PARTICIPATION OF AFRICAN AMERICANS IN A SMOKING CESSATION TRIAL: A QUANTITATIVE AND QUALITATIVE STUDY

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African Americans (AAs) have been considered a hard to reach research population. In a clinical trial of bupropion for smoking cessation, failure to return for randomization was concerning during the initial phase of recruitment.

There were three study goals: to review the research on clinical trial participation barriers, to use quantitative analyses to identify differences between randomized (n = 66) and non-randomized (n = 54) participants, and to use focus groups and interviews (2 groups and 2 interviews, 17 participants) to elicit participation barriers and suggestions for participation enhancement.

Randomized participants were older (44.1 vs. 37.6; p = 0.0019), predominately female (81.8% vs. 63.0%; p = 0.0201), more likely to have some college (33.3% vs. 16.7%; p = 0.0380), and less likely to be employed full time (32.4% vs. 53.7%; p = 0.0347). Randomized participants reported higher motivation to quit smoking (8.3 vs. 7.3; p = 0.0083) and higher confidence to quit (8.2 vs. 7.3; p = 0.0357). A logistic regression model specified age, gender, and motivation to quit, as predictors of randomization. Focus groups identified transportation, lack of readiness to quit, inadequate reminders, and employment conflicts as barriers to participation.

Knowledge of differences between those who return for enrollment and those who do not may be used to increase AA enrollment in clinical trials. (*J Natl Med Assoc.* 2002;94:609–618.)

Key Words: clinical trials ♦ participation ♦ randomization ♦ African Americans

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INTRODUCTION

Ethnic minorities are often underrepresented in clinical trials,[1–3] particularly in primary prevention trials.[2] A lack of minority participation in clinical trials restricts the ability to generalize treatment outcomes to the entire population.[3,4] In some instances, ethnic minorities respond differently to treatments than whites,[3,4] yet this potential variability in treatment outcomes may go undiscovered. Failure to recruit ethnic minorities to participate in clinical trials also results in denied opportuni-

ties to benefit from state-of-the-art therapies and interventions for cancer and primary prevention.[1,5,6] This issue is particularly relevant to African Americans (AAs) because they suffer greater morbidity and mortality from most preventable illnesses.[7] In the following paragraphs, we review research on barriers to clinical trial participation in general, and those specific to enrolling African Americans.

In several studies socioeconomic status and demographic characteristics repeatedly served as predictors of participation. For example, persons with less than 12 years of education,[8] individuals without regular health care,[8] African Americans,[9,10] males,[11] full-time employees,[11] and those with higher annual household incomes[11] were less likely to be in a clinical trial. Individuals who were middle aged, divorced/separated, and able to pay for some or all of their medical expenses were more likely to participate in a clinical trial.[9]

In addition to demographic differences, there are environmental barriers that hinder participation of groups such as low-income African Americans. Researchers have categorized clinical trial participation barriers into four main areas: access, sociocultural factors, structural factors, and provider beliefs. Access issues include inadequate health care,[3] illiteracy,[2,6,9] and lack of transportation.[3,9,12,13] Sociocultural barriers include factors such as mistrust of research,[1,8,14–16] and the opinions of friends and family members.[17–20] For example, in an HIV vaccine trial, willingness to participate was significantly affected by the opinions of parents, siblings, or spouse/sexual partners.[20] Structural factors include a general lack of infrastructure to support research,[6,21] along with inadequate staffing and time for recruitment. Provider beliefs may be particularly important. For example, a survey of 220 AAs found that 37% would participate in a risk reduction program and/or trial if recommended by their physician.[5] Unfortunately, health care providers may be uninformed of clinical trials,[6,22,23] distrusting of academic medicine,[6] biased in their referral for trials,[6,24,25] or simply in support of the standard therapy over the experimental therapy offered in a trial.[24] All of these factors, along with time constraints and lack of reimbursements,[6] can lead to poor minority recruitment.

Correlates to participation are not limited to environmental and recruitment factors; individual knowledge, attitudes, and beliefs can also be important. For example, in a smoking cessation study of low-income women, a higher intention to quit and lower self-efficacy were predictive of participation.[26] Similarly, perceptions of trial efficacy and knowledge of the disease process of interest prior to study enrollment may be important. In a study of willingness to participate in cancer prevention or treatment trials, Millon-Underwood et al found a significant correlation between perceived efficacy of the trial and willingness to participate.[5] In an HIV vaccine trial, a 3% increase over baseline levels in willingness to participate was observed after patients were educated about the HIV virus and the vaccine.[20]

Although some researchers have begun to explore issues related to participation in clinical trials, the literature lacks direct data from the perspective of potential participants who were eligible, yet choose not to enroll. Clinical trials continue to under-enroll ethnic minorities[2], suggesting that further investigation is needed. This study enriches the body of literature on the differences between participants and non-participants with regards to correlates of clinical trial participation. This study is the first, to our knowledge, to provide qualitative data from individuals who were eligible, yet chose not to enroll in a clinical trial. We chose to combine qualitative and quantitative data, to provide a more rich and complete description of the non-participants and their reasons for not participating.

The purpose of this study was to identify characteristics of those who opted not to participate in a clinical trial of African American smokers. In addition, focus groups were used to help understand why some eligible smokers did not return for enrollment and what strate-

gies might make their participation more likely in the future. Quantitative analyses were used to examine the correlates of returning for randomization among a pool of eligible individuals who agreed to participate. Qualitative analyses were used to elicit specific participation incentive ideas, barriers encountered, and suggestions for barrier removal strategies.

METHODS

Participants

Participants were drawn from those screened and found eligible for a randomized clinical trial of bupropion as an aid for smoking cessation among AAs (parent study).[27] The main outcome of the trial was 7-day smoking cessation rates at 6 months. The trial randomized 600 African American smokers over 16 months, ending April 2000.[28] Over a 6-month period, participants were asked to return to the study site for 6 visits. Each participant received 8 motivational interviewing sessions (in person or via phone), a culturally tailored smoking cessation guidebook, and 7 weeks of medication (either bupropion or placebo).

The sample discussed in this paper included only those participants recruited during the first 6 months of the parent study.* During this period, staff approached individuals in the waiting room of the Swope Parkway Health Center (Kansas City, MO) where the parent study was conducted. If individuals expressed an interest in the program, they were screened for eligibility. If eligible, an initial assessment was conducted, and the randomization appointment was scheduled. Exclusion criteria included: smoking less than 10 cigarettes per day, excessive alcohol use, recent drug treatment (within the last 6 months), and use of certain medications known to interact with bupropion.

For the quantitative analysis, those who agreed to participate in the bupropion study, underwent the baseline assessment, and scheduled an appointment for randomization but never returned (non-randomized; n = 54), were compared to a group who returned for randomization into the study (randomized; n = 66). To gather qualitative data, the non-randomized participants were invited to participate in follow-up focus groups. These groups were designed to elicit barriers to participating in the bupropion study and to provide suggestions for increasing the likelihood of sustained enrollment in future studies.

We successfully contacted 46% (25/54) of the non-randomized participants and all agreed to participate. The other 29 non-randomized participants either had disconnected or incorrect phone numbers (12/29), were unable to be reached after repeatedly leaving messages at their homes and the homes of their family and friends (14/29), or moved out of the city (1/29). Two (2/29) were not contacted to participate in the focus groups because they had not yet been identified in the database. Postcards with information about the focus groups and a number to call if interested were sent to all non-randomized participants who could not be reached by telephone after repeated calls.

Initially, those who agreed to participate in the focus groups were given six choices of dates and times (spanning three days) in an effort to discover which times were most convenient for the majority. Based on this initial information, three focus groups were scheduled. Confirmation letters (and reminder postcards for the second and third groups) were mailed to all who agreed to participate approximately 1-2 weeks in advance. In addition, focus group participants were given a reminder phone call within 24 hours of their scheduled session.

Two focus groups (comprised of 8 and 7 participants) and two individual interviews (conducted due to schedule conflicts) were completed for a total of 17 participants. All qualitative data were analyzed collectively. To simplify reporting we refer to participants in the qualitative study as "focus group" partici-

*After approximately 6 months of recruitment, procedures were altered slightly so that baseline and randomization assessments were conducted at the same visit. Because of this protocol difference, these later participants are excluded from this study.

Table 1. Sample Description

	Randomized % (n = 66)	Non-Randomized % (n = 54)	P value
Female	81.82	62.96	0.0201
Married	15.15	14.81	0.9590
Some college	33.33	16.67	0.0380
>$1600/month	23.81	20.75	0.6943
Insured	69.70	55.56	0.1098
Employed Full-time	32.38	53.70	0.0347
Drove themselves	59.09	56.86	0.8086
Smokers in home	28.79	42.59	0.1147
Friends who smoke	89.06	94.23	0.3240
	Mean (± SD)	**Mean (±SD)**	**P value**
Age	44.08 (12.1)	37.57 (10.34)	0.0019
Cigarettes/day	17.60 (8.64)	17.80 (8.64)	0.8980
Hassles	4.42 (2.61)	4.63 (2.81)	0.6819
Depression score*	16.26 (9.77)	15.70 (9.08)	0.7473
Dependence*	4.57 (2.12)	5.09 (2.42)	0.2172
Confidence to quit	8.18 (2.07)	7.33 (2.26)	0.0357
Motivation to quit	8.33 (1.76)	7.31 (2.28)	0.0083
Previous quits	4.02 (7.82)	2.94 (5.09)	0.3698

*20-item CES-D short depression scale (a score of 16 or greater indicates depressive symptoms)
**Fagerstrom Dependence Test (0–2 = very low dependence; 3–4 = low dependence; 5 = medium dependence; 6–7 = high dependence; 8–10 = very high dependence)

pants. The participation rate was 68% (17/25) among those contacted and 32% (17/54) among all non-randomized. There were no significant differences between the 17 focus group participants and the other 37 non-randomized participants on demographic and smoking characteristics listed on Table 1. Participants received $50 reimbursement for their time and transportation costs.

Quantitative Measures

The baseline assessment included measures of demographic information, smoking behaviors, depressive symptoms, hassles, nicotine dependence, motivation and confidence to quit smoking. Standard demographic and smoking behavior questions were modified from prior studies.[29] Depressive symptoms were measured with the Center for Epidemiologic Studies Depression Scale (CES-D).[30] It is a twenty-item scale designed to identify those with significant levels of depressive symptoms (persons who score ≥16). Hassles, or daily sources of frustration (e.g., having a check late or lost in the mail or having a violent argument with a friend or relative), were measured using a modified, eleven-item hassles index.[31] Each respondent reported whether or not a particular event happened to them or someone important to them in the past three months. Nicotine dependence was assessed with the Fagerström test.[32] Dependence was scored on a scale from 1 to 10 and was categorized as very low (0-2), low (3-4), medium (5), high (6-7), or very high (8-10). Motivation and confidence to quit were assessed using a 1 to 10 scale. Both were analyzed as continuous variables.

Qualitative Measures

Focus groups were conducted after the quantitative analysis was complete. The focus group moderator utilized a pre-determined set of questions that were derived from the literature review and the researchers prior experi-

ences. A key question was: "What made it difficult for you to return for your randomization visit?" Another key question asked: "What would have made it easier or more likely for you to return for randomization?" Participants were also asked to discuss their readiness to quit and which program components were of interest. To elicit more barrier removal strategies, participants were asked to explain how a researcher might get their friend or relative into a study relevant to their health concerns.

Quantitative Analysis

Summary statistics included means and standard deviations for continuous variables and frequencies and percents for categorical variables. Comparisons of categorical variables and continuous variables, between randomized and non-randomized participants, were made using the Chi-square test and the two-sample t-test, respectively.

In order to determine the joint effects of the variables on returning for randomization, a logistic regression model was developed. All variables in Table 1 were considered for inclusion in the final model. Categorical variables were converted to "dummy" 0/1 variables. Stepwise regression at the 0.1 significance level and best subset score method were used to determine the appropriate model.

Qualitative Analysis

The focus groups and interviews were audiotaped and later transcribed. The focus groups were also videotaped. All discussions were analyzed using the Q.S.R. NUD*IST 4 (1994) computer program, which is specially designed for qualitative data analysis.[33] Transcriptions were edited for typographical errors, then read in their entirety. Coding was performed by the focus group moderator and a second reader unfamiliar with the topic.[34]

The two reviewers discussed all coding schema. When a discrepancy occurred, the interview text was re-read to help clarify the meaning. If further discrepancies existed, the coders re-examined the concepts (or themes) to identify areas of potential overlap or to further delineate the concept.

RESULTS

Quantitative Analysis

The demographic characteristics of age, gender, employment, and educational level differed between the randomized and non-randomized groups (Table 1). Randomized participants were older, more likely to be female, and to have at least some college. Randomized participants were less likely to be employed full-time.

Those who returned for randomization also had significantly higher motivation (8.33 vs. 7.31; $p = 0.0083$) and confidence (8.18 vs. 7.33; $p = 0.0357$) to quit smoking. Other smoking-related variables were similar: both groups smoked approximately 18 cigarettes per day, had made three to four attempts to quit smoking in the last year, and had medium levels of nicotine dependence. The presence of smokers in the home or friends who smoke were also similar. Comparison between the groups on psychological measures, such as depression, hassles, and nicotine dependence, revealed no significant differences.

When all variables were examined simultaneously, the logistic regression model identified gender, age, and motivation to quit as final predictors for returning for randomization. Adjusted odds ratios (95% confidence intervals) are reported. The adjusted odds ratio of participation was higher for women [OR = 3.07 (1.23, 7.63)], older individuals [OR = 1.06 (1.02, 1.20)], and those who reported higher motivation to quit smoking [OR = 1.28 (1.05, 1.57)].

Qualitative Analysis

First level coding identified five main themes: barriers to participation, reasons for participation, suggestions for enhancing participation, and social support for participation. Qualitative analysis also revealed a prevalence of misinformation about the clinical trial and

Table 2. Participation barriers and participation enhancement strategies discussed by participants in the qualitative study

Participation Barriers
Transportation
Non-ownership of a car
Unreliable car
Unwilling or unreliable transportation provided by others
Medication issues
Concern about taking pill
Disinterest in prospect of receiving placebo
Concern about drug interactions and bupropion side effects
Schedule conflicts
Employers unwilling to grant time off
Combined work and school schedules conflicted with randomization appointment
Forgot appointment
Lack of childcare
Not ready to quit smoking
Participation Enhancement
Increased desire to quit smoking
Working less hours
Reminder phone calls and postcards
Encouragement from friends and family
More convenient appointment time
Support group of smokers
Transportation
Providing bus tokens or a van to transport participants
A prayer session
Certainty of receiving the actual medication (vs. placebo)

diseases in general. A summary of the main themes is found in Table 2 and discussed below.

Barriers

Focus group participants identified medication concerns, schedule conflicts, transportation issues, forgotten appointments, lack of childcare, inadequate readiness to quit, and perceived nicotine addiction insensitivity as barriers to participation in the program. Participants discussed a number of concerns about the medication. One participant decided not to return for randomization because she did not like the idea of taking a pill everyday. She commented on her concerns: "It scared me because I'm not used to taking no pills every day and I don't think I could do that. I couldn't take birth control pills so I know I couldn't do that [take the study medication]." Another focus group participant was concerned about receiving a placebo pill: "I wanted to do the program. When they started talking about how you wouldn't know what kind of pill you'd take, I said no, I don't need anyone playing with my mind. What if I quit by taking a placebo, a little sugar pill? I said no, no one is playing with me."

Inability to take time off from work or school, problems with transportation, forgotten appointments, and lack of childcare were also emphasized. Some participants reported that they had employers who frowned upon frequent requests for time off and others, who were full-time employees or full-time students, found it difficult to keep their randomization appointments. Some cited lack of transportation or unreliable vehicles as reasons for not returning. Other participants stated they simply forgot their appointment and subsequently lost interest in the program.

The problem of inadequate readiness to quit was well illustrated by one participant's story. She stated the staff member who approached her about joining the study caught her by surprise. She was visiting the health center for other reasons and had not given much thought to joining a quit-smoking program. Though she was interested in quitting smoking and agreed to participate in the program, she later realized she was not yet ready to quit.

One participant expressed a level of discomfort with study staff during the initial assessment due to perceived nicotine addiction insensitivity. She felt the questions asked and the discussion that ensued would have been more appropriate with a staff person who was a current or former smoker because they would have had similar experiences battling nicotine addiction.

Reasons for Participating

Reasons for participation included the participants' recognition of their need to quit

smoking and simply being tired of their habit. When asked "What were some of the things that interested you in the program?", one participant stated: "I'm just tired of smoking." Another participant said: ". . .I've been smoking too long, I want to stop, I'm tired. But I can't kick the habit." The free gifts (which included $100 disbursed over a six-month period, a t-shirt, a tote bag, a water bottle, a key chain, and a magnet) offered to participants were also mentioned as an incentive.

Suggestions for Increasing Participation

The incorporation of a support group was repeatedly mentioned as a way to increase participation in future studies. It was also suggested that reminders be included in the form of phone calls, letters, and postcards. The use of a more central location for the study site was also mentioned. Some participants had to travel a considerable distance to the health center. Others felt better promotion of the study could have increased participation. Specifically, the use of flyers, letters, visiting grocery stores, and utilizing television was suggested to enhance promotion. Focus group members also suggested using incentives (such as money, prizes, and other gifts) and providing free transportation or bus tokens.

Support

In general, participants received positive support from friends and family regarding participation in the study. Family and friends were eager to see their loved one quit smoking. Participants reported that family members believed smoking cessation would improve the entire family's quality of life. Several participants had children with health problems which were suspected to be related to smoke exposure. Those who reported they did not receive support indicated their family and friends doubted the need to join a program for smoking cessation. These family members felt the participant should have the ability to quit on their own.

Misinformation

A theme of misinformation about diseases in general was evident in the discussion groups. Participants discussed their thoughts on the etiology of cancer. A few stated they did not believe smoking caused cancer and another participant stated her belief that individuals were born with cancer. It was also mentioned that the prevalence of cancer was greater in whites than AAs.

DISCUSSION

The purpose of this study was to identify the distinguishing characteristics of those eligible participants that did not return for enrollment. Through the use of focus groups, we also sought to better understand participation barriers, as perceived by a cohort of eligible, nonrandomized participants, and to elicit strategies for enhancing participation. Quantitative analyses that compared those who returned for randomization to those who did not revealed that younger individuals, males, individuals employed full-time, and those without some college were less likely to return for randomization.

The differences noted in age and employment status may suggest that younger individuals and those employed full-time do not have the time to participate in clinical trials. Focus group participants supported this theory by citing employment constraints as reasons for not returning for randomization. Another study of clinical trial participation found that those who were employed full-time were less likely to enroll.[11] In addition, older age has been associated with increased likelihood of clinical trial participation.[9,35] This is similar to our finding that older individuals, with age analyzed as a continuous variable, were more likely to participate in this smoking cessation trial. Another barrier to participation cited by focus group participants was lack of childcare. This problem is usually more common among younger individuals, who are more likely to have young children in the home.

Males were less likely to be randomized into the parent study, comprising less than half of those enrolled. A study cited in the introduction also found male gender associated with a decreased likelihood of participation.[11] Our research group, in a previous study,[36] found that women may be more interested in taking steps to reduce the risks associated with unhealthy behaviors, such as smoking. There may be a correlation between gender, harm reduction strategies, and clinical trial participation.

Individuals without at least some college were also less likely to be randomized into this trial. A similar association was found in another study where individuals with less than 12 years of education were less likely to participate in a clinical trial.[8]

Psychological factors, specifically motivation to quit smoking and confidence to quit smoking, were significantly higher among the randomized participants in our study. A smoking cessation trial of low-income women found a higher intention to quit was associated with clinical trial participation.[26] Our focus group participants also identified a psychological factor, specifically, lack of readiness to quit as a participation barrier.

The joint effects of older age, female gender, and higher motivation to quit were significant predictors of randomization by logistic regression analysis. As previously noted, these three variables, considered individually, significantly differed between randomized and non-randomized participants. These results strongly support that differences noted in this study are real and significant.

These quantitative data, along with the qualitative evidence gathered from the focus groups, suggests several potential areas for enhanced recruitment and retention of African Americans in clinical trials. Barriers such as lack of transportation and childcare, mentioned by focus group participants, might be removed by providing bus tokens, monetary reimbursement, and on-site childcare as has been suggested in other studies.[8,9,18,37] Appointment reminders in the form of phone calls or postcards could also be used to enhance retention.

Barriers related to psychological factors such as motivation and confidence to quit smoking and general "readiness" for behavior change might be difficult to overcome. Focus group members, a cohort of non-randomized participants who had lower motivation and confidence to quit smoking at the time of recruitment, continued to express an interest in quitting smoking during the focus group sessions. In fact, one focus group participant decided to spearhead a support group. Allowing potential participants more time to consider enrollment and providing motivation-related behavior change interventions prior to enrollment might help motivate those who are interested but not yet ready to change their behavior.

In order to expand our knowledge related to ethnic minorities' participation, retention, and recruitment in clinical trials, continued documentation of successful recruitment and retention efforts is needed. In addition, a randomized trial comparing different recruitment strategies might be useful. Such an investigation would help to assess the effectiveness of barrier removal strategies that have been identified in the literature on clinical trial participation.

A weakness of this study is the small sample size. Though the parent study enrolled 600 AA smokers, only a total of 120 randomized and non-randomized participants could be used for comparison in the present study. Because recruitment protocols were significantly altered, we only sampled those under the initial protocol in order to reduce possible confounding variables. Another limitation is the lack of qualitative data on randomized participants. Though we chose to focus on the non-randomized participants, qualitative data on those individuals who did participate might be useful. Despite these weaknesses, the combination of a quantitative and qualitative study is a strength. We believe using the two analytic approaches

provides a more complete picture of the study sample.

The experiences of the parent study illustrate that African Americans can be successfully recruited for clinical trials. In fact, many of the barrier removal strategies identified by the non-randomized focus group participants were incorporated into the second recruitment phase and recruitment goals of the parent study were met ahead of schedule.[27] Continued efforts should be made to include African Americans in clinical trials. If successful, these efforts may improve the ability to generalize study findings and increase minorities' access to state-of-the-art treatments.

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