disparities [13]. Moreover, in order to achieve adequate representation of all groups in health research, it is essential to understand the reasons which serve to motivate or deter participants, particularly ethnic minorities, from participating in research. Previous studies conducted by Gysels et al. [24], Tolmie et al. [25], James et al. [26] and Gilliss et al. [19] have mentioned the following reasons for participating in a research study: altruism, concerns about care, the need to talk to someone, and/or the need for information or access to services. While the motivation to participate in research may initially be out of curiosity, once enrolled, personal benefit and

altruistic motives may supersede the reason [25]. James et al. [26], conducted a study looking at the perceived barriers and benefits to CRC screening among African American church members in North Carolina. The results concluded that having had a colonoscopy was positively associated with greater perceived benefits. Additionally, Good et al. [12] conducted a qualitative study in central Virginia, which sought to identify and describe the different barriers which prevent African Americans from obtaining CRC screening. The results of this study indicated the need to increase outreach and education about the topic of CRC screenings as well as its availability. While there are numerous reasons why a person decides to participate and/or refuse to participate in research studies, the current study examines the benefits participants have actually experienced, which, in turn, can lead to a better understanding of more effective ways to recruit more ethnic minorities in future studies.

Methods

The IRB-approved prospective, randomized, longitudinal clinical trial parent study was designed to investigate the effectiveness of different print educational brochures in reducing African Americans' perceived barriers and increasing their adherence to CRC screening recommendations [27]. Participants were culturally matched with an African American interviewer, who conducted the baseline and up to four follow-up interviews (2 weeks, 3, 6, and 12 months) throughout the 12-month study period. The 2-week follow-up entailed a review of study materials and was not considered to be a full follow-up assessment.

During the final assessment, approximately 12 months following the baseline interview, participants were asked "What are you most proud of regarding your participation in the study?" These open ended responses were coded to assess what benefits participants received by participating in the study. Initially, the responses were coded into nine different categories: (1) can share information with others, (2) helping others, (3) realized people care, (4) knowledge or awareness about colonoscopy and general health, (5) proud of participating and completing study, (6) educational material and information, (7) want to have the test, (8) talking about it and (9) other. Two separate coders sorted the responses and were instructed that responses could fit into multiple categories if applicable; differences were then compared. Given some ambiguity amongst some of the categories, these categories were further sorted into three broader groups: *External Benefit (EB)*, *Internal Benefit (IB)*, or *Other*, depending on the type of benefit the participant received by participating in the study. EB is defined as benefits which affect other people, IB is defined as benefits which affect "self" as a result of one's action, and *Other*, incorporates all other responses. After revising the categories, the responses were coded once again by two separate coders and reviewed for consistency. A committee was assembled to discuss any discrepancies after the second round of coding, which was then finalized. The final six categories are shown in Table 1.

Results

This paper reports on the 115 participants (of the initial 159) who completed a 12-month follow-up interview. The overall retention rate (defined as completing at least one other

interview post-baseline, excluding the 2 week follow-up interview) for the study period. 140 of the 159 parent study participants meet this retention definition resulting in a 88.1% retention rate. As seen in Table 2, the majority of 115 participants for the present study were between the ages of 50–55 (54.8%), female (73.9%), and were not married (72.2%). Most participants had some college education or greater (42.6%), had an annual income less than \$10,000 (45.1%), and were not employed (87.8%). When comparing the demographics of participants who completed the 12-month interview and those who did not; there was only one statistically significant ($P = 0.012$) difference. Participants who were married/partnered were more like to complete the 12-month interview then those who were not married/partnered.

As stated earlier, the primary goal of this analysis was to understand the benefits participants reported experiencing as a result of their participation in the research study. Table 3 depicts the frequency within each of the six response categories stated by the participants. The greatest benefit participants reported was “Knowledge, awareness, and/or information about colonoscopy and general health” by almost two-thirds of the respondents ($N = 76$, 64.4%). Statements such as “The study has enlightened me about the colonoscopy and importance of taking the test and it encouraged me to take the test. The research gave me more insight.” were the most common types of response within that category. Followed by statements such as “The information that I have received about my health and things I should be doing to improve my health. I am going to get the colonoscopy done” were categorized under “Wants to have the test” ($N = 32$, 27.1%). “Proud of participating and completing the study” ($N = 19$, 16.1%) encompassed statements such as “Proud of participating in a study that may help people of color get proper health, and alleviate fears. Helps doctors be more in tune to the health of people of color”. These responses all form part of the Internal Benefits category. Responses could fall into more than one category; therefore responses are not mutually exclusive.

Discussion

Understanding the benefits which participants experienced and the reasons which motivated a participant to enroll in a research study is not only of great importance, but essential if we as a society are to move forward and benefit from research for the good of all communities.

This study was successful in a number of ways. First, we gained better insight of what benefits the participants felt they received as a result of enrolling and participating in this study. Although these benefits were primarily indirect for the participant, the statements participants provided indicate the importance of such benefits to them. Benefits, such as a sense of empowerment, as well as an increase in knowledge that came about as a result of the study, may lead to better health advocacy, study participation and outcomes. This can be seen by statements such as “It was an opportunity to get information and enlightened me on things I didn't know about and it is a constant reminder to get the test done”. This sense of empowerment does not only serve as an indirect benefit to the participant, but indirectly, can also aid in bridging the existing health disparity gaps. Moreover, increased knowledge is a benefit that is often under emphasized during time of recruitment and enrollment into research. Although an increase in knowledge can be easily quantified by the use of pre/post

tests, within the context of this qualitative study its effects are also reflected within the statements provided by the participants. Knowledge is a powerful tool, not only is it beneficial for the participant, but it has also been linked to an increase in positive attitudes and behaviors [12, 16, 26, 27].

Additionally, as a result of incorporating many of the strategies, such as face-to-face recruitment and culturally matched recruiters, which were successful in previous studies, our overall retention rate was relatively high. Consequently, when possible, participants completed their follow-up interviews with the same culturally matched recruiter/interviewer; not only did this provide consistency but it allowed for a rapport to be established, as well as a sense of trust and open communication.

In conclusion, despite the study limitations including a relatively small sample size, study participants who were predominantly female and an all urban setting, the recruitment and retentions goals of this study were successful. Furthermore, this study illustrates some of the benefits of participation in research, which can be discussed with possible participants at the time of recruitment and may lead to an increase in research participation by ethnic minorities. Future studies could also incorporate the use of face-to-face recruitment, culturally matched recruiters, as well as consistency with regard to the interviewer who follows the participant over the course of the study period. Incorporating these different methods brought about vast benefits to both the participant, as well as the research study. Integrating these steps could assist future studies in order to increase retention rates.

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Table 1

Benefit categories

Title		Category	Example
1.	Helping others and sharing information with others	External	<i>"That I gave information that might help other people"</i>
2.	Knowledge, awareness and/or information about colonoscopy and general health; talking about it	Internal	<i>"I got the understanding about colonoscopy, the purpose of having it; it did me a lot of good. I'm educated about it."</i>
3.	Proud of participating and completing study	Internal	<i>"The fact that I participated!"</i>
4.	Educational materials received (brochure)	Internal	<i>"The information I was given, I would have never thought about having it otherwise"</i>
5.	Wants to have the test or had test	Internal	<i>"That everything is satisfactory, I'm happy I had the procedure done. I feel great, looking forward to having it done again"</i>
6.	Other	Other	<i>"The fact that everything was good"</i>

Table 2

Overall patient demographics

Variable	N=	%=
Mean age (SD)		
50–55	63	54.8
56 and up	52	45.2
Gender		
Male	30	26.1
Female	85	73.9
Marital status		
Married or live with partner	32	27.8
Not married	83	72.2
Education		
Less than high school	33	28.7
High school, GED or vocational	33	28.7
Some college or greater	49	42.6
Income (\$)		
Less than 10,000	51	45.1
10,000–25,000	39	34.6
Greater than 25,000	23	20.3
Employment status		
Employed	14	12.2
Not employed	101	87.8

Table 3

Reported benefits of participation

Responses	N*	%*
Helping others and sharing information with others	13	11.02
Knowledge, awareness and/or information about colonoscopy and general health	76	64.41
Proud of participating and completing study	19	16.10
Educational materials received (brochures)	7	5.93
Wants to have the test	32	27.12
Talking about it	17	14.41

* N and % do not total 100 as responses are not mutually exclusive