Motivators for enrollment and completion of pregnancy outcomes research: A comparison of African-American and Caucasian women's perspectives

By

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Abstract

Women and minority populations, specifically African-Americans, continue to be under represented in medical research. The exclusion of women and minorities from clinical trials raises questions about whether treatment outcomes are generalizable to these populations and about equity in the provision of health care. Despite the recognition of the need to include women and minorities in medical research, many factors limit their participation. This study explored the motivators for participation, retention and satisfaction of reproductive-aged women who participated in the Right from the Start Study (RFTS), an ongoing, prospective study of early pregnancy risk factors for spontaneous abortion and preterm birth. The goal was to improve our understanding of factors important to participation in pregnancy-outcomes research, and to determine if these factors varied between African-American and white women.

Three focus groups, two with African-American women and one with white women, were conducted to learn about the women's opinions on participation in pregnancy outcomes research. The majority of the women in all focus groups indicated that facilitative aspects of the study, such as free ultrasounds and pregnancy tests were the most important reason for participating in the RFTS study. However, factors influencing retention and satisfaction with research differed between the racial groups. Interest in the research topic, familial altruism and personal relevance were the major themes expressed by the African-American women;

whereas, Caucasian women were motivated by commitment, convenience and reimbursement.

By using the themes that emerged from these focus groups in combination with the literature on participation and retention in medical research, the design of future research trials involving reproductive-aged women can be improved to reflect better understanding of the factors affecting enrollment, retention and satisfaction with research. We speculate that all studies involving reproductive-aged women, and especially African-American women, should focus on improving and emphasizing individual benefits of participation. Research designed to study reproductive-aged women should include components that are purposeful to the participant, such as tests that the participant values, and should employ staff who are friendly and compassionate. If the barriers known to impede participation are lessened while factors that improve satisfaction and enrollment are enhanced, the participation and retention of women in future trials can be ensured.

Introduction

Women and minority populations, specifically African-Americans, continue to be under represented in medical research. Historical events, as well as social and individual factors have influenced the participation of these populations in clinical research. For example, the thalidomide tragedy of the 1960s brought attention to the potential dangers of investigational drugs for women's reproductive health, in part as a result, in the 1970s reproductive-aged women were excluded from clinical trials.[1] The Tuskegee Syphilis Study conducted from 1932-1972, which withheld treatment from African-American participants, created a general mistrust of research among African Americans that is still a frequent reason for non-participation in clinical trials.[2]

The exclusion of women and minorities from clinical trials raises questions about whether treatment outcomes can be generalized to these populations and about equity in the provision of health care. [3, 4] Gender differences in cardiovascular disease outcomes are a notable example: results extrapolated from clinical trials in men are not always generalizable to women. For example, based on evidence from five major randomized control trials investigating aspirin as primary prevention of vascular disease, aspirin was recommended for use as primary prevention of

myocardial infarction in both men and women. However, women were included in only two of the five trials and accounted for only 20% of those studied.[5, 6] The Women's Health Study, a subsequent large, randomized control trial of women, found that aspirin lowered the risk of stroke without affecting the risk of myocardial infarction or death from cardiovascular events in women.[6] These findings differ significantly from the outcomes for men.

Gender differences also exist in the field of organ failure and transplantation: certain forms of liver and kidney disease are more common in either men or women and appear to be subject to hormonal fluctuation.[7] Also, investigations into rheumatoid arthritis have shown that the phenotype of rheumatoid arthritis, the positivity of rheumatoid-factor, the joints affected, and radiographic damage differ by gender, and it is hypothesized that these differences have implications for the management of patients.[8] Thus, research to on these conditions must include both women and men in order to accurately assess interventions and outcomes.[7]

The importance of inclusion of minority populations is demonstrated by hypertension and the associated cardiovascular outcomes.[9] Based on trials in predominantly white populations, angiotensin-converting enzyme (ACE) inhibitors were recommended as the first alternative to diuretics for control of hypertension for all patients.[9] However, ALLHAT (the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack

Trial), a double-blinded randomized controlled trial that included a substantial number of black participants, found that ACE inhibitors significantly increased the risk of stroke in blacks.[9] This provided evidence that the first alternative to diuretics for hypertension control in blacks without renal disease should be calcium channel blockers, a different therapeutic recommendation than for whites.

In an attempt to address deficiencies pertaining to minorities and women, the National Institutes of Health released the Health Revitalization Act Subtitle B in 1993, which mandates that trials be designed and implemented in a manner that ensures a valid analysis of whether the variables being studied affect women and members of minority groups.[10] Nevertheless, despite the recognition of the need to include women and minorities in medical research, many factors limit their participation.

Barriers known to impede participation in research include undesirable side effects, time commitment, lack of value for clinical research, lack of transportation to study site, and the complexity of trial information.[1] Factors related to trust, which are prominent in African-American populations, include feeling like a "guinea pig", lack of evidence for the therapeutic benefit of trials, invasive protocols, belief that the intervention will not be effective, and belief that the investigator is more interested in the research than in patient well-being or that the investigator will attribute patient suffering to the experimental intervention.[1]

Recruitment

Recruitment into medical research is a complex process that involves identification of study sites, development of recruitment procedures, identification of study participants and implementation of procedures to recruit and retain subjects.[11] A significant amount of literature addresses the recruitment of minority populations not only because researchers recognized the need for minority participation, but also because recruitment of diverse populations requires a concerted efforts must be made to recruit diverse populations.[1]–Commonly cited barriers to recruitment that are specific to minority participants exist on multiple levels. Individual level barriers include mistrust of the medical and research community, lack of knowledge of research, low economic status, cultural and linguistic factors, lack of access, fear of invasive procedures, and limited community involvement in the design of studies.[1, 11-13] Sociocultural factors, such as racism and differences in health beliefs and health behaviors may also influence willingness to participate in research.[1]

At the institutional level, physicians and researchers impose barriers to recruitment of minorities. Physician referral can impede participation if the referring physician does not trust the sponsoring institution or if there are limited numbers of ethnic and racial minorities in the practices referring patients to studies.[11] Researcher biases including failure to accommodate the cultural and economic diversity of potential study participants, inaccurate beliefs that certain populations are not at

risk for specific conditions or illnesses, and failure to include minority institutions in study sites, also limit participation.[1] Additionally, the cost of recruiting minority participants, such as the cost of translating materials or hiring a translator, may influence researcher willingness to include minority groups.[3]

The literature addressing recruitment barriers specifically for women is limited and generally focuses on older women and women with cancer. Barriers to recruitment for women have included transportation issues, fear of not knowing whether they would receive treatment or placebo, and availability of child or family care.[14] Although women of all ethnic groups experienced these barriers, African-American and Hispanic women were most likely to perceive the barriers.[14]

Enrollment

Issues with enrollment in medical research also limit participation. In cancer clinical trials, reasons for non-participation have included patient choice, lack of referring physician participation in the research, and lack of physician and patient knowledge about the study topic.[15] Patients in cancer clinical trials chose not to participate because of discomfort with medical procedures, objection to randomization, feeling unwell, anger at the medical staff, wanting to forget the illness, and conflicts with religious beliefs.[15]

An additional enrollment barrier, specific to minority population is the use of restrictive exclusion criteria.[1] Many of these general exclusions

are without justification.[3] For example, language requirements, such as ability to understand and speak English, severely limit the ability of certain populations to participate.[3] The informed consent process can hinder participation if the forms and procedures are above the participants' reading level, the benefits of the trial are not made clear, the effectiveness of routine care is not explained, or the complexity of the process invokes fear.[1] Labeling of minorities as hard to reach populations and claims that statistical power is reduced with the inclusion of women and minorities are excuses for the failure to include such populations.[1]

Barriers to enrollment at the provider level include provider attitudes towards patients, including opinions that people from low SES are difficult to reach, have deviant behaviors or cannot understand the design.[3] These opinions may be projected to members of minority populations and negatively influence their willingness to participate.[3] Additionally, only a small percentage of minority physicians participate in medical research.[1] If these providers are caring for predominantly minority populations, access to trials is limited or nonexistent if the providers do not participate in trials.[1] Logistical factors such as the proximity of study centers to minority communities, study center hours of operation, and ancillary services are also barriers to enrollment by minority populations.[16]

The literature has addressed these issues primarily in postmenopausal women and typically women with medical conditions,

such as cancer. The investigation of these barriers in women of reproductive age is limited.

Retention

Retention of subjects is an underappreciated component of research design that is addressed infrequently in the literature.[14, 17, 18] The external and internal validity of a study is threatened when participants fail to complete the trial.[16, 19] Drop-outs may alter the demographics of the study population, limiting the generalizability of the results, or affect the power of the study to detect a difference by limiting the opportunity to collect data.[20]

Documentation of problems with retention in medical research is lacking, and little is known about why subjects withdraw their consent from participation because they are rarely asked.[18, 21] Additionally, the distinction between recruitment and retention is not clear in the literature.[22] Thus, factors affecting retention are not known.

Focus group data indicates that barriers to retention include loss of interest in the study, conflicts with scheduling study visits, competing demands for time, site location inconvenience, lack of resources for day care and transportation, poor health, a death in the family, ill family members, family demands, financial difficulties, job conflicts, heavy work load, stress, decreased social support, inability to provide alternate phone contacts, and personality issues with staff.[18, 21] Participants who withdraw from research trials report concerns about expenses, lack of child care,

difficulty reading study materials, and a perceived lack of sensitivity on the part of the research staff.[21] Little is known about retention of ethnic minorities and whether this is influenced by race or ethnicity.[21] Little has been published on the difficulties encountered by ethnic minorities while participating in research.[21]

Facilitators

To generate "participant-friendly" research, it will be important not only to diminish barriers to enrollment but also to amplify factors that serve as incentives for participation, in order to make participation more appealing, increase recruitment, and increase participant satisfaction.[10, 23, 24] Most current research has focused on barriers to recruitment; few studies of minority populations have focused on factors that facilitate participation studies.[13] Motivators for the participation of minority groups in research include a perception of low risk of the study, noninvasive research, sharing of the findings with the participants and their primary care providers, findings that will benefit their community, and incentives such as monetary compensation, free parking, childcare, flexible times for study visits, provision of health information, and physical exams.[11, 13, 14]

Community involvement in study design, using participatory models of research, is thought to be related to minority participation, since community involvement increases awareness of studies, improves communication, strengthens the trust between researchers and the

community, and increases knowledge by explaining the relevance, validity, usefulness and utilization of the research data.[13, 14]

Cancer genetics research has shown that active recruitment, using in-person recruitment from clinic populations, mailings, and telephone recruitment, is more effective in enrolling a high representation of ethnic/racial minorities.[11] This type of recruitment is thought to produce a more generalizable study sample, with less chance of self-selection bias, enhanced awareness of cancer genetics among minorities, and less mistrust of the research process.[11] Factors that enhance minority women's participation in cancer screening research include providing incentives, keeping participants informed, and having a friendly and encouraging study staff.[14] Increased frequency of contact, participant bonding or identification with the study, and community advisory boards have also been reported to maximize participation in research.[18]

Deficits in the Literature

To address the health care issues of any population, research must include elements that aim not only to recruit the target population but also to retain these participants. Thus, addressing each of the aspects of the research process for participants should improve the representation of women and minorities in medical research. In particular, it is important to understanding the factors that motivate those who do and do not participate in medical research, the recruitment techniques specific to these populations, barriers to participation, and factors influencing the

retention of participants. Unfortunately, the literature on these issues in women is sparse.

Articles that have addressed the difficulties of retaining participants in outcomes research focused on the need for more practical strategies for retention in difficult-to-reach populations, such as women and minorities, but did not report details about retention methods and long-term follow-up rates.[18] Studies of positive motivators for enrollment by women indicate that retention is greatest among women who are wealthier, married, better educated, and employed.[25] However, few publications address facilitating factors for women.

Concerns of women about participating in research while pregnant include balancing altruism with self-protection, the quality of care received during the research, and the practical inconveniences of participation.[26] Thus pregnancy adds an additional factor that complicates participation in research, but studies of these issues for pregnant women are lacking.

The purpose of this study was to explore the motivators for participation, retention and satisfaction of reproductive-aged women who participated in the Right from the Start Study (RFTS). RFTS is an ongoing, prospective study of early pregnancy risk factors for spontaneous abortion and preterm birth.[23] The goals of the study are to determine what environmental, biological and genetic factors are related to pregnancy outcomes, and whether there are any ethnic/racial differences in exposures and outcomes. Phase I focused on environmental exposures

by evaluating the effects of drinking-water disinfection by-products on spontaneous abortion. Phase II, currently in progress, aims to determine the effects of fibroids on spontaneous abortion and birth outcomes.

The research presented here was designed to improve our understanding of factors important to participation in pregnancy-outcomes research, and to determine if these factors varied between African-American and white women. For all women, we explored willingness, attitudes and perceived risk of participating in pregnancy-outcomes research, and evaluated the recruitment materials used for RFTS. We assessed general knowledge of genetic research because future phases of RFTS will include genetic studies of fibroid heritability. For African-American women, we also wanted information about factors that might affect minority participation in pregnancy-outcomes research involving a genetic component.

Methods

Participant Selection

The population for study consisted of participants in the first phase of Right From the Start: A Study of Early Pregnancy Health (RFTS), an ongoing, prospective study of early pregnancy risk factors for spontaneous abortion and preterm birth.[23] Recruitment for RFTS occurred between December 2000 and June 2003; the recruitment techniques for RFTS have been described elsewhere.[27]

In Raleigh, North Carolina, women were recruited from prenatal care sites and community locations defined by their water supply systems (residence in the geographical area served by the city water), using informational posters, brochures, advertisements, e-mails, and referral by physicians.[23] The recruitment areas included >100 different venues such as bookstores, coffee ships, fitness centers, child care facilities, beauty salons, work sites, churches, and physician offices.[23] To be eligible for enrollment, women had to meet the following criteria: a positive pregnancy test, pregnancy attained without fertility treatments, gestational age less than 13 weeks, intent to deliver in the study areas, maternal age 18 years or older, residence in the geographical areas served by city water, and ability to speak English.

After enrollment, participants completed a follow-up phone interview at 27 weeks.[28] The interview reviewed health behaviors, reproductive history, and demographic information, including self-identified race, and asked participants to give their opinions about the study and suggestions for improvements.[28] Open-ended responses from the 27-week interviews of women who completed the RFTS were transcribed verbatim into text, entered into NUDIS-Vivo (version 1.1) and examined by two investigators (GL and CL).[28] Grounded theory, or the constant comparative method, was applied to these data.[29-31] In this approach theory is generated from the data, or if existing theories seem appropriate, these may be elaborated and modified as data are compared to them.[29, 31]

Two investigators (GL and CL) classified responses into content areas and identified emerging themes and concepts from the data.[28] Discussion and reexamination of the text by the PIs confirmed the content areas.[28] Because of the large size of the initial RFTS cohort, the PIs used quantitative methods to calculate the frequency of responses assigned to each content area and performed univariate analyses of the relationships of these frequencies and distributions to participant characteristics in STATA (version 8.0).[28]

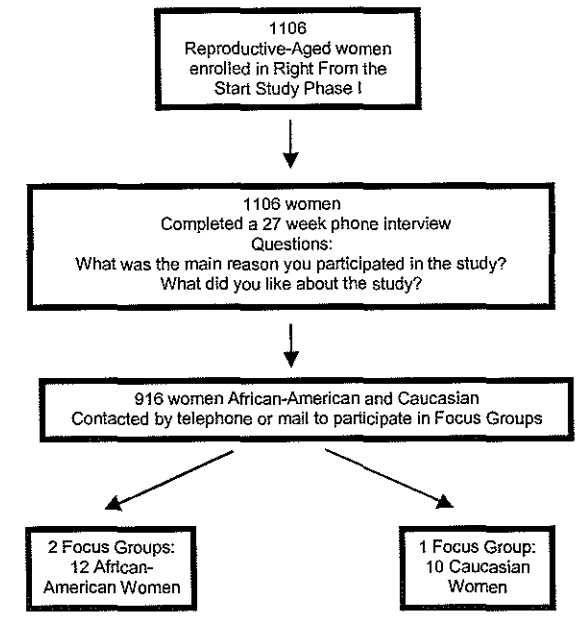
Responses to the two brief interview questions, "What was the main reason you participated in the study?" and "What did you like about the study?", indicated that for African-American women, staff characteristics, facilitative aspects (free ultrasound or pregnancy test), study convenience, and personal relevance were the most common factors influencing participation in the RFTS study and satisfaction (Figure 1). Although Caucasian women valued facilitative and staff characteristics, convenience and altruism also significantly influenced their participation and satisfaction.

From the original RFTS cohort, the women who consented to be contacted for further studies related to the RFTS project were approached for the current study. A total of 916 Caucasian and African-American women were contacted and invited to participate in a 2-hour focus group. The women were contacted via telephone by the study coordinator; those who could not be contacted by phone were sent a letter. To be included in

the focus groups, women must have participated in the initial RFTS project, been able to provide their own transportation, and be willing to discuss sensitive topics related to race, health and their participation in the RFTS. The 22 women who agreed to participate were contacted by phone or mail 2-3 days prior to the focus group to remind them of the date, time and setting and to answer any questions.

We conducted three focus groups, two with African-American women and one with white women (Figure 1). Participants were informed about the purpose and objectives of the study, the format and two hour duration of the focus groups. Informed consent was obtained at the beginning of each focus group interview, and participants received a $30 honorarium at the conclusion of the group. Refreshments, parking and childcare were provided at no charge. The institutional review board of the University of North Carolina at Chapel Hill approved all RFTS procedures, including the focus group interviews.

Figure 1: Study Design



Study Design

Focus groups were used to learn about the women's opinions on participation in pregnancy outcomes research. Focus groups allow clarification and exploration of participant views in a way that is not accessible through other interviewing methods.[29] The open-ended format of focus groups allows participants to determine the manner in which they will respond, and the group setting encourages interaction among participants and allows people to change their opinion.[30] These benefits of focus groups allow a more complete understanding of the motivations, behaviors, feelings, decision-making strategies and how people think about a topic.[30] In this study, specific emphasis was placed on five topics:

1) the role of race / ethnicity and willingness to participate in pregnancy outcomes research;

2) attractiveness and risks of participating in this type of research;

3) reactions to the recruitment materials used in the RFTS study and suggestions for enhancing the recruitment of minority women;

4) general knowledge of genetic research and African-American women's perspectives on participation in pregnancy outcomes research involving a genetic component;

5) changes in perceptions if women were asked to participate in more invasive procedures such as donating blood samples for genetic research.

Data Collection

Professional moderators, whose race was concordant with that of the focus group, conducted focus groups. Each moderator met with the principal investigator (PI) to review the interview questions and the moderator's guide. Table 1 shows the topic areas in the guide.

A note taker was present for all focus groups to record verbal and non-verbal

Table 1: Participation in Research Questions and Topic Areas from Focus Group Moderator's Guide

Introduction and Icebreakers
Have you participated in other research studies besides RFTS in the past?
What reasons motivated you to participate in those studies?
General perceptions about motivation to participate in research
Most important reason for participation in this study?
Most important reason for staying in this study?
Hardest thing that you had to do for this study?
Ever consider quitting?
Worries that women like yourself have when it comes to participating in research?
General Perceptions about recruitment material/study enrollment
How did you hear about the RFTS study?
Importance of the study staff in your participation and sticking with the study?
Suggestions for handling miscarriages?
Memorable and best aspects of the advertising materials?
Use of the internet for recruitment?
Appropriateness of these materials?
Suggestions for changing material to make them more appropriate?
Willingness to participate in Genetic Research
What comes to mind when you hear the phrase "genetic research"?
General perceptions and conceptualization of the risk of Genetic Research
Describe good and not so good things about "genetic research"?
Advantages and disadvantages of participating in "genetic research"?
Factors effecting willingness to participate in Genetic Research
How do you feel about participating in genetic research?
Concerns that women like yourself may have when it comes to participating in genetic research?
Concerns that information given is really confidential?
Factors effecting the request of donation of blood samples for Genetic Research
What would be important to know before agreeing to participate in this type of research?
Would you have your blood tested for some things and not for others?
Do you need to know how much money you will be paid?
Would you like to have the option of testing for some genes and not others?
What would be important factors that would change your mind if you would not participate?
What kind of subjects do you think you or women like yourself would not participate in?
Would you give blood if your name was not associated with it?

communications and cues. Immediately after each focus, the PI met with the moderator and notetaker to discuss impressions and compare findings with those from the other focus group sessions. All group discussions were audio-taped, transcribed verbatim into text and entered into NUDIST-Vivo (version1.1) text analysis program.

Data Analysis

As previously described, content areas from the initial analysis were used to define topic areas and probes for the moderator's guide used in the focus groups.[28] For each focus group, the transcript was reviewed with the audiotaped interviews for accuracy. The PIs (GL, CL, GF) independently reviewed the transcripts after each focus group to identify emerging themes and concepts, to reduce interpreter bias. Research team meetings were used to refine the meaning of each content area, discuss alternative interpretations, and reach agreement on each category. Based on these meetings, the PIs sorted participants' comments into content areas.

Results

Between December 2000 and June 2003, 1106 women enrolled and completed the RFTS study at the Raleigh, North Carolina site. After randomly contacting an equal number of women from this cohort, twenty-two women, 12 African-American and 10 Caucasian, participated in the focus groups. Their mean age was 33 years; mean ages were 35 for Caucasian women 32 for African-American (Table 2). The groups were

similar in the number of children, pregnancies, and miscarriages (Table 2). The majority in both groups had one or two children and had been pregnant three or more times. Equal numbers of women in the two groups reported miscarriages, ranging from none to two or more.

Table 2: Focus Group Demographics

	All (n=22)	African-American/Black (n=12)	Caucasian/ White (n=10)
Age (Mean in years)	33	32	35
Marital Status			
Single (never married)	14% (3)	25% (3)	0% (0)
Married	78% (17)	58% (7)	100% (10)
Widowed/ Long-term Stable	9% (2)	17% (2)	0% (0)
Education Level			
Grade, Middle or High School	5% (1)	8% (1)	0% (0)
High School Graduate/ GED	9% (2)	8% (1)	10% (1)
Community College/ Technical School	37% (8)	50% (6)	20% (2)
College Graduate	37% (8)	17% (2)	60% (6)
Graduate School	14% (3)	17% (2)	10% (1)
Employment Type			
Homemaker	32% (7)	0% (0)	70% (7)
Working outside of home for pay	46% (10)	67% (8)	20% (2)
Working at home for pay	14% (3)	17% (2)	10% (1)
Unemployed, Laid off, Looking for work	9% (2)	17% (2)	0% (0)
Employment Time			
Full-time	46% (10)	25% (3)	70% (7)
Part-time	46% (10)	75% (9)	10% (1)
Temporary	9% (2)	0% (0)	20% (2)
Household Income			
Under $29,000	18% (4)	33% (4)	0% (0)
$30,000 - $49,000	18% (4)	17% (2)	20% (2)
$50,000 - $59,000	23% (5)	17% (2)	30% (3)
Above $59,000	37% (8)	25% (3)	50%(5)
Don't Know	5% (1)	8% (1)	0% (0)
Number of children			
1	32% (7)	42% (5)	20% (2)
2	37% (8)	25% (3)	50% (5)
≥3	32% (7)	33% (4)	30% (3)
Number of pregnancies			
1	9% (2)	17% (2)	0% (0)
2	14% (3)	8% (1)	20% (2)
≥3	77% (17)	75%(9)	80% (8)
Number of miscarriages			
0	37% (8)	33% (4)	40% (4)
1	37% (8)	42% (5)	30% (3)
≥2	27% (6)	25% (3)	30% (3)

The groups differed in marital status, education level, employment type and household income (Table 2). All Caucasian women but only 58% of the African-American women were married. Seventy percent of Caucasian women, but only 34% of African-American women had a college education or higher. Eighty-four percent of African-American women reported employment for pay, compared to 30% of Caucasian women.

General Reasons for Participation in Research

The majority of the women in all focus groups indicated that facilitative aspects of the study, such as free ultrasounds and pregnancy tests were the most important reason for participating in the RFTS study (Table 3). One participant said,

Table 3: Grouped Responses to the Question "What were the most important reasons for you participating in THIS (the RFTS) study?
Facilitative
Free ultrasound
Free Pregnancy Test
Altruism
Contribute to science and medical knowledge
Helping others
Personal Relevance
Concern for self health
Desire to learn something that may apply to self health
Non-Experimental
Non-invasive
No drugs
Could not hurt them
Relevance to women
Research topic related to women or black women
Importance of study
Important subject of research
Convenience
Reimbursement
Participation in research
Generally like to participate in research

The catch for me was the ultrasound. If they hadn't offered the ultrasound, I would not have made the phone call.

Most of the participants agreed with this statement and other, similar sentiments.

Another common theme influencing participation in all groups was altruism, wanting to contribute to science or medical knowledge or help others (Table 3). Altruistic motivations for participation were reflected in statements similar to the comment of one African-American participant:

> *Information could be valuable to another person who is in my situation."*

Another African-American woman said,

> *They (study staff) told me that it (the RFTS study) was to help new mothers know the differences in how they feel and if it's (research) the way that something can be changed to make a person feel better or something like that, that's why I participated.*

Similar parallels were made in the Caucasian focus groups. A participant in the Caucasian group said that she "*enrolled because it (miscarriage) was so devastating that I was in it for the health purposes because I didn't want women to have to go through that.*"

Personal relevance, concern for self health or a desire to learn something that they might apply to self health also emerged as common reason for participating (Table 3). Several participants made direct connections between their pregnancy experiences and their motivation to participate. As stated by one participant,

> *I participated because I was a high risk mom.*

Other participants viewed participation in the study as a means of direct personal gain through increased knowledge about themselves and their pregnancy. For example, they commented:

> *It (RFTS) gave you an opportunity to find out things about yourself that you didn't really think about.*

> *I was pregnant getting ready to have my first child and it educated me on a lot of things I had not even thought about.*

Retention in and Satisfaction with Research

In their responses to the questions, "What were the most important reasons you decided to stay in this study?" and "What was the hardest

thing you had to do for the study and did you ever consider quitting?" the two racial groups differed. Responses of both African-American groups included (1) interest in the research topic; (2) familial altruism – remained in the study to help a family member; and (3) personal relevance – remained in the study due to concern for self health or a desire to learn something they might apply to self health (Table 4). This broad theme of personal relevance emerged as a factor influencing participation, retention and satisfaction with research.

Table 4: Grouped Responses to the Question "What was the most important reason you decided to stay in (the RFTS) study?

African-American	Caucasian
Interest in research topic	Commitment
Familial altruism	Convenience
Personal Relevance	Reimbursement
Altruism	Control

This theme of personal relevance recurred in the African-American women's perceptions of the hardest components of study participation. They felt that the invasive tests and questions and withholding of the results of the tests received and the results of the study were the hardest aspects of the study. Further, they thought invasive tests and invasive questions were significant concerns that would affect the participation of other African-American women in research, as these reflected in these statements:

> *It (the study) might get too personal. Especially with the whole issue of fibroids some women are embarrassed or ashamed about that and don't want to (talk about it). My best friend is very private and I could see her being like 'I don't want anybody going all into that.*

Then they (the study staff) got to abortions and how many you had, and they do ask a lot of personal questions though. Stuff about your sex life. They ask all that kind of stuff.

Most Caucasian women said that commitment and convenience were the major factors influencing their retention in the study and their satisfaction. These themes expressed were not by the African-American women. Half of the Caucasian participants said that "it (the RFTS study) was easy" and "they (the study staff) worked around your schedule." However, some of the group felt that certain components of the study, such as the phone interviews and the daily journal, were inconvenient and were the most difficult element of the study. These themes were also not expressed by the African-American women.

For both groups of women, fear of being experimented on and concerns about confidentiality were factors influencing participation. Confidentiality concerns centered on the exchange of their personal information without consent, which could lead to being called for more studies, or being dropped by insurers, and seeing their information become public. Concerns they felt women like them might have about research participation included being treated like a guinea pig, not being treated like a human being, and having to take experimental medications.

That you are not going to be treated like a human being, and that your concerns and that people are not going to be sensitive to how you feel about what is being done to you.

Staff Characteristics

Characteristics of the staff were major factors in the decision to participate and remain in the study, for both African-American and Caucasian women. Both groups said that staff characteristics such as being nice, friendly, making them feel comfortable, polite, personable, supportive and approachable were important in their decision to participate and remain in the study. However, only the African-Americans felt that professional characteristics, such as being a good communicator and making sure they (the participants) understood the study, were important in their decision to participate and remain in the study. This may have been related to the arching theme of personal relevance among African-American women, since these professional characteristics helped participants understand how the study would affect them and how they would benefit.

Recruitment Materials

In response to the question, "How would you suggest we change these materials to make them more appropriate for women like yourself?", both groups suggested changes in the ethnicity of the graphics on the recruitment materials. All African-American women felt that these changes would be more appropriate for women similar to them. In both African-American groups, the discussion focused on the need for recruitment materials to clearly represent the minority groups being sought for the research. As one participant said,

> *If they want African American mothers then I can't see particularly a Spanish baby or Indian baby representing me if they are trying to get my attention...If it's (the study) for minorities, there are several minorities now, we (African-Americans) are not the only ones, then they should go ahead an mix it (graphics on the recruitment materials) up a little.*

However, African-Americans also raised the issue of suspicion in regard to depiction of minorities in recruitment materials. As expressed by one participant,

> *They (researchers) shouldn't try too hard to attract black females cause then you start feeling like you being singled out or that you are being patronized....it almost becomes stereotypical depending on how the brochure is put together...They really want some black folks, now why?*

Clearly, the decision to include minority populations of interest in recruitment materials must balance informing minority populations of the need to have them participate and suspicions that these populations are explicitly targeted.

Perceptions about Participation in Genetic Research

All participants, African-American and Caucasian, had similar knowledge of genetic research. When asked, "What comes to mind when you hear the phrase "genetic research?", both groups made associations with cloning and invasive tests/questions (Table 5). Their perceptions about cloning were reflected in the comments of an African-American woman, who remarked,

> *Let mother nature take its course and let it be. As long as it's (the baby) healthy that is all it should be about. Oh I want this hair color and this color eyes and he has to be this*

tall...that don't make sense. You (are) not asking for a child, you (are) asking for a robot.

African-American groups also made associations with nonspecific negative thoughts (Table 5), as in the statement of one African-American woman,

I generally, when I hear genetic research, I hear negative. There's nothing positive...I'm sure there is of course with all the disease...my first thought is generally negative.

Both groups also made positive associations with the term "genetic research" (Table 5). Discussions focused on the potential for treatment of disease through the use of genetic research and on prevention in general, with comments such as

They do all those gene therapy treatments now. People that are in wheel chairs now that could maybe walk again, like Christopher Reeves.

When asked, "What do you think are some advantages of participating in genetic research?", the groups differed by race. The African-American groups focused on prevention in their family, education about their health and preparation for future diseases. As noted by one participant,

Table 5: Grouped Responses to the Question "What comes to mind when you hear the phrase "genetic research?"

African-American and Caucasian	African-American	Caucasian
Cloning Cures Invasive tests/experiments	Prevention - general Negative	Genetic Counseling

If I am or my children or my future children are going to be predisposed to certain illnesses, I'd like to be able to know about it. If I could know about it ahead of time and study it and get all the information and best prepare for that, I think that would put me at a great advantage in life...If you have the gene and your spouse has the gene, you already know what your chances are, they can tell you that now. I feel like

> *if we can have all that in place for more, other illnesses, allergies, things of that nature, it puts you at an advantage. I can respond better, I can live a healthier life, cause I can prepare.*

Again, the theme of personal relevance appeared with these African-American women. In contrast, Caucasian women focused on using genetic research to find out about diseases such as non-terminal and chronic diseases.

Among African-American women, the potential to help themselves or their family, and the approval of their doctors were major factors influencing their willingness to participate in genetic research involving blood sampling. As noted by one participant,

> *…My doctor said this is a really good study…if he had not said that I probably wouldn't have done it (the RFTS study).*

The issues that African-American women had about participating in genetic research appeared to relate to trust. Distrust of the medical system, invasive procedures, personal relevance and risk of disease were specific concerns that these women had about participating in genetic research:

> *How do we (research participants) know that once she's (the women participating in genetic research) prodded and probed at , what kind of guarantee do we have that this is going to be used for our family specifically.*

Other reasons included the use of the blood samples and the methods employed to obtain the blood. Additionally, issues with confidentially were raised as a factor affecting participation in genetic research. Specifically, the requirement of providing their name with a

blood sample was a factor in participation in genetic research. These factors all relate to issues with trust of the medical research.

Discussion

The under representation of women and minority populations, specifically African-Americans, in medical research is an area of concern in the research community. Exclusion of these groups from clinical trials limits the generalizability of study results and creates inequities in the provision of health care.[3, 4] Despite widespread recognition of the need to include women and minorities in medical research, many factors still limit their participation.

In order to increase the participation of minorities and women, barriers to participation and factors that enhance participation must be addressed in study design. Although some barriers are common to all study populations,[1] African-American populations and women have specific barriers and motivators.

A significant amount of literature describes barriers to recruitment and enrollment in minority populations, specifically African-Americans.[1, 3, 11-16] However, the literature addressing barriers to participation of women in medical research primarily focuses on postmenopausal women and women with medical conditions, such as cancer. Investigations of the barriers and facilitators to improved attrition of reproductive-aged women are sparse. Our research specifically addresses retention and satisfaction with participation in medical research among African-American and

Caucasian women who had previously participated in pregnancy outcomes research.

We found that motivators for entering research for both African-American and Caucasian women included the facilitative aspects of the study, such as free ultrasounds and pregnancy tests. Other common reasons for enrollment included altruism, desire to contribute to science and medical knowledge, and personal relevance, a desire to learn something applicable to self health. These findings are consistent with the findings we published earlier with a larger cohort of participants.[23]

However, distinct differences emerged between the two racial groups in the factors influencing their completion of the study. For African-American women, interest in the research topic, familial altruism, remaining in the study to help a family member, and personal relevance were the major factors in their decision to remain in the study. In contrast, Caucasian women mentioned remaining in the study because they had agreed to, convenience, and ease of completing study components. This difference may provide insight into study elements that could be adapted to increase the retention of target populations.

Both African-American and Caucasian women felt that their racial/ethnic group should be included in recruitment materials. However, African-American women stated that explicit solicitation of minorities could be viewed as suspicious. This issue of trust is consistent with the mistrust of the medical community that is a commonly cited barrier to participation

among minorities.[1, 11-13] Thus, the decision to include minority figures in recruitment materials must be balanced with explanations of why they are being asked to participate.

The level of knowledge about genetic research was also similar in both groups. However, African-Americans had more non-specific negative associations with genetic research. This is consistent with the findings from a national survey of attitudes toward genetic testing, in which African-Americans reported greater concerns about the negative consequences of genetic testing than Caucasians.[32, 33] We found that Caucasian women focused on using genetic research to find out about certain diseases, such as non-terminal and chronic diseases, while African-American women focused on prevention in their family, education about their health and preparation for future diseases. These findings are similar to previous research which reported that African-American and Caucasian women and men identified prevention and treatment of genetically linked diseases as the main benefits of genetic research.[34] Bates et al. also found that all ethnic groups expressed concerns about the potential for genetic discrimination, and these concerns were more prominent among African-American participants.[34]

One of the most prevalent findings of this study is the theme of personal relevance that recurred among the African-American women. Personal relevance influenced participation, retention and satisfaction. We perceived that this theme centers on aspects of the study that directly

relate to a woman's knowledge, such as the results of the tests and of the study, and elements directly impinging on the participant at the individual level, such as invasive questions, which are not themes expressed by the Caucasian women.

Limitations of focus groups include the potential for participants to hold back because of perceived threats or group pressure or feelings that it is improper to discuss a topic in front of a group, and fears about who is listening or how the information will be used.[30] In our focus groups, these factors were minimized by the race concordance between the group participants and the moderator, and the assurance of confidentially during the informed consent process.

Additionally, the focus group interview is a hypothesis generating tool used to explore participant experiences, attitudes and beliefs.[29] Typically, quantitative research is used to validate the findings of focus groups interviews.[30] Hence, whether making changes to study design to incorporate the factors found here to influence research participation will actually increase enrollment, participant satisfaction and retention remains unknown. The next step is to compare enrollment, satisfaction and retention of cohorts of women in studies with and without these changes in study design.

Another limitation of our study was the sample of participants. All women had previously volunteered to participate in research, and their attitudes and beliefs may not be representative of all reproductive-aged

women. Specifically, in this cohort, the majority of women had had previous miscarriages, which may have increased their concern about other pregnancies and influenced their participation in a study that offered a first trimester ultrasound. In cohorts where miscarriages may be less prevalent, factors motivating participation and retention in research may differ.

By using the themes that emerged from these focus groups in combination with the literature on participation and retention in medical research, the design of future research trials involving reproductive-aged women can be improved to reflect better understanding of the factors affecting enrollment, retention and satisfaction with research. Based on our findings, we speculate that all studies involving reproductive-aged women, and especially African-American women, should focus on improving and emphasizing individual benefits of participation. Research designed to study reproductive-aged women should include components that are purposeful to the participant, such as tests that the participant values, and should employ staff who are friendly and compassionate. Research designed to investigate African-American women should emphasize the information provided about the participant's individual health, since personal relevance appears to be a significant motivator. Recruitment materials should target African-Americans with careful explanations about the benefits of research participation.

Finally, studies focusing on genetic research in women should take into consideration the fact that women in general make negative associations with genetic research. The research design should highlight the potential for cures and prevention in recruitment techniques, and reassure participants of the confidentiality of participation.

If the barriers known to impede participation are lessened while factors that improve satisfaction and enrollment are enhanced, the participation and retention of women in future trials can be ensured. Ultimately, this enhanced participation will lead to better research and patient care.

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