



Published in final edited form as:

J Immigr Minor Health. 2021 February ; 23(1): 19–25. doi:10.1007/s10903-020-01015-4.

Sex Differences in Willingness to Participate in Research Based on Study Risk Level Among a Community Sample of African Americans in North Central Florida

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Abstract

This study examined the association between sex, study risks and willingness to participate in research among a community sample of African Americans. We hypothesized that African American males would be more willing to participate in studies involving both minimal and greater-than-minimal risk. The study sample was recruited through a community engagement program (HealthStreet). Interviewers obtained information on socio-demographic variables and willingness to participate in various research types. We categorized research types into minimal risk and greater-than-minimal risk based on the IRB classification. The study sample comprised 6544 African-Americans; 58.4% were females. About 92.6% of the participants were willing to participate in surveys and 58.1% in research requiring medication use. More males would participate in minimal risk studies requiring review of medical records (males 87.0% vs. females 84.2%, $p = 0.0021$) and studies involving giving a blood sample (males 84.2% vs. females 81.7%, $p = 0.0083$). Also, more males would participate in greater than minimal risk studies involving the use of medication (60.5% v. 56.3% $p = 0.0007$). More males were willing to participate in minimal risk studies (studies involving the review of medical records and giving blood samples) and greater-than-minimal risk study involving the use of medication.

Keywords

Willingness to participate; Research; Risk; African-Americans; Sex differences

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Conflict of interest The authors declare that they have no conflict of interest.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Introduction

There have been several studies in the literature with mixed results regarding race and willingness to participate in research. While some studies [1, 2] found no racial differences in research participation, some studies [3–7] found higher willingness to participate in research among whites and some other studies [8, 9] found higher willingness to participate among blacks. More studies are needed to understand the research participation and perception among African Americans. The implication of differential willingness to participate in research among races may also be noticed in the healthcare system as a perception of bias in the healthcare system and erosion of trust among specific subpopulations [10].

Among African Americans, potential research participants often consider the risk associated with research before making a decision on whether to participate or not. Studies [11, 12] have shown African Americans would rather participate in low/minimal risk studies (e.g. surveys), than high/greater than minimal risk (e.g. new medication trial). Males and females have different perceptions of risks regarding clinical trials [13]. Trust is an essential component of research participation [5, 14–16]. There are many dimensions of trust to be considered in the researcher-participant relationship and these various aspects of trust either enhance or impede the decision to take part in a research. For example, at the initial phase of the research process, dispositional trust (a human characteristic of having the tendency to trust another) [17] and the propensity to trust [18] will influence the researcher-participant relationship as different individuals have varying propensities to trust someone they just met including a researcher. Hurd and colleagues [19] described various stages of trust, from “swift trust” to more “traditional trust.” Swift trust is like Cooper’s [20] perception of trustworthiness that occurs at the initial phase of the relationship where participants assess if the researcher is trustworthy and can deliver on what he/she is saying about the research. Swift trust is a necessary stage of trust starting at study recruitment before the more traditional trust is developed as the research/clinical trial progresses; it exists even in the absence of a strong long-lasting interpersonal relationship [19]. When trust is central to a relationship, there’s reciprocal sharing of information [21] that is rooted in the shared experiences during the research process, thus gradually building a traditional trust and laying the foundation for study retention. The concept of trust and research is particularly important among African Americans given a history of mistrust of researchers and health care providers in this community [22, 23]. African Americans have lower trust in research and researchers compared to Whites [5]. Lang and colleagues [24] showed that lack of trust is the primary reason why African American males are unwilling to participate in research. Current research suggests that the willingness to participate in research is significantly affected by sex and the direction of these findings are mixed [13, 25–36]. While some studies showed that females were more likely to participate in health research than males [25–30], others found females to be less interested than males [13, 31–36]. In general, females are more averse to engage in risk-taking behavior, whereas males take risks detrimental to health in many communities [36–39].

There are limited studies that investigated the association between sex, study risk and willingness to participate in research among African Americans, an under-represented

community in research. Given the inconsistencies in the literature on race, sex and willingness to participate in research, we examined sex differences and the impact of study risk level on the willingness to participate in various types of research among a large sample of community dwelling African-Americans. Given that there are social and health-risk behaviors common among African American males with negative health outcome implications [40–43], we hypothesized that African American males would be more willing to participate in both minimal risk and greater than minimal risk studies than African American females. This study expands current knowledge by identifying the association between sex, research risk and willingness to participate in research in a large study sample of an ethnic minority population.

Methods

For this analysis, a subsample of people who self-identified as African American was drawn from the overall sample of community members enrolled in HealthStreet's [44] registry in North Central Florida. HealthStreet is the University of Florida Clinical and Translational Science Awards supported community engagement program. A total of 6544 African Americans were interviewed by Community Health Workers (CHWs) from November 2011 to December 2019. CHWs conduct daily community outreach and gather community member's health information by administering a 20 to 25-min health intake. CHWs are members of the community that share a common culture and language with the community members giving them credibility and easy access to the community members [8, 44, 45]. Community members were approached at different locations in the community. Examples of locations where members were contacted include laundromats, churches, recreational parks, libraries, shopping centers, gas stations, barbershops, bus stops, public event gatherings and community centers. CHWs obtained informed consent from all participants before the intake interviews were conducted. Research protocols and procedures were approved by the University of Florida Institutional Review Board (IRB).

The HealthStreet Health Needs Assessment includes questions on socio-demographic characteristics, research perceptions, health conditions and concerns of the participants. This analysis focuses on the self-reported research perceptions of participants. The questions that were analyzed include: "Have you ever been in a health research study?" with yes/no responses and "How interested are you in being in a research study" with responses categorized as "definitely/maybe" or "not at all." To assess willingness to participate in seven different types of studies, participants were asked if they would volunteer for various study types with yes/no responses. Using the IRB classification of studies into minimal risks and greater than minimal risks [46] as used by Slomka et al. [12], we grouped the study types into two categories: minimal risk studies (surveys about participants' health, review of medical records, giving a blood sample) and greater than minimal risk studies (having to take study medications, use of medical equipment, staying overnight in a hospital/clinic, giving a sample for genetic studies). Based on these categorizations, we created three indices of research risk as composite measures of risk consideration in willingness to participate in research studies: minimal study risk index (score of 0–3), greater than minimal risk study index (score of 0–4) and general study risk index (score of 0–7). Thus, if a respondent answered "yes" to volunteering for two of the three research types in minimal risk study

category, his or her index score would be 2, meaning that willingness to volunteer for minimal risk study is high. If a respondent said he/she would not volunteer for any research, his or her index score would be 0, indicating no interest in participating in minimal study types. A similar interpretation applied to the greater than minimal risk index and the general risk index involving both study categories.

We also further classified study participants into four broad categories: those willing to participate in minimal risk studies only (minimal risk only), those willing to participate in greater than minimal risk studies only (greater than minimal risk only), those willing to participate in both minimal risk and greater than minimal risk studies (both) and those unwilling to participate in any studies (none). Additionally, participants were also asked about research compensation expectations: “how much money do you think is a fair amount for participating in an hour and a half long study, which involves an interview and blood test?” and “would you participate in a study with no monetary compensation?” with yes/no answers.

Description of analyses

The data was analyzed using SAS 9.4 (ref). Chi-square tests were conducted for all yes/no and categorical answers. The t-test was used to examine the sex differences in age, research compensation expectation and three risk indices. p-values < 0.05 were considered statistically significant.

Results

Among the 6544 African Americans in this analysis, 41.6% were male and the mean age was 43.1 years. Nearly 80% had at least a high school education; 82.4% were unmarried and 65.0% were unemployed (Table 1). Nearly all the participants (92.4%) were definitely or maybe interested in participating in a research study, only 15.2% had ever been in a health research study. More females had ever participated in health research than males (17.3% v. 12.3%, $p < 0.0001$); they were generally more interested in participating (definitely/maybe) than their male counterparts (93.0% v. 91.7%, $p = 0.0469$) (Table 2).

Furthermore, studies that only asked question about participants' health, a minimal risk study, had the highest percentage of respondents willing to participate (92.6%). In comparison, research that required participants to take medication, a greater than minimal risk study, had the lowest percentage of willingness to participate (58.1%). Sex differences were observed in the willingness to participate in minimal risk studies that required the review of medical records (males 87.0% vs. females 84.2%, $p = 0.0021$) and studies that involved giving a blood sample (males 84.2% vs. females 81.7%, $p = 0.0083$) (Table 2). Our study showed that minimal risk studies were more likely to be of interest to African American males than females (2.63 v. 2.58, $p > 0.0201$). This was also seen in study involving the use of medication, a greater-than-minimal risk study (60.5% v. 56.3%, $p = 0.0007$) (Table 2).

In this study sample, African American males were less willing to participate in research if they did not get paid compared to their female counterpart (males 71.1% vs. females 76.8%,

$p < 0.0001$). Furthermore, males expected a larger amount of money as fair reimbursement for participating in a research study that lasted about 1.5 h, involved an interview and a blood test than females (males \$113 vs. females \$106, $p = 0.0073$) (Table 2).

Discussion

Our study addressed gaps in the literature on African American's willingness to participate in research by analyzing the impact of study risk levels and sex, among a population of 6544 African Americans who completed a face-to-face interview. Our hypothesis that African American males would be more willing to participate in both minimal risk as well as greater than minimal risk research than African American females was supported. We found that males were more willing to participate in minimal risk research (studies that review medical records and ask for blood samples) and greater-than-minimal risk research (study that requires the use of medication).

Among females, the reduced willingness to participate in research involving the review of medical records is consistent with a previous study [47] that confirmed the same and speculated that privacy concerns might be the reason behind it. This study also showed that males were more willing than females to participate in studies that require the withdrawal of blood. The reason for this disparity is not apparent and may indeed highlight a research need to identify a potential differential perception of risks between study participants and researchers. For example, while researchers (IRB) may have classified studies involving venipuncture and blood draw as minimal risk study [48, 49], some participants may consider the idea of needle stick insertion into their skin invasive and to them such study is a greater than minimal risk study. It is possible that in our study some participants may have considered the drawing of blood as greater than minimal risk instead of minimal risk as classified by the IRB, especially since some studies have shown that males are more likely to take risks than females [36–39], hence higher willingness of African American male participants in our study to participate in studies involving blood draw. Further, particularly in underrepresented communities with a history of mistrust of research [22, 23, 50], they may worry that the results from the blood test may further define their community in terms of a particular health outcome. These explanations, though speculative, underscore the need for future studies to examine the categorization of research risk levels from the perspectives of both the participants' and the researchers.

Our findings that African American male participants were more likely to volunteer for greater than minimal risk study (study requiring the use of medication) is consistent with Ding and colleagues [13] who showed that in a multiracial cardiovascular prevention clinical trial, with a study sample of 783 participants (35% African Americans), females had a higher perceived risk of cardiovascular trial participation than males and a lower willingness to participate than males.

Findings from this study also showed that, overall, participants were more willing to participate in minimal risk studies than greater than minimal risk, consistent with previous studies [11, 31]. Although our study showed that males were more willing to participate in some types of health research than females, interestingly, more females reported prior

participation in research and expressed general interest in being in a study. We suspect this may be because females participate more in community services than males [51–53], and they are more likely to volunteer for research overall [25–30]. The result, however, exemplifies a point made by Browne and colleagues [54] that analyzing behavioral intentions, such as willingness to participate, may help our understanding of the likelihood of research participation, but it may not predict actual enrollment. Future studies should examine the disparity between willingness to participate and actual participation. Our study also showed that male participants expected higher reimbursement for research compared to females. It is possible that pay expectations are gender-based and could be the reason for women suggesting lower pay than men. [55, 56].

Limitations and Strengths

Although the unemployment rate is disproportionately higher among African Americans [57], the prevailing unemployment rate among participants does not reflect the unemployment rate in the counties assessed and this may affect the generalizability of the results. However, we believe that our large sample size of an ethnic minority, in Florida, the third largest state in the USA, bolstered our results. Our careful study design and data collection provided confidence in the integrity of the data. Our study's main strength is that the assessments were conducted by trained CHWs, who were recruited from the same community as participants, therefore, are culturally sensitive in their assessments, engendering more trust [58] in intake interviews with community members.

Conclusions

Our finding that sex differences exist among African Americans in their willingness to participate in minimal risk research and studies involving the use of medications, but not the other greater than minimal risk studies, underscore the need for future research to examine this topic further. Given the disparities that exist for research participation and trust in the health care system among the minority population [10], an understanding of the factors that influence research participation is of utmost importance. Given our finding that fewer African American females would be willing to participate in minimal risk studies and greater than minimal risk study involving the use of medication than male African Americans, recruitment efforts should employ special enhancement strategies [59] that are tailored towards engaging equally representative male and female samples to increase willingness and, subsequent, actual participation in research studies. Future research should also explore the influence of sex and study risks in a multiracial study population.

Funding

Funding was provided by National Institutes of Health and National Clinical and Translational Science Award with Grant No. UL1 TR001427 and National Institute on Drug Abuse with Grant No. T32DA035167, PI: Linda B Cottler.

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Table 1

Demographic characteristics of study participants, n = 6544

Variables	Total n = 6544	Male n = 2724 (n %)	Female n = 3820 (n %)	p value
Mean age (years) (SD)	43.1 (16.0)	43.3 (16.0)	43.0 (16.0)	0.5263
<i>Education</i>				
< High school	1514 (23.2)	722 (26.6)	792 (20.8)	< .0001
High school	5018 (76.8)	1997 (73.5)	3021 (79.2)	
<i>Employment</i>				
Employed	2290 (35.0)	936 (34.4)	1354 (35.5)	0.3649
Unemployed	4254 (65)	1788 (65.6)	2466 (64.6)	
<i>Marital status</i>				
Married	1151 (17.6)	463 (17.0)	688 (18.0)	0.2885
Other	5393 (82.4)	2261 (83.0)	3132 (82.0)	

Other: never married, separated, divorced, widowed

Table 2

Research types and risk categorization by sex, n = 6544

Variables	Total n = 6544 (n %)	Male n = 2724 (n %)	Female n = 3820 (n %)	p value
Ever been in a health research study?	994 (15.2)	334 (12.3)	660 (17.3)	<.0001
<i>In general, how interested are you in being in a research study?</i>				
Definitely/Maybe	6049 (92.4)	2497 (91.7)	3552 (93.0)	0.0469
Not at all	495 (7.6)	227 (8.3)	268 (7.0)	
<i>Willingness to volunteer for research by study type (categorized by risk level) Minimal risk studies</i>				
Study that requires a health survey	6063 (92.6)	2511 (92.2)	3552 (93.0)	0.2194
Study that requires a review of medical record	5587 (85.4)	2369 (87.0)	3218 (84.2)	0.0021
Study that requires a blood sample donation	5413 (82.7)	2293 (84.2)	3120 (81.7)	0.0083
Minimal risk scale, 0–3 [mean (SD)]	2.6 (0.8)	2.63 (0.8)	2.58 (0.8)	0.0201
<i>Greater than minimal risk studies</i>				
Study that requires an overnight hospital/clinic stay	4625 (70.7)	1948 (71.5)	2677 (70.1)	0.2091
Study that requires the use of medical equipment	5343 (81.6)	2198 (80.7)	3145 (82.3)	0.0912
Study that requires a sample for genetic studies	5406 (82.6)	2233 (82.0)	3173 (83.1)	0.2524
Study that requires the use of medication	3801 (58.1)	1649 (60.5)	2152 (56.3)	0.0007
Greater than minimal risk scale, 0–4 [mean (SD)]	2.9 (1.3)	2.9 (1.3)	2.9 (1.2)	0.3586
Gen risk scale, 0–7 (Mean, SD) (minimal risk + Greater than minimal risk risk)	5.5 (1.8)	5.6 (1.8)	5.5 (1.8)	0.1047
<i>Patterns of interest in participation by risk types</i>				
Minimal risk only	260 (4.0)	116 (4.3)	144 (3.8)	0.8826
Greater than minimal risk only	61 (0.9)	22 (0.8)	39 (1.0)	
Both	6035 (92.2)	2493 (91.5)	3542 (92.7)	
Neither	188 (2.9)	93 (3.4)	95 (2.5)	
Reimbursement expectation				
<i>Would you participate in a study if you didn't get paid?</i>	4872 (74.4)	1937 (71.1)	2935 (76.8)	<.0001
Fair amount of reimbursement for study participation, mean (SD)	105.9 (175.3)	113.3 (195.4)	105.8 (159.1)	0.0073